

Akers Biosciences, Inc.

Form S-1/A

December 15, 2017

As filed with the Securities and Exchange Commission on December 14, 2017

Registration No. 333-221746

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

Amendment No. 3
to
FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

AKERS BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in its Charter)

New Jersey	2835	22-2983783
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)
	201 Grove Road	
	Thorofare, New Jersey USA 08086	
	(856) 848-8698	

(Address, including Zip Code, and Telephone Number,
including Area Code, of Registrant's Principal Executive Offices)

John J. Gormally
Chief Executive Officer
Akers Biosciences, Inc.
201 Grove Road
Thorofare, New Jersey USA 08086
(856) 848-8698

(Name, Address, including Zip Code, and Telephone Number,
including Area Code, of Agent for Service)

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

Copy to:

Joseph M. Lucosky, Esq.
Lucosky Brookman LLP
101 Wood Avenue South
Woodbridge, NJ 08830
(732) 395-4400

Anthony J. Marsico, Esq.
Mintz, Levin, Cohn, Ferris,
Glovsky and Popeo, P.C.
666 Third Avenue
New York, NY 10017
(212) 935-3000

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒ x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐ "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large Accelerated Filer ☐ "

Non-Accelerated Filer ☐ "

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 to Section 7(a)(2)(B) of the Securities Act. ☐ "

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price ⁽¹⁾	Amount of Registration Fee
Class A Units Consisting of:	\$ 3,450,000	\$ 429.53
(i) Common Stock, no par value per share ⁽²⁾		
(ii) Warrants to purchase Common Stock ⁽³⁾		
Class B Units Consisting of:		
(i) Series B Convertible Preferred Stock, no par value per share	\$ 3,450,000	\$ 429.53
(ii) Warrants to Purchase Common Stock ⁽³⁾		
(iii) Common Stock issuable upon conversion of the Series B Convertible Preferred Stock, no par value per share ⁽²⁾⁽⁴⁾		
Common Stock issuable upon the exercise of the Warrants to purchase Common Stock ⁽²⁾	\$ 8,625,000	\$ 1,073.81
Underwriter's Warrants to Purchase Common Stock ⁽²⁾		
Common Stock Underlying Underwriter's Warrant ⁽³⁾⁽⁵⁾	\$ 375,000	\$ 46.69
Total	\$ 15,900,000	\$ 1,979.55 ⁽⁶⁾

Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act (1) of 1933, as amended (the "Securities Act"). Includes shares and warrants to be sold upon exercise of the underwriter's option to purchase additional shares and warrants. See "Underwriting."

(2) Pursuant to Rule 416 under the Securities Act, the shares of common stock registered hereby also include an indeterminate number of additional shares of common stock as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions.

(3) In accordance with Rule 457(g) under the Securities Act, because the shares of common stock underlying the warrants are registered hereby, no separate registration fee is required with respect to the warrants.

(4) No separate fee is required pursuant to Rule 457(i) under the Securities Act.

(5) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. The underwriter's warrants are exercisable at a per share exercise price equal to 125% of the public offering price per share of common stock. The proposed maximum aggregate offering price of the underwriter's warrants is \$375,000, which is equal to 125% of \$300,000 (5% of \$6,000,000).

(6) Previously paid.

Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with section 8(A) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the commission, acting pursuant to said section 8(A), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED DECEMBER 14, 2017
7,692,308 Class A Units Consisting of Common Stock and Warrants and
3,000 Class B Units Consisting of Series B Convertible Preferred Stock and Warrants (and 7,692,308 shares of
common stock underlying shares of Series B Convertible Preferred Stock and 7,692,308 shares of common
stock underlying Warrants)

We are offering an aggregate of 7,692,308 Class A Units consisting of one share of our common stock and one warrant to purchase one share of our common stock, at an exercise price equal to 125% of the public offering price of the Class A Units per share of common stock, which warrants will be exercisable upon issuance and will expire five years from date of issuance. The shares of common stock and warrants that are part of a Class A Unit are immediately separable and will be issued separately in this offering.

We are also offering to those purchasers, if any, whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing Class A Units, to purchase Class B Units. Each Class B Unit will consist of one share of our newly designated Series B Convertible Preferred Stock, or the Series B Preferred, with a stated value of \$1,000 and convertible into shares of our common stock at the public offering price of the Class A Units, together with the equivalent number of warrants as would have been issued to such purchaser of Class B Units if they had purchased Class A Units based on the public offering price. The Series B Preferred do not generally have any voting rights unless and until converted into shares of common stock. The shares of Series B Preferred and warrants that are part of a Class B Unit are immediately separable and will be issued separately in this offering.

The number of shares of our common stock outstanding after this offering will fluctuate depending on how many Class B Units are sold in this offering and whether and to what extent holders of Series B Preferred shares convert their shares to common stock.

Our common stock is currently listed on The Nasdaq Capital Market ("NASDAQ") under the symbol "AKER". On December 12, 2017, the last reported sale price for our common stock on NASDAQ was \$0.39 per share. Our common stock is also currently traded on the AIM market of the London Stock Exchange, or AIM, under the symbol "AKR.L". Shares traded under the "AKR.L" symbol are deemed to be unrestricted by the AIM market. At present, there is a very limited market for our common stock in the AIM market. We intend to continue trading on AIM upon completion of this offering. The public offering price per Class A Unit will be determined between us and the underwriter based on the closing price of our common stock on the pricing date and market conditions at the time of

pricing, and may be at a discount to the current market price.

Assuming an offering price of \$0.39 per Class A unit, the Series B Preferred included in the Class B Units will be convertible into an aggregate total of 7,692,308 shares of Common Stock and the Warrants included in the Class B Units will be exercisable for an aggregate total of 7,692,308 shares of Common Stock.

There is no established public trading market for the warrants or the Series B Preferred and we do not expect an active trading market to develop. We do not intend to list the warrants or the Series B Preferred on any securities exchange or other trading market. Without an active trading market, the liquidity of the warrants and the Series B Preferred will be limited.

We are an “emerging growth company” as the term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for future filings.

Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page 10 of this prospectus for a discussion that should be considered in connection with an investment in our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if the prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Class A Unit	Per Class B Unit	Total
Public offering price	\$	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$
(1) The underwriter will receive compensation in addition to the discounts and commissions. See “Underwriting” for a full description of compensation payable to the underwriter.			

We have granted a 45-day option to the underwriter to purchase a maximum of 2,307,692 additional shares of common stock (15% of the shares of common stock included in the Class A Units and the shares of common stock underlying the shares of Series B Preferred included as part of the Class B Units sold in this offering) and warrants to purchase a maximum of 2,307,692 shares of common stock (15% of the warrants included as part of the Units sold in this offering), solely to cover over-allotments, if any.

The underwriter expects to deliver the securities against payment therefor on or about , 2017.

Joseph Gunnar & Co.

The date of this prospectus is , 2017.

TABLE OF CONTENTS

	Page
Summary	1
The Offering	7
Summary Financial Data	9
Risk Factors	10
Use of Proceeds	31
Dividend Policy	33
Capitalization	34
Dilution	35
Cautionary Note Regarding Forward-Looking Statements	36
Management's Discussion and Analysis of Financial Condition and Results of Operations	37
Business	55
Management	71
Executive Compensation	77
Related Party Transactions	82
Description of Securities	86
Shares Eligible for Future Sale	90
Underwriting	92
Legal Matters	99
Experts	99
Where You Can Find More Information	99
Index to Financial Statements	F-1

You should rely only on information contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We have not, and the underwriter has not, authorized anyone to provide you with additional information or information different from that contained in this prospectus or in any free writing prospectus. Neither the delivery of this prospectus nor the sale of our securities means that the information contained in this prospectus or any free writing prospectus is correct after the date of this prospectus or such free writing prospectus. This prospectus is not an offer to sell or the solicitation of an offer to buy our securities in any circumstances under which the offer or solicitation is unlawful or in any state or other jurisdiction where the offer is not permitted.

No person is authorized in connection with this prospectus to give any information or to make any representations about us, the securities offered hereby or any matter discussed in this prospectus, other than the information and representations contained in this prospectus. If any other information or representation is given or made, such information or representation may not be relied upon as having been authorized by us.

Neither we nor the underwriter have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourself about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

This prospectus may include market and industry data that has been obtained from third party sources, including industry publications, as well as industry data prepared by our management on the basis of its knowledge of and experience in the industries in which we operate (including our management's estimates and assumptions relating to such industries based on that knowledge). Internally prepared and third party market forecasts, in particular, are estimates only and may be inaccurate, especially over long periods of time. References in this prospectus to any publications, reports, surveys or articles prepared by third parties should not be construed as depicting the complete findings of the entire publication, report, survey or article. The information in any such publication, report, survey or article is not incorporated by reference in this prospectus.

PROSPECTUS SUMMARY

This summary highlights selected information appearing elsewhere in this prospectus. While this summary highlights what we consider to be important information about us, you should carefully read this entire prospectus before investing in our common stock, especially the risks and other information we discuss under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operation” and our consolidated financial statements and related notes beginning on page F-1. Our fiscal year end is December 31 and our fiscal years ended December 31, 2015, 2016, and 2017 are sometimes referred to herein as fiscal years 2015, 2016 and 2017, respectively. Some of the statements made in this prospectus discuss future events and developments, including our future strategy and our ability to generate revenue, income and cash flow. These forward-looking statements involve risks and uncertainties which could cause actual results to differ materially from those contemplated in these forward-looking statements. See “Cautionary Note Regarding Forward-Looking Statements”. Unless the context provides otherwise, all references herein to “Akers”, “ABI”, “Akers Bio”, the “Company”, “we”, “our” and “us” refer to Akers Biosciences, Inc. “£” refers to the British Pound.

This prospectus assumes the over-allotment option of the underwriter has not been exercised, unless otherwise indicated.

Overview

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

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

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

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

- cost pressures/efficiency of healthcare delivery;
- need for fast, easy to use, accurate at-home tests for individuals to monitor their personal health and wellness;
- need for affordable mass screening tests for key infectious diseases, cardiac conditions, and metabolic markers; and
- public health needs in developing countries lacking basic health infrastructure.

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

Strategy

Akers' strategy is to target carefully chosen, high margin market segments within the diagnostics industry where (i) existing tests do not meet clinical requirements, or (ii) where an emerging, unfulfilled need has been identified. The

Company seeks to develop tests for applications based on their ability to compliment a particular treatment, lifestyle or testing regimen that requires a time and cost-efficient diagnostic alternative or solution. Akers utilizes its existing platform technologies to internally develop its new products as the Company's proprietary methods.

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

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

- Clinical Laboratories;
- Physicians' Office and Urgent Care Clinics;
- Retail;
- Nutraceutical Suppliers; and
- Health and Fitness.

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

Product Portfolio

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

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

Akers designed its products based on single-use assay platforms with straightforward test procedures that can be completed in minutes. In the U.S. some of the Company's clinical laboratory products and those with medical intended uses generally require "prescription use" Federal Drug Administration ("FDA") 510(k) clearance prior to product marketing given that they will be ordered or used by medical practitioners in the course of his or her professional practice. Despite this categorization, Akers' professional use products are still designed for ease of use, can be utilized near or at the point-of-care, and do not require the use of expensive equipment or a highly trained or specialized staff. As a result, an individual's current health status can rapidly be incorporated into diagnostic and treatment decisions, improving the overall efficiency of the healthcare experience for the patient, and ultimately the payor. In addition, in the developing world, the portability and ease-of-use of such point-of-care tests can serve to drastically improve the level of disease screening and subsequent patient care. We believe the benefits of our technology platforms are therefore well-suited to the diagnostic demands of countries in the developing world that seek to deliver modern medical diagnosis with limited medical infrastructure. In addition, some of our products have received FDA 510(k) clearance for over-the-counter ("OTC") use. Other self-tests deliver personal health information of a non-medical nature, on-demand, and are not FDA regulated; these products are still manufactured in compliance with its ISO 13485

quality management system (“QMS-Compliant”). Akers believes that all its technology platforms and products address the needs of the evolving healthcare delivery system that is moving patient care closer to or in the home.

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

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

Our marketed and emerging products include:

Product	Platform	Marketed/Pipeline	Not FDA-regulated; QMS-Compliant Only	FDA Clearance Required <i>Prescription Use/OTC</i>	FDA Clearance Status Obtained/Needed	Description
BreathScan™	MPC	Marketed		OTC	Obtained	Disposable breath alcohol detector
BreathScan® PRO	MPC	Marketed		OTC	Obtained	Quantitative breath alcohol detection system
Breath Diabetic Ketoacidosis®	MPC	Pipeline		Prescription Use	Needed	Disposable breath ketone device for diabetic monitoring
METRON®	MPC	Marketed		Health and wellness	n/a	Disposable breath ketone device to monitor ketosis
Breath PulmoHealth “Check”®	MPC	Pipeline		Prescription Use	Needed	A suite of breath tests for biomarkers indicating asthma, chronic obstructive pulmonary disease (COPD), and lung cancer
BreathScan Lync	MPC	Marketed		Health and wellness	n/a	Non-invasive, quantitative measurement of biological markers for health and wellness
Product	Platform	Market/Pipeline	Not FDA-regulated; QMS-Compliant Only	FDA Clearance Required <i>Prescription Use/OTC</i>	FDA Clearance Status Obtained/Needed	Description
PIFA®	PIFA	Marketed		Prescription Use	Obtained	Rapid tests for Heparin/PF4 antibodies to detect an allergy to the widely used blood thinner, Heparin
Heparin/PF4 & PIFA PLUSS®	PIFA	Pipeline			Needed	

PIFA PLUSS® Chlamydia			Prescription Use		Rapid tests for the most prevalent sexually transmitted disease
seraSTAT®	seraStat	Marketed	Prescription Use	Obtained	Rapid Blood Cell Separator, marketed under the brand name seraSTAT®, further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically.
Tri-Cholesterol “Check”®	REA	Marketed	OTC	Obtained	Rapid test for Total and high density lipoprotein cholesterol and estimates low density lipo protein
BreathScan OxiCHek	MPC	Marketed	Health and wellness	n/a	Breath test for oxidative stress using the Lync reader and digital app
BreathScan KetoChek	MPC	Pipeline	Health and wellness	n/a	Breath test for ketosis using the Lync reader and digital app

How We Generate Revenue

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

Our Current Target Markets

Regarding the Company's test for the heparin drug allergy, the testing market largely resides within the clinical hospital laboratories of medical facilities. In the U.S., the Company accesses decision makers within these institutions through profiling by its highly trained technical sales team and collaborative prospecting with distributor sales representatives. Internationally, Akers provides comprehensive training to its distributor partners which will enable them to implement the same selling and technical training strategies.

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

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

Our Risks and Challenges

An investment in our securities involves a high degree of risk including risks related to the following:

- We have a history of operating losses and we cannot guarantee that we can ever achieve sustained profitability.
- Due to our dependence on a limited number of customers, we are subject to a concentration of credit risk.
- Because we may not be able to obtain necessary regulatory clearances or approvals for some of our products, we may not generate revenue in the amounts we expect, or in the amounts necessary to continue our business.
- The commercial success of our products will depend upon the degree of market acceptance by physicians, hospitals, third-party payors, and others in the medical community.
- 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 rely on key executive officers, and their knowledge of our business and technical expertise would be difficult to replace.

Recent Developments

Warrant Exercise Agreements

On October 12, 2017 (the "Closing Date"), the Company entered into Warrant Exercise Agreements (the "Exercise Agreements") with holders (the "Exercising Holders") of its outstanding warrants to purchase up to 724,200 shares of

common stock of the Company issued in March 2017 (collectively, the “Original Warrants”) whereby the exercising holders and the Company agreed that the holders would, subject to beneficial ownership limitations on exercise contained in the Original Warrants, exercise all of the Original Warrants. The Company received aggregate gross proceeds before expenses of approximately \$724,200 and issued an aggregate of 724,200 shares of Common Stock (the “Exercise Shares”) from the exercise of all of the Original Warrants by the exercising holders. In order to induce

the Exercising Holders to exercise the Original Warrants, the Company agreed to reduce the exercise price on such warrants from \$1.96 to \$1.00 per share.

The Original Warrants and Exercised Shares were registered pursuant to the Company's Registration Statement on Form S-3 (File No. 333-217390), filed with the U.S. Securities and Exchange Commission (the "SEC") under the Securities Act, including Amendment No. 1, thereto, which became effective on June 30, 2017.

In connection with the exercise of the Original Warrants, the Company issued an additional warrant to each Exercising Holder for the number of shares of Common Stock equal to one hundred percent of the number of exercised shares purchased by such Exercising Holder (the "Warrant Shares"), with an exercise price of \$1.26 per share (each, an "Additional Warrant", and collectively, the "Additional Warrants"). The Additional Warrants are substantially identical to the Original Warrants, except that the exercise price of the Additional Warrant is \$1.26 and such warrant is not exercisable for six months after issuance.

Company Information

The Company was incorporated under the laws of the State of New Jersey on March 9, 1989 under the name A.R.C. Enterprises, Inc. The Company changed its name to Akers Research Corporation on September 28, 1990. On February 24, 1996 the Company changed its name from Akers Research Corporation to Akers Laboratories, Inc. On March 26, 2002 the Company changed its name to Akers Biosciences, Inc. The Company was co-founded by the current Executive Chairman of the Board of Directors (the "Board"), Raymond F. Akers, Jr., PhD.

On May 22, 2002, the Company was first admitted and commenced trading of its shares on the Alternative Investment Market of the London Stock Exchange ("AIM") and currently trades under the symbols "AKR.L". Our executive offices are located at 201 Grove Road Thorofare, New Jersey USA 08086, and our telephone number is (856) 848-8698. Our website address is www.akersbio.com. Information contained in our website does not form part of the prospectus and is intended for informational purposes only.

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to provide only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure obligations regarding executive compensation arrangements;
- not being required to hold a non-binding advisory vote on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the date we completed our initial public offering, which was January 23, 2014, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded \$700.0 million as of the prior June 30th, or (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

We refer to the Jumpstart Our Business Startups Act of 2012 in this prospectus as the “JOBS Act,” and references in this prospectus to “emerging growth company” have the meaning associated with that term as used in the JOBS Act.

Notwithstanding the above, we are also currently a “smaller reporting company” meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than \$75 million and annual revenues of less than \$50 million during the most recently completed fiscal year. In the event that we are still considered a smaller reporting company at such time as we cease to be an emerging growth company, the disclosure we will be required to provide in our filings with the SEC will increase, but will still be less than it would be if we were not considered either an emerging growth company or a smaller reporting company. Specifically, similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”), requiring that independent registered public accounting firms provide an attestation report on the effectiveness of their internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in their annual reports.

THE OFFERING

Class A Units offered:

7,692,308 Class A Units with each Class A Unit consisting of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price equal to 125% of the public offering price of the Class A Units per share of common stock. The Class A Units will not be certificated and the shares of common stock and warrants that are part of such units will be immediately separable and will be issued separately in this offering.

Offering Price per Class A Unit

\$[] combined price for each Class A Unit.

Class B Units offered:

3,000 Class B Units are also being offered to those purchasers, if any, whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering. Each Class B Unit will consist of one share of our Series B Preferred, with a stated value of \$1,000 and convertible into shares of our common stock, at the public offering price of the Class A Units, together with the equivalent number of warrants as would have been issued to such purchaser if they had purchased Class A units based on the public offering price. The Series B Preferred generally do not have any voting rights but are convertible into shares of common stock. The Class B Units will not be certificated and the shares of Series B Preferred and warrants that are part of such units are immediately separable and will be issued separately in this offering.

Offering Price per Class B Unit

\$1,000 combined price for each Class B Unit.

Warrants

Each warrant included in the Units will have an exercise price equal to 125% of the public offering price of the Class A Units per share of common stock, will be exercisable upon issuance, and will expire five years from the date of issuance.

Series B Convertible Preferred Stock:

The Series B Preferred will be convertible into shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences, rights and limitations) at any time at the option of the holder, at the public offering price of the Class A Units. See “Description of Securities — Preferred Stock — Series B Convertible Preferred Stock” for a discussion of the terms of the B Preferred.

Over-allotment option:

We have granted a 45-day option to the underwriter to purchase a maximum of 2,307,692 additional shares of common stock (15% of the shares of common stock included in the Class A Units and the shares of common stock underlying the shares of Series B Preferred included as part of the Class B Units sold in this offering) and warrants to purchase a maximum of 2,307,692 shares of common stock (15% of the warrants included as part of the Units sold in this

offering), solely to cover over-allotments, if any.

Common stock outstanding after this offering:

17,612,860 shares. If the underwriter's over-allotment option is exercised in full, the total number of shares of our common stock outstanding immediately following the option exercise will be 19,920,552 shares. Excludes shares of common stock that may be issued upon exercise of the warrants.

Series B Convertible Preferred Stock Outstanding after this offering:

3,000 Series B Preferred shares.

Use of Proceeds:

We estimate that the net proceeds from our sale of shares of our common stock in this offering will be approximately \$5.4 million, or approximately \$6.2 million if the underwriter's over-allotment option is exercised in full, at an assumed public offering price of \$0.39 per Class A Unit and \$1,000 per Class B Unit, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We expect to use the net proceeds of this offering for general corporate purposes, including working capital, product development, marketing activities, expanding our internal sales organization and further developing sales channels and other capital expenditures.

Risk Factors:

See the section entitled “Risk Factors” beginning on page 10 for a discussion of factors to consider carefully before deciding whether to purchase shares of our common stock.

NASDAQ Capital Market Symbol:

AKER. There is no established public trading market for the Warrants or Series B Preferred, and we do not expect an active trading market to develop. We do not intend to list the warrants or the Series B Preferred on any securities exchange or other trading market. Without an active trading market, the liquidity of the warrants and the Series B Preferred will be limited.

AIM Symbol

AKR.L

Lock-up:

We have agreed with the underwriter not to offer for sale, issue or sell, or register for offer or sale, any of our common stock or securities convertible into our common stock for a period of 180 days after the date of this prospectus, subject to certain exceptions. In addition, our directors and officers agreed with the underwriter not to offer for sale, issue, sell, contract to sell, pledge or otherwise dispose of any of our common stock or securities convertible into common stock for a period of 180 days after the date of this prospectus. See “Underwriting” section on page 92.

The number of shares of common stock to be issued and outstanding after this offering is based on 9,920,552 shares of common stock issued and outstanding as of December 12, 2017, and excludes:

- 1,054,893 shares reserved for future issuances under our 2017 Equity Incentive Plan (the “2017 Plan”). All future grants will be made pursuant to the 2017 Plan at the market price per share on the date of issuance;
- 255,000 shares reserved for outstanding stock options issued under our 2013 Stock Incentive Plan (the “2013 Plan”) as amended; and
- 1,490,570 shares issuable upon exercise of outstanding warrants weighted average exercise price of \$1.39 per share.
- 7,692,308 shares of our common stock issuable upon exercise of the warrants to be issued in this offering;
- 7,692,308 shares of our common stock issuable upon conversion of the Series B Preferred to be issued in this offering; and
- 769,231 shares of our common stock issuable by the Company upon exercise of the underwriter’s warrants (5% of the shares of common stock sold in this offering, including shares issuable upon conversion of the Series B Preferred Stock but excluding any securities sold upon exercise of the underwriter’s over-allotment option or shares issuable upon exercise of the warrants).
- The number of shares of our common stock outstanding after this offering will fluctuate depending on how many Class B Units are sold in this offering and whether and to what extent holders of Series B Preferred shares

convert their shares to common stock.

- To the extent we sell any Class B Units in this offering, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series B Preferred issued as part of the Class B Units.

Except as otherwise indicated herein, all information in this prospectus, including the number of shares that will be outstanding after this offering, assumes no exercise by the underwriter of their over-allotment option.

SUMMARY FINANCIAL DATA

The following tables set forth a summary of our historical financial data as of, and for the period ended on, the dates indicated. We have derived the statement of operations data for the years ended December 31, 2016 and 2015 from our audited financial statements included elsewhere in this prospectus. The statement of operations data for the nine months ended September 30, 2017 and 2016 and the balance sheet data as of September 30, 2017 have been derived from our unaudited financial statements appearing elsewhere in this prospectus. This unaudited interim financial information has been prepared on the same basis as our audited financial statements and, in our opinion, reflects all adjustments, consisting only of normal and recurring adjustments, that we consider necessary for a fair presentation of our financial position as of September 30, 2017 and operating results for the periods ended September 30, 2017 and 2016. You should read this data together with our financial statements and related notes appearing elsewhere in this prospectus and the sections in this prospectus entitled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” The historical results are not necessarily indicative of the results to be expected for any future periods and the results from the nine months ended September 30, 2017 should not be considered indicative of results expected for the fiscal year 2017.

Summary of Statement of Operations Data

	Nine Months Ended September 30,		Fiscal Year Ended December 31,	
	2017	2016	2016	2015
Total revenue	\$ 2,540,942	\$ 2,307,708	\$ 2,960,912	\$ 2,115,050
Cost of sales	\$ 846,487	\$ 713,576	\$ 1,083,087	\$ 950,792
Gross profit	\$ 1,694,455	\$ 1,594,132	\$ 1,877,825	\$ 1,164,258
Net loss	\$ (3,193,571)	\$ (2,207,707)	\$ (3,303,538)	\$ (9,311,913)
Basic and diluted net loss per share	\$ (0.39)	\$ (.41)	\$ (.61)	\$ (1.81)
Weighted average basic and diluted shares outstanding	8,268,851	5,428,859	5,430,205	5,140,920

Summary of Balance Sheet Information

The following table presents consolidated balance sheet data as of September 30, 2017 on:

- an actual basis;
- a pro forma basis, giving effect to (i) the Exercise Agreements; and (ii) the issuance of stock grants to officers and key employees; and
- a pro forma, as adjusted basis, giving effect to (i) the sale by us of 7,692,308 Class A Units, at the assumed public offering price of \$0.39 per Class A Unit and 3,000 Class B Units, at the public offering price of \$1,000 per Class B Unit, after deducting underwriting discounts and commissions and estimated offering expenses.

The pro forma as adjusted information set forth below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

	As of September 30, 2017		
	Actual	Pro Forma	As Adjusted
Current assets	\$ 3,983,292	\$ 4,664,040	\$ 10,064,040
Total asset	\$ 5,528,333	\$ 6,209,081	\$ 11,609,081
Long-term Liabilities	\$ —	\$ —	\$ —

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

Total liabilities	\$	1,581,792	\$	1,581,792	\$	1,581,792
Total stockholders' equity	\$	3,946,541	\$	4,627,289	\$	10,027,289
9						

RISK FACTORS

Our business faces many risks and an investment in our common stock involves significant risks. Prospective investors are strongly encouraged to consider carefully the risks described below, as well as other information contained herein before investing. Investors are further advised that the risks described below may not be the only risks we face. Additional risks that we do not yet know of, or that we currently think are immaterial, may also negatively impact our business operations or financial results. If any of the events or circumstances described in this section occurs, our business, financial condition or results of operations could suffer. Prospective investors in our common stock should consider the following risks before deciding whether to purchase shares of our common stock.

Risks Related to the Company and Our Business

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

We have recorded a net loss attributable to common stockholders in most reporting periods since our inception. Our net loss for the nine month periods ended September 30, 2017 and September 30, 2016 were \$3,193,571 and \$2,207,707, respectively. Our net loss for the years ended December 31, 2016 and December 31, 2015 were \$3,303,538 and \$9,311,913, respectively. Our accumulated deficit at September 30, 2017 was \$100,673,108. Our accumulated deficit at December 31, 2016 was \$97,479,537. Losses are expected to continue for the foreseeable future. The Company expects to continue to have development costs as it develops its next generation of products. We may never achieve profitable operations or positive cash flow.

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

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

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

As of September 30, 2017, we had two principal U.S. customers; Cardinal Health, Inc. (“Cardinal Health”) and Fisher Healthcare (“Fisher”) each has the non-exclusive right to distribute PIFA Heparin/PF4 Rapid Assays within the U.S. NovoTek Pharmaceuticals Ltd (“NovoTek”) has exclusive distribution rights to PIFA Heparin/PF4 Rapid Assays in the Peoples Republic of China.

For the nine months ended September 30, 2017, Cardinal Health, Fisher and NovoTek accounted for approximately 67% of the Company’s product revenue. For the year ended December 31, 2016, Cardinal Health, Fisher and NovoTek accounted for approximately 75% 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, 2016, three customers accounted for 30% of our trade receivables as compared to the nine months ended September 30, 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. To date, we have not experienced any significant difficulty locating and obtaining the materials necessary to fulfill our production requirements. For the nine months ended September 30, 2017, one supplier accounted for 11% of the Company's purchases. One supplier accounted for 27% of the Company's total purchases during the year ended December 31, 2016. Any prolonged inability to obtain certain materials or components could have an adverse effect on the Company's financial condition or results of operations and could result in damage to its relationships with its customers and, accordingly, adversely affect the Company's business.

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

We intend to invest significantly in our business; therefore, we expect cash flows from operations to be inadequate to cover our anticipated expenses. We believe we have sufficient capital to satisfy our needs for at least the next twelve months. We may need to obtain significant additional financing, both in the short and long-term, to make planned capital expenditures, to cover operating expenses, upgrades to our manufacturing operations, our ongoing product development and to fund to potential acquisitions, if any. We may not be able to secure adequate additional financing when needed on acceptable terms, or at all. To execute our business strategy, we may issue additional equity securities in public or private offerings. If we cannot secure sufficient additional funding we may be forced to forego strategic opportunities and/or delay, scale back or eliminate future product development which would harm our business and our ability to generate positive cash flow in the future.

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

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

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

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

uses, in certain markets, or at all.

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

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

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

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

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

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

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

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

We plan to market some of our products in foreign jurisdictions, initially in China and the European Union (“EU”). Many foreign countries in which we market or may market our products have regulatory bodies and restrictions similar to those of the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ. Companies are now required to obtain a CE Mark, which shows conformance with the requirements of applicable European Conformity directives, prior to the sale of some medical devices within the European Union. Some of our current products that require CE Markings have them and it is anticipated that additional and future products may require them as well. We may be required to conduct additional testing or to provide additional information, resulting in additional expenses, to obtain necessary approvals. If we fail to obtain approval in such foreign jurisdictions, we would not be able to sell our

products in such jurisdictions, thereby reducing the potential revenue from the sale of our products.

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

Any medical device that is legally marketed in the U.S. may be exported anywhere in the world without prior FDA notification or approval. Medical devices that are not FDA-cleared for marketing legally in the U.S. may be exported

under section 801(e)(1) of the FD&C Act, provided that they are intended for export only, they are class I or class II devices, and they are:

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

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

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

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

Further, some foreign countries, such as Canada and India, require that a medical device company’s manufacturing facility be certified for compliance with the ISO 13485, an international standard for quality systems management. The International Organization for Standardization (“ISO”) is the world’s largest developer of standards with 148 member countries. The Company’s quality management system received a certification of compliance with the ISO 13485:2003 requirements on February 4, 2015. The failure by the Company to maintain this certification may limit Akers’ ability to obtain foreign regulatory approval on a timely basis, if at all and to do so may cause Akers to incur additional costs or prevent Akers from marketing its products in foreign countries, which may have a material adverse effect on its business and results of operations.

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

According to “In Vitro Diagnostic Tests Come out of the Lab and Into the Home”, an article published by MDDI online in March 2013, the diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Several companies produce diagnostic tests that compete directly with our testing product line, including but not limited to, Abbott, ACON Laboratories, Inc., Alere, Diagnostica Stago, SA, Immucor, Inc., OraSure Technologies, Inc., and Quidel Corporation. Many of these competitors have substantially greater financial, technical, marketing and other resources than we do and enjoy other competitive advantages, including, greater name recognition; established relationships with health care professionals, companies and consumers; additional lines of products and the ability to offer rebates or higher discounts and incentives. As new products enter the market, our products may become obsolete or a competitor’s products may be more effective or more effectively marketed and sold than ours. Although we have no specific knowledge of any

competitor's product that will render our products obsolete, if we fail to maintain and enhance our competitive position or fail to introduce new products and product features, our customers may decide to use products developed by our competitors, which could result in a loss of revenue and cash flow.

In addition, the point-of-care diagnostics industry is undergoing rapid technological changes, with frequent introductions of new technology-driven products and services, some of which focus on automated systems to provide rapid results. As new technologies become introduced into the point-of-care diagnostic testing market, we may be required to commit considerable additional efforts, time and resources to enhance our current product portfolio or develop new

products. We may not have the available time and resources to accomplish this and many of our competitors have substantially greater financial and other resources to invest in technological improvements. We may not be able to effectively implement new technology-driven products and services or be successful in marketing these products and services to our customers, especially if rapid, manual testing products become secondary, in large markets, to automated point-of-care systems. If these potential developments come to fruition our operating results could be materially harmed.

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

Conducting clinical trials is a lengthy, time-consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through clinical trials the safety and effectiveness of our products. We have incurred, and we will continue to incur, substantial expense for, and devote a significant amount of time to, product development, pilot trial testing, clinical trials and regulated, compliant manufacturing processes. Research and development expenses for the nine months ended September 30, 2017 totaled \$952,724, which was a 2% increase as compared to \$932,858 for the nine months ended September 30, 2016. The estimated research and development expense for the year ending December 31, 2017 is \$1,250,000.

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

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

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

Even if our clinical trials are completed as planned, their results may not support either the further clinical development or the commercialization of our product candidates. The FDA or government authorities may not agree with our conclusions regarding the results of our clinical trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results from any later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our 510(k)'s and, ultimately, our ability to commercialize our product candidates and generate

product revenue. Each medical device marketed in the U.S. must receive a 510(k) clearance from the FDA. A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent (“SE”), to a legally marketed device. Companies must compare their device to one or more similar legally marketed devices, commonly known as “predicates”, and make and support their substantial equivalency claims. The submitting company may not proceed with product marketing until it receives an order from the FDA declaring a device substantially equivalent. The substantially equivalent determination is usually made within 90 days, based on the information submitted by the applicant.

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

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

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

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

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

- fines, injunctions and civil penalties;
- recall, detention or seizure of our products;
- the issuance of public notices or warnings;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance of new products;
- withdrawing 510(k) clearance already granted; and
- criminal prosecution.

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

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

Achieving market acceptance for our existing products such as our direct-to-consumer offerings (disposable breathalyzers) and clinical laboratory testing solutions (Particle Immuno Filtration Assay (“PIFA”) based heparin-induced thrombocytopenia and infectious disease rapid tests) and introducing new products (breath condensate detectors for the health & wellness categories) require substantial marketing efforts and will require our sales account executives, contract partners, outside sales agents and distributors to make significant expenditures of time and money. In some instances we will be significantly or totally reliant on the marketing efforts and expenditures of our contract partners,

outside sales agents and distributors. The Company has aligned its sales resources with the regional sales segmentation of our clinical products distributors. Although this has positively impacted sales, the large account executive territories may prove to be inefficient as we commercialize products and may hinder our revenue growth.

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

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

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

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

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

Technology is an important component of our business and growth strategy, and our success depends to a significant extent on the development, implementation and acceptance of new products. Commitments to develop new products must be made well in advance of any resulting sales, and technologies and standards may change during development, potentially rendering our products outdated or uncompetitive before their introduction. Our ability to develop products to meet evolving industry requirements and at prices acceptable to our customers will be dependent on a number of factors including, funding availability to complete development efforts, our ability to test and refine products, successfully conduct clinical trials and seek to obtain required FDA clearance or foreign approval/certification for products that require such regulatory authorizations. Physician patients and third party payors and the medical community may be slow to adopt any of our products. Moreover, there can be no assurance that the products that we are developing will receive FDA clearance, work effectively in the marketplace or gain market acceptance. We may expend considerable funds and other resources on the development of next-generation products without any guarantee that these products will be successful.

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

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

The Company does not control the efforts of its distributors and its distributors are not prohibited from selling competing products. Our ability to sell our products depends largely on the Company's relationships with such distributors. Accordingly, we are subject to the risk that they may not commit the financial and other resources to market and sell our products to our level of expectation, they may experience financial hardship or they may otherwise terminate our relationship on short notice. In the U.S. clinical laboratory marketplace, many of our existing and potential customers purchase our products through our two national distributors, Cardinal Health and Fisher Health. Our sales account executives work in tandem with the distributor's sales representatives to gain access to decision makers within the

majority of U.S. medical facilities. In addition, the Company relies on its distribution network to negotiate pricing arrangements and contracts with Group Purchasing Organizations and their affiliated hospitals and other members. For the years ended December 31, 2016 and 2015, 87% and 78%, respectively of total product revenue from the sale of the Company's Heparin/PF4 Assay products was generated through our U.S. distributors' purchases, with Cardinal Health and Fisher accounting for 63% and 65% of such sales for each year ended December 31, 2016 and 2015. In the future, if we are unable to maintain existing relationships and/or grow to be recognized as a prominent medical device supplier within these organizations, and/or develop new relationships with additional U.S. and international distributors, our competitive position would likely suffer and our business would be harmed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our business is vulnerable to inflation.

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

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

Our ability to negotiate favorable contracts with non-governmental payors, including managed-care plans or Group Purchasing Organizations (“GPOs”), even if facilitated by our distributors, may significantly affect revenue and operating results. Our customers continue to face cost reduction pressures that may cause them to curtail their use of, or reimbursement for some of our products, to negotiate reduced fees or other concessions or to delay payment. Furthermore, the increasing leverage of organized buying groups among non-governmental payors may reduce market

prices for our products and services, thereby reducing our profitability. Reductions in price increases or the amounts received from current customers or lower pricing for our products to new customers could have a material adverse effect on the financial position, cash flows and results of operations.

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

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

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

For some of our products, our success in non-U.S. markets may depend upon the availability of coverage and reimbursement from the third-party payors through which health care providers are paid in those markets. Health care payment systems in non-U.S. markets vary significantly by country, and include single-payor, government managed systems as well as systems in which private payors and government-managed systems exist, side-by-side. For some of our products, our ability to achieve market acceptance or significant sales volume in international markets may be dependent on the availability of reimbursement for our products under health care payment systems in such markets. There can be no assurance that reimbursement for our products, will be obtained or that such reimbursement will be adequate.

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

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

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

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) created new federal statutes to prevent healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may

result in fines or imprisonment or exclusion from government sponsored programs. HIPAA also established uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses.

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

We may fail to recruit and retain qualified personnel.

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

We may face risks in connection with potential acquisitions.

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

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

We are dependent on the management team of Akers Bio to execute against its business plan. Failure could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

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

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

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

Our success depends significantly on our ability to protect our rights to the patents, trademarks, trade secrets, copyrights and all other intellectual property rights used in our products. Protecting our intellectual property rights is

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

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

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

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

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

Some or all of our patent applications may not result in the issue of patents, or the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors, if any, may be challenged and subsequently narrowed, invalidated, found unenforceable or circumvented. Patent litigation is widespread in the biotechnology industry and could harm our business. Litigation might be necessary to protect our patent position. Patentability, invalidity, freedom-to-operate or other opinions may be required to determine the scope and validity of third-party proprietary rights. If we choose to go to court to stop a third party from using the inventions protected by our patent, that third party would have the right to ask the court to rule that such patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and we may not have the required resources to pursue such litigation or to protect our patent rights. In addition, there is a risk that the court will decide that our patents are not valid or that we cannot stop the other party from using their inventions. There is also the risk that, even if the validity of these patents is upheld, the court will find that the third party's activities do not infringe our rights in these patents.

Furthermore, a third party may claim that we are infringing the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party's treble damages or attorneys' fees for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our

products or methods of use either do not infringe the claims of the relevant patent and/or that the third party patent claims are invalid, and we may not be able to do this. Proving invalidity in the United States, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

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

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

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

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

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

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

The laws in some foreign jurisdictions may not provide protection for our trade secrets and other intellectual property. If our trade secrets or other intellectual property are misappropriated in foreign jurisdictions, we may be without adequate remedies to address these issues. Additionally, we also rely on confidentiality and assignment of invention

agreements to protect our intellectual property. These agreements may provide for contractual remedies in the event of misappropriation. We do not know to what extent, if any, these agreements and any remedies for their breach, will be enforced by a foreign or domestic court. In the event our intellectual property is misappropriated or infringed upon and an adequate remedy is not available, our future prospects will likely diminish.

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

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

The manufacturing and marketing of professional and consumer diagnostics involve an inherent risk of product liability claims. For example, a defect in one of our diagnostic products could lead to a false positive or false negative result, affecting the eventual diagnosis. Our product development and production are extremely complex and could expose our products to defects. Manufacturing and design defects could lead to recalls, either voluntary or required by the FDA or other government authorities, and could result in the removal of a product from the market. Defects in our products could also harm our reputation, lead to product liability claims, claims that inaccurate test results lead to death or injury, negative publicity and decrease sales of our products. We have obtained \$10,000,000 of product liability insurance and we have never received a product liability claim, and have generally not seen product liability claims for screening tests that are accompanied by appropriate disclaimers. However, in the event there is a claim, this insurance may not fully cover our potential liabilities. In addition, as we attempt to bring new products to market, we may need to increase our product liability coverage which would be a significant additional expense that we may not be able to afford. If we are unable to obtain sufficient insurance coverage at an acceptable cost to protect us, we may be forced to abandon efforts to commercialize our products or those of our strategic partners, which would reduce our revenue.

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

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

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

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

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can utilize the extended transition period provided in Section 7(a)(2)(B) of the Securities Act which allows us to delay the adoption of compliance with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to

utilize this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards as they become applicable to public companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest of (i) December 31, 2019 (the end of the fiscal year in which the fifth anniversary of our initial public offering in the U.S. occurred), (ii) the last day of the first fiscal year in

which our annual gross revenue exceed \$1.07 billion, (iii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter or (iv) the date on which we have issued more than \$1 billion in non-convertible debt during the preceding three-year period.

We have not engaged our independent registered public accounting firm to perform an audit of our internal control over financial reporting as of any balance sheet date or for any period reported in our financial statements. Had our independent registered public accounting firm performed an audit of our internal control over financial reporting, material weaknesses may have been identified. For so long as we qualify as an “emerging growth company” under the JOBS Act, we will not have to provide an auditor’s attestation report on our internal controls in future annual reports on Form 10-K as otherwise required by Section 404(b) of the Sarbanes-Oxley Act. During the course of the evaluation, documentation or attestation, our independent registered public accounting firm may identify weaknesses and deficiencies that we may not otherwise identify in a timely manner or at all as a result of the deferred implementation of this additional level of review.

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

On September 14, 2012, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with Mr. Thomas J. Knox (a member of our Board from July 2013 through August 2017). Pursuant to the Purchase Agreement, Mr. Knox purchased, amongst other things, 10,000,000 shares of the Series A Preferred Stock. The Series A Preferred Stock were convertible at any time into 320,512 shares of common stock. The Company requested that Mr. Knox convert the Series A Preferred Stock, and though under no obligation to do so, on November 15, 2013, Mr. Knox converted all 10,000,000 shares of Series A Preferred Stock into 320,512 shares of common stock pursuant to the terms of the Series A Preferred Stock. In order to satisfy the required onetime payment of \$500,000 (the “Purchase Price”) due upon conversion as set forth in the Purchase Agreement, Mr. Knox issued a promissory note in favor of the Company for the principal aggregate amount of \$500,000 (the “2013 Knox Note”). The 2013 Knox Note required payment of the principal in full prior to maturity date of November 15, 2014 (the “Maturity Date”) with interest on the unpaid principal balance at the rate of the thirty day average LIBOR per annum commencing on November 15, 2013. The 320,512 shares of common stock were to be held by the Company as collateral until all amounts owing under the 2013 Knox Note were paid in full.

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

Risks Related to the Market

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

Recent global economic conditions, including a disruption of financial markets, could adversely affect us, primarily through limiting our access to capital. In addition, the continuation or worsening of general market conditions in

economies important to our businesses may adversely affect our clients' level of spending and ability to obtain financing, leading to us being unable to generate the levels of sales that we require. Current and continued disruption of financial markets could have a material adverse effect on the Company's business, financial condition, results of operations and future prospects.

Risks Relating to our Common Stock

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

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

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

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

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

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

If we are unable to regain compliance by May 29, 2018, we may be eligible for an additional 180 calendar day compliance period to demonstrate compliance with the bid price requirement. To qualify, we will be required to meet the continued listing requirement for market value of publicly held shares set forth in Market Place Rule 5550(a) and all other initial listing standards for NASDAQ set forth in Marketplace Rule 5505, with the exception of the bid price requirement, and will need to provide written notice to NASDAQ of its intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. If we do not qualify for the second compliance period or fails to regain compliance during the second 180-day period, then NASDAQ will notify us of its determination to delist the common stock, at which point we would have an opportunity to appeal the delisting determination to a Hearings Panel.

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

If our common stock is delisted as a result of our failure to comply with the Bid Price Rule or any other NASDAQ continued listing requirement, we would expect our common stock to be traded in the over-the-counter market, which could adversely affect the liquidity of our common stock. Additionally, delisting would substantially impair our ability

to raise additional funds to fund our operations, to meaningfully advance the development of our products, and we could face other significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- a reduced amount of news and analyst coverage for us;
- reduced liquidity for our stockholders;
- potential loss of confidence by employees and potential future partners or collaborators; and
- loss of institutional investor interest and fewer business development opportunities.

Substantial doubt exists about our ability to continue as a going concern within one year of September 30, 2017.

Substantial doubt exists about the Company's ability to continue as a going concern within one year after the financial statements are issued. The Company has identified three conditions or events that support this determination:

The Company's current working capital position.

The Company is working diligently to raise additional working capital either through various financial institutions, investment banks or other sources while minimizing dilution to the shareholders.

Executive management continues to monitor expenses and directives are in place to restrict non-essential expenses until the working capital situation is resolved.

Negotiations are underway with multiple customers for the Company's products and are anticipated to be completed during the three months ending March 31, 2018. All parties are confident that a solution can be achieved but a significant delay will impact revenue projections.

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

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

If the proceeds from this offering are insufficient for us to continue as a going concern, it could make it more difficult for us to raise additional capital, should it be needed, or cause our customers, suppliers and other business partners to lose confidence in us thereby resulting in a reduction of revenue, loss of supply resources and other effects that would be significantly harmful to our business. If adequate funds are not available when needed, our liquidity, financial condition and operating results would be materially and adversely affected, and we may not be able to operate our business without significant changes in our operations or at all.

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

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

- variations in our revenue and operating expenses;
- actual or anticipated changes in the estimates of our operating results or changes in stock market analyst recommendations regarding our ordinary shares, other comparable companies or our industry generally;
- market conditions in our industry and the economy as a whole;
- developments in the financial markets and worldwide or regional economies;
- announcements of innovations or new products or services by us or our competitors;
- announcements by the government relating to regulations that govern our industry;
- sales of our common stock or other securities by us or in the open market; and

- changes in the market valuations of other comparable companies.

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

The Series B Preferred Stock will be an unlisted security and as such there will not be public market for such securities.

There is no established public trading market for the Series B Preferred Stock, and we do not expect a market to develop. In addition, the Series B Preferred Stock is not listed, and we do not intend to apply for listing of the Series B Preferred Stock on any securities exchange or trading system. Without an active market, the liquidity of the Series B Preferred Stock is limited, and investors may be unable to liquidate their investments in the Series B Preferred Stock.

Holders of Series B Preferred will have limited voting rights.

Except with respect to certain material changes in the terms of the Series B Preferred and certain other matters and except as may be required by New Jersey law, holders of Series B Preferred will have no voting rights. You will have no right to vote for any members of our board of directors.

Holders of the warrants will not have rights of common stockholders until such Warrants are exercised.

The warrants being offered do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay the exercise price prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value.

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

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

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

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

As of December 12, 2017, we had outstanding warrants to purchase up to 1,490,570 shares of our common stock at a weighted exercise price of \$1.39 per share.

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

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

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

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

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

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

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

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

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

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

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

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us

change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

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

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 ("PFO") have concluded that, as of December 31, 2016, our internal controls over financial reporting were not effective. As of September 30, 2017 and based upon that evaluation, the Company's CEO and PFO concluded that the Company's disclosure controls and procedures are 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 CEO and PFO, as appropriate, to allow timely decisions regarding required disclosure.

As a result of our evaluation, we identified a material weakness in our controls related to segregation of duties and other immaterial weaknesses in several areas of data management and documentation.

The Company's management is composed of a small number of professionals resulting in a situation where limitations on segregation of duties exists. Accordingly, as a result of the material weakness identified above, we have concluded that the control deficiencies result in a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented on a timely basis by the Company's internal controls. The Company has committed to hiring a Financial Controller during the year ending December 31, 2017 which will allow for a higher level of segregation and improve the Company's overall compliance with COSO.

While the material weakness set forth above were the result of the scale of our operations and are intrinsic to our small size, the Company believes the risk of material misstatements relative to financial reporting are minimal.

Risks Related to the Offering

Investors in this offering will experience immediate and substantial dilution in net tangible book value.

The public offering price per share of common stock in this offering will be substantially higher than the net tangible book value per share of our outstanding shares of common stock. Accordingly, investors in this offering will pay a price per share that substantially exceeds the net tangible book value per share of our common stock. Based on an at an assumed public offering price of \$0.39 per Class A Unit and \$1,000 per Class B Unit, investors in this offering will incur immediate dilution of \$0.04 per share. See “Dilution” for a more complete description of how the value of your investment will be diluted upon the completion of this offering.

We may need additional capital, and the sale of additional shares or equity or debt securities could result in additional dilution to our stockholders.

We believe that our existing cash, together with the net proceeds from this offering, will be sufficient to meet our anticipated cash needs for at least the next twelve months. We may, however, require additional cash resources due to changed business conditions or other future developments. If these resources are insufficient to satisfy our cash requirements, we may seek to sell additional equity or debt securities or obtain one or more credit facilities. The sale of additional equity securities could result in additional dilution to our stockholders and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. The incurrence of indebtedness would result in increased debt service obligations and could result in operating and financing covenants that would restrict our operations. It is uncertain whether financing will be available in amounts or on terms acceptable to us, if at all.

If we raise additional funds through government or other third-party funding, collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue stream or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products that we would otherwise prefer to develop and market ourselves.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section of this prospectus entitled "Use of Proceeds." You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our securities to decline and delay the development of our product candidates. Pending the application of these funds, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Sales of a substantial number of shares of our common stock following this offering may adversely affect the market price of our common stock and the issuance of additional shares will dilute all other stockholders.

Sales of a substantial number of shares of our common stock in the public market or otherwise following this offering, or the perception that such sales could occur, could adversely affect the market price of our common stock. After completion of this offering at an assumed offering price of \$0.39 per Class A Unit and \$1,000 per Class B Unit, our existing stockholders will own approximately 56% of our common stock, assuming there is no exercise of the underwriter's over-allotment option.

After completion of this offering at an assumed offering price of \$0.39 per Class A Unit and \$1,000 per Class B Unit, there will be 17,612,860 shares of our common stock outstanding. This excludes shares of common stock that may be issued upon exercise of the warrants and conversion of the Series B Preferred to be issued in this offering. In addition, our certificate of incorporation, as amended, permits the issuance of up to approximately 482,387,140 additional shares of common stock after the completion of this offering. Thus, we have the ability to issue substantial amounts of common stock in the future, which would dilute the percentage ownership held by the investors who purchase shares of our common stock in this offering.

We and our officers, directors and certain stockholders have agreed, subject to customary exceptions, not to, without the prior written consent of Joseph Gunnar & Co., LLC, the sole underwriter, during the period ending 180 days from the date of this offering in the case of us and our certain directors and officers, 90 days from the date of this offering in

the case of our stockholders who beneficially own more than 5% of our common stock, directly or indirectly, offer to sell, sell, pledge or otherwise transfer or dispose of any of shares of our common stock, enter into any swap or other derivatives transaction that transfers to another any of the economic benefits or risks of ownership of shares of our common stock, make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of common stock or securities convertible into or exercisable or exchangeable for common stock or any other securities of the Company or publicly disclose the intention to do any of the foregoing.

After the lock-up agreements with our directors and officers pertaining to this offering expire, up to _____ of the shares that had been locked up will be eligible for future sale in the public market. Sales of a significant number of these shares of common stock in the public market could reduce the market price of the common stock.

USE OF PROCEEDS

We estimate that the net proceeds from sale of Units offered by us will be approximately \$5.4 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, and assuming a public offering price of \$0.39 per Class A Unit and \$1,000 per Class B Unit. If the underwriter's over-allotment option is exercised in full, we estimate that our net proceeds will be approximately \$6.2 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and assuming a public offering price of \$0.39 per Class A Unit and \$1,000 per Class B Unit.

The principal purposes of this offering are to increase our capitalization and financial flexibility, and increase our visibility in the marketplace. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds of this offering. However, we currently intend to use the net proceeds to us from this offering, together with existing cash, primarily for general corporate purposes, including working capital, product development, marketing activities, expanding our internal sales organization and further developing sales channels and other capital expenditures. We may also use a portion of the net proceeds for the acquisition of, or investment in, businesses, products, technologies or other assets that complement our business, although we have no present commitments or agreements to enter into any material acquisitions or investments. We will have broad discretion over the uses of the net proceeds in this offering.

The information discussed above is illustrative only and may change based on the actual public offering price and other terms of this Offering determined at pricing.

MARKET PRICE INFORMATION FOR OUR SHARES

Our common stock began trading on The Nasdaq Capital Market on January 23, 2014 under the symbol “AKER”. Prior to such date our common stock was not previously listed or quoted on any other U.S. market. Our common stock began trading on AIM in May 2002 under the symbol “AKR.L”.

The following table shows the high and low market prices per share of our common stock on The Nasdaq for each fiscal quarter for the two most recent fiscal years. Market prices for our shares have fluctuated significantly since they were listed on Nasdaq and trading volume on Nasdaq have been very small in relation to the number of our total outstanding shares.

Quarter ended	Low Price	High Price
Through December 12, 2017	\$ 0.36	\$ 1.82
September 30, 2017	0.70	1.30
June 30, 2017	1.15	2.10
March 30, 2017	1.15	2.90
December 31, 2016	1.55	3.60
September 30, 2016	2.47	3.70
June 30, 2016	1.43	3.50
March 31, 2016	1.08	2.47
December 31, 2015	1.12	3.73
September 30, 2015	2.27	4.54
June 30, 2015	3.65	5.28
March 31, 2015	3.08	4.85

The following table shows the high and low market prices per share of our common stock on AIM for each fiscal quarter for the two most recent fiscal years. Market prices for our shares have fluctuated significantly since they were listed on AIM and trading volume on AIM have been very small in relation to the number of our total outstanding shares.

Quarter Ended	Low Price		High Price		Exchange
	GBP	USD	GBP	USD	Rate
Through December 12, 2017	£ 0.42	\$ 0.55	£ 0.85	\$ 1.12	\$ 1.3227
September 30, 2017	0.65	0.85	1.02	1.34	1.3092
June 30, 2017	0.90	1.15	1.50	1.92	1.2788
March 30, 2017	0.86	1.07	1.90	2.35	1.2388
December 31, 2016	1.45	1.80	2.55	3.17	1.2429
September 30, 2016	1.94	2.55	2.55	3.35	1.3127
June 30, 2016	1.05	1.51	2.15	3.08	1.4344
March 31, 2016	0.79	1.13	1.50	2.15	1.4324
December 31, 2015	0.83	1.26	2.09	3.17	1.5173
September 30, 2015	1.41	2.18	2.83	4.38	1.5492
June 30, 2015	2.60	3.98	3.30	5.06	1.5320
March 31, 2015	2.10	3.18	2.83	4.29	1.5146

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

DIVIDEND POLICY

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our board of directors.

CAPITALIZATION

The following table presents a summary of our cash, cash equivalents, short-term investments and capitalization as of September 30, 2017:

- an actual basis;
- a pro forma basis, giving effect to (i) the Exercise Agreements; (ii) the issuance of stock grants to officers and key employees; and
- a pro forma, as adjusted basis, giving effect to (i) the sale by us 7,692,308 Class A Units, at the assumed public offering price of \$0.39 per Class A Unit and 3,000 Class B Units, at the public offering price of \$1,000 per Class B Unit.

The pro forma information below is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this table together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited and unaudited consolidated financial statements and the related notes appearing elsewhere in this prospectus.

	As of September 30, 2017		
	Actual	Pro Forma	As Adjusted
Cash, cash equivalents and short-term investments	\$ 145,311	\$ 826,059	\$ 6,226,059
Long-term debt	\$ —	\$ —	\$ —
Stockholders’ equity			
Convertible preferred stock 50,000,000 shares authorized, no par value; no shares issued and outstanding (actual); and no shares issued and outstanding (pro forma) and 3,000 issued and outstanding (as adjusted)	\$ —	\$ —	\$ 2,700,000
Common stock 500,000,000 shares authorized, no par value; 8,901,245 shares issued and outstanding (actual); 9,920,552 shares issued and outstanding (pro forma); 17,612,860 shares issued and outstanding (as adjusted)	\$ 104,628,437	\$ 105,309,185	\$ 108,009,185
Accumulated deficit	\$ (100,673,108)	\$ (100,673,108)	\$ (100,673,108)
Deferred Compensation	\$ (8,788)	\$ (8,788)	\$ (8,788)
Total stockholders’ equity (deficit)	\$ 3,946,541	\$ 4,627,289	\$ 10,027,289
Total capitalization	\$ 3,946,541	\$ 4,627,289	\$ 10,027,289

Excludes (i) 1,490,570 shares of our common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of \$1.39 per share as of December 12, 2017, (ii) 1,054,893 shares reserved for future issuances under our 2017 Plan. All future grants will be made pursuant to the 2017 Plan at the market price per share on the date of issuance, (iii) 255,000 shares reserved for outstanding stock options issued under our 2013 Plan, as amended (iv) shares of our common stock issuable upon exercise of the warrants to be issued in this offering, (v) shares of our common stock issuable upon conversion of the Series B Preferred to be issued in this offering, (vi) shares of our common stock issuable by the Company upon exercise of the underwriter’s warrants (5% of the shares of common stock sold in this offering, including shares issuable upon conversion of the Series B Preferred but excluding any securities sold upon exercise of the underwriter’s over-allotment option or shares issuable upon exercise of the

warrants).

The number of shares of our common stock outstanding after this offering will fluctuate depending on how many Class B Units are sold in this offering and whether and to what extent holders of Series B Preferred shares convert their shares to common stock

To the extent we sell any Class B Units in this offering, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series B Preferred issued as part of the Class B Units.

The information discussed above is illustrative only and may change based on the actual public offering price and other terms of this offering determined at pricing.

DILUTION

If you invest in our securities, your investment will be diluted immediately to the extent of the difference between the public offering price you pay in this offering, and the pro forma net tangible book value per share of common stock immediately after this offering.

Net tangible book value per share represents the amount of our total tangible assets reduced by our total liabilities, divided by the outstanding shares of common stock. Tangible assets equal our total assets less intangible assets. As of September 30, 2017, our actual net tangible deficit value was \$2.77 million and our net tangible book value per share was \$0.3115.

Our pro forma net tangible book value of our Common Stock as of September 30, 2017 was \$8.85 million, or \$0.3499 per share. Pro forma net tangible book value represents pro forma total tangible assets less pro forma total liabilities and pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of September 30, 2017, each after giving effect to the receipt of the net proceeds from our sale in this offering of shares of common stock at an assumed public offering price of \$0.39 per Class A Unit and \$1,000 per Class B Unit, and assuming all Class B units were converted to common stock, applying proceeds as set forth in Use of Proceeds and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

The following table illustrates this dilution on a per share basis to new investors:

Assumed public offering price per share of common stock	\$0.39
Historical net tangible book value per share as of September 30, 2017	\$0.3115
Proforma net tangible book value per share as of September 30, 2017	\$0.3482
As adjusted proforma net tangible book value per share after this offering	\$0.3499
Increase in proforma net tangible book value per share attributable to this offering	\$0.0384
Dilution to new investors	\$0.0401

Excludes (i) 1,490,570 shares of our common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of \$1.39 per share as of December 12, 2017, (ii) 1,054,893 shares reserved for future issuances under our 2017 Plan. All future grants will be made pursuant to the 2017 Plan at the market price per share on the date of issuance, (iii) 255,000 shares reserved for outstanding stock options issued under our 2013 Plan, as amended (iv) shares of our common stock issuable upon exercise of the warrants to be issued in this offering, (v) shares of our common stock issuable by the Company upon exercise of the underwriter's warrants (5% of the shares of common stock sold in this offering, including shares issuable upon conversion of the Series B Preferred but excluding any securities sold upon exercise of the underwriter's over-allotment option or shares issuable upon exercise of the warrants).

The number of shares of our common stock outstanding after this offering will fluctuate depending on how many Class B Units are sold in this offering and whether and to what extent holders of Series B Preferred shares convert their shares to common stock

To the extent we sell any Class B Units in this offering, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series B Preferred issued as part of the Class B Units. If the underwriter's over-allotment option is exercised in full, our adjusted pro forma net tangible book value following the offering will be \$0.3500 per share, and the dilution to new investors in the offering will be \$0.0400 per share. The number of shares of our common stock to be outstanding after this offering also assumes only the Common Stock are sold in this offering. To the extent we sell any Series B Preferred Stock, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series B Preferred Stock.

The information discussed above is illustrative only and may change based on the actual public offering price and other terms of this Offering determined at pricing.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. Forward-looking statements present our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Forward-looking statements involve risks and uncertainties and include statements regarding, among other things, our projected revenue growth and profitability, our growth strategies and opportunity, anticipated trends in our market and our anticipated needs for working capital. They are generally identifiable by use of the words “may,” “will,” “should,” “anticipate,” “estimate,” “plans,” “potential,” “projects,” “continuing,” “ongoing,” “expects,” “management believes,” “we intend” or the negative of these words or other variations on these words or comparable terminology. These statements may be found under the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” as well as in this prospectus generally. In particular, these include statements relating to future actions, prospective products, market acceptance, future performance or results of current and anticipated products, sales efforts, expenses, and the outcome of contingencies such as legal proceedings and financial results.

Examples of forward-looking statements in this prospectus include, but are not limited to, our expectations regarding our business strategy, business prospects, operating results, operating expenses, working capital, liquidity and capital expenditure requirements. Important assumptions relating to the forward-looking statements include, among others, assumptions regarding demand for our products and services, the cost, terms and availability of components, pricing levels, the timing and cost of capital expenditures, competitive conditions and general economic conditions. These statements are based on our management’s expectations, beliefs and assumptions concerning future events affecting us, which in turn are based on currently available information. These assumptions could prove inaccurate. Although we believe that the estimates and projections reflected in the forward-looking statements are reasonable, our expectations may prove to be incorrect.

Important factors that could cause actual results to differ materially from the results and events anticipated or implied by such forward-looking statements include, but are not limited to:

- changes in the market acceptance of our products and services;
- increased levels of competition;
- changes in political, economic or regulatory conditions generally and in the markets in which we operate;
- our relationships with our key customers;
- adverse conditions in the industries in which our customers operate;
- our ability to retain and attract senior management and other key employees;
- our ability to quickly and effectively respond to new technological developments;
- our ability to protect our trade secrets or other proprietary rights, operate without infringing upon the proprietary rights of others and prevent others from infringing on the proprietary rights of the Company; and
- other risks, including those described in the “Risk Factors” discussion of this prospectus.

We operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for us to predict all of those risks, nor can we assess the impact of all of those risks on our business or the extent to which any factor may cause actual results to differ materially from those contained in any forward-looking statement. The forward-looking statements in this prospectus are based on assumptions management believes are

reasonable. However, due to the uncertainties associated with forward-looking statements, you should not place undue reliance on any forward-looking statements. Further, forward-looking statements speak only as of the date they are made, and unless required by law, we expressly disclaim any obligation or undertaking to publicly update any of them in light of new information, future events, or otherwise.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the related notes included elsewhere in this prospectus. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, particularly in "Risk Factors."

Overview

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

All of Akers' rapid, single-use tests are performed in vitro (outside the body) and are designed to enhance patient well-being and reduce the cost of healthcare. The Company's current product offerings and pipeline products focus on delivering diagnostic assistance in a wide variety of healthcare fields/specialties, including cardiology/emergency medicine, metabolism/nutrition, diabetes, oncology and infectious disease detection, as well as 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 disease states and medical conditions can be performed on single-patient specimens, without sacrificing accuracy.

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

- cost pressures/efficiency of healthcare delivery;
- need for affordable mass screening tests for key infectious diseases, cardiac conditions, and metabolic markers;
- need for easy to use, accurate at-home tests for individuals to monitor their personal health and wellness; and
- public health needs in developing countries lacking basic health infrastructure.

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

Management's Plans and Basis of Presentation

To date, the Company has in large part relied on equity financing to fund its operations, raising \$13,101,336, net of expenses, in an initial public offering on the Nasdaq Capital Market in 2014. The Company has experienced recurring losses and negative cash flows from operations. Management's strategic plans include the following:

- continuing to advance the development and commercialization of the Company's products, especially those that utilize MPC Biosensor, PIFA and seraSTAT technologies;
- continuing to strengthen and forge domestic and international relationships with well-established sales organizations with strong distribution channels in specific target markets for both our currently marketed and emerging products;

- establishing clinical protocols that support regulatory submissions and publication of data within peer-reviewed journals; and
- continuing to monitor and implement cost control initiatives to conserve cash.

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

- some of Akers' distribution partnerships have been recently established or are in the process of being initiated and, therefore, consistent and historical ordering patterns have not been instituted;
- the Company continues to incur expenses related to the initial commercialization and marketing activities for its wellness products and product development (research, clinical trials, regulatory tasks) costs for its emerging products including Breath PulmoHealth, BreathScan® DKA and PIFA PLUS® Infectious Disease point-of-care tests; and
- to expand the use of its clinical laboratory products, the Company may need to invest in additional marketing support programs to increase brand awareness.

At September 30, 2017, Akers had cash and cash equivalents of \$145,311, working capital of \$2,401,500, stockholders' equity of \$3,946,541 and an accumulated deficit of \$100,673,108. Substantial doubt exists about the Company's ability to continue as a going concern within one year after the financial statements are issued. The Company has identified three conditions or events that support this determination:

The Company's current working capital position;

Negotiations are underway with multiple customers for the Company's products and are anticipated to be completed during the three months ending March 31, 2018. All parties are confident that a solution can be achieved but a significant delay will impact revenue projections. All parties are confident that a solution can be achieved but a significant delay will impact revenue projections; and

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

Please refer to Note 3, Management Plan, of the Financial Statements as of and for the three and nine months ended September 30, 2017 for the Company's plans to address the going concern.

Summary of Statements of Operations for the Nine Months Ended September 30, 2017 and 2016:

Revenue

Akers' revenue for the nine months ended September 30, 2017 totaled \$2,540,942, a 10% increase from the same period in 2016. The table below summarizes our revenue by product line and geographic region for the nine months ended September 30, 2017 and 2016 as well as the percentage of change year-over-year:

Product Lines	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Percent Change	
Particle ImmunoFiltration Assay ("PIFA")	\$ 1,477,726	\$ 2,029,095	(27	)%
MicroParticle Catalyzed Biosensor ("MPC")	381,569	195,040	96	%
Rapid Enzymatic Assay ("REA")	27,500	—	100	%
Other	616,647	83,573	638	%
Total Product Revenue	2,503,442	2,307,708	8	%

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

License & Service Revenue	37,500	—	100	%
Total Revenue	\$ 2,540,942	\$ 2,307,708	10	%
38				

Revenue from the Company's PIFA Heparin/PF4 Rapid Assay products decreased 27% during the nine months ended September 30, 2017 over the same period of 2016. Additional revenue from PIFA related components, totaling \$500,000, during the nine months ended September 30, 2017 is included in other revenue. During the nine months ended September 30, 2016 the Company recognized approximately \$494,000 (2017: \$-) in PIFA revenue from the Company's distribution partner in the People's Republic of China ("PRC"). The distributor continues to work with the various provincial governments in the PRC to finalize reimbursement rates for the providers. Once these rates are established, the distributor expects strong demand for the PIFA products.

The Company is taking steps to improve its market presence and to educate the marketplace through the preparation and publication of additional clinical studies and physician seminars on the risks associated with heparin induced thrombocytopenia.

The Company's MPC breathalyzer technology product sales increased 96% during the nine months ended September 30, 2017 over the same period of 2016. Sales in this category include the BreathScan OxiChek and BreathScan Lync products as well as the traditional BreathScan Breath Alcohol product lines.

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

The Company began shipping the Tri-Cholesterol product, based on the Company's REA technology, during the nine months ended September 30, 2017. The first order, totaling \$27,500, was fulfilled in September and two additional orders have been received to date and will ship before the end of the fourth quarter.

Other operating revenue increased to \$616,647 (2016: \$83,573) during the nine months ended September 30, 2017 as compared to the same period of 2016. The product group consists of fees received for shipping and handling and the sale of components. The significant increase resulted from an initial order, as explained above, for manufacturing components from NovoTek totaling \$500,000. NovoTek will utilize these components along with additional materials to be purchased in a future period to assemble PIFA Heparin/PF4 products in either the PRC or Poland.

During August 2017, the Company received a non-refundable \$50,000 fee from a potential customer for the Company's BreathScan OxiChek products in exchange for the use of equipment, access to product documentation and data, technical support and to restrict the Company from actively pursuing another commercial partner in a specific market segment.

The Company recognized \$37,500 of this fee as License & Service Revenue during the three months ended September 30, 2017 and will recognize the balance of \$12,500 in the three months ended December 31, 2017.

The table below summarizes our revenue by geographic region for the nine months ended September 30, 2017 and 2016 as well as the percentage of change year-over-year:

Geographic Region	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Percent Change	
United States	\$ 1,755,695	\$ 1,721,967	2	%
People's Republic of China	627,132	506,781	24	%
Rest of World	158,115	78,960	100	%
Total Revenue	\$ 2,540,942	\$ 2,307,708	10	%

Domestic sales represent the most significant portion of the Company's revenue, contributing 69.1% (2016: 74.6%). The primary sales and marketing efforts are concentrated on expanding the Company's domestic market share in the rapid clinical diagnostic and health and wellness segments and the recent introduction of the Tri-Cholesterol test has

allowed the Company to re-enter the retail market.

Revenue from China continues to be highly unpredictable. NovoTek Pharmaceuticals (“NovoTek”), our distribution partner for the PIFA Heparin/PF4 Rapid Assay products, continues to pursue approvals for reimbursement rates from the various Provinces and although they anticipate receipt of these approvals, their timing is unknown. Over the past

39

several years, NovoTek has created significant product demand by identifying and working with the key opinion leaders and seeding the marketplace with sample products. As a result, they anticipate strong demand for the PIFA Heparin/PF4 Rapid Assay product once reimbursement rates are approved.

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

The Company's gross margin declined to 67% (2016: 69%) for the nine months ended September 30, 2017. The initial commercial production of the Company's new Tri-Cholesterol product contributed to the decline in gross margin. One-time costs associated with the transition from Research and Development to Manufacturing as the production plans were implemented and adjusted included engineering, raw material waste as processes were fine-tuned to meet commercial production levels, training of the production staff and increased quality review and testing. The inclusion of several of the Research and Development department's professional staff as part of the initial production team significantly increased direct labor costs.

Cost of sales for the nine months ended September 30, 2017 totaled \$846,488 (2016: \$713,576). Direct cost of sales increased to 16% of product revenue while other cost of sales remained steady at 17% for the nine months ended September 30, 2017 as compared to 14% and 17% respectively for the same period in 2016.

Direct cost of sales for the nine-month period ended September 30, 2017 were \$420,189 (2016: \$325,922). Other cost of sales for the nine months ended September 30, 2017 were \$426,299 (2016: \$387,654).

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2017, totaled \$2,440,023, which was a 6% increase as compared to \$2,298,099 for the nine months ended September 30, 2016.

The table below summarizes our general and administrative expenses for the nine months ended September 30, 2017 and 2016 as well as the percentage of change year-over-year:

Description	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Percent Change	
Personnel Costs	\$ 781,833	\$ 712,683	10	%
Professional Service Costs	866,403	587,196	48	%
Stock Market & Investor Relations Costs	320,446	322,956	(1)	)%
Other General and Administrative Costs	471,341	675,264	(30)	)%
Total General and Administrative Expense	\$ 2,440,023	\$ 2,298,099	6	%

Personnel expenses increased by 10% for the nine months ended September 30, 2017 as compared to the same period of 2016. The increase is related to the creation of the Controller's position in the Finance department, salary adjustments for executive management and higher employee benefit expenses.

Professional service costs increased by 48% for the nine months ended September 30, 2017 as compared to the same period of 2016. A significant increase in accounting and audit (\$140,130 (2016: \$80,896)), personnel recruitment (\$22,355 (2016: \$409)), engineering (\$82,718 (2016: \$51,072)), legal fees (\$568,225 (2016: \$443,065)) and general consulting services (\$52,975 (2016: \$5,513)) accounted for the change.

The Company's other general and administrative expenses declined by 30% for the nine months ended September 30, 2017 as compared to the same period of 2016. Continued efforts to reduce costs resulted in savings across several expense categories, the most significant of which resulted from the travel restrictions put in place earlier in the year. Travel expenses for the executive and administrative staff totaled \$36,345 (2016: \$114,293).

Sales and Marketing Expenses

Sales and marketing expenses for the nine months ended September 30, 2017 totaled \$1,382,416 which was a 22% decrease as compared to \$1,764,952 for the nine months ended September 30, 2016.

The table below summarizes our sales and marketing expenses for the nine months ended September 30, 2017 and 2016 as well as the percentage of change year-over-year:

Description	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Percent Change
Personnel Costs	\$ 702,319	\$ 937,777	(25) %
Professional Service Costs	204,237	384,114	(47) %
Royalties and Outside Commission Costs	192,470	178,873	8 %
Other Sales and Marketing Costs	283,390	264,188	7 %
Total Sales and Marketing Expenses	\$ 1,382,416	\$ 1,764,952	(22) %

Personnel costs decreased 25% in the nine months ended September 30, 2017 as compared to the same period of 2016. The Company has reduced its sales and marketing staff from 10 members on January 1, 2016 to 4 as of September 30, 2017. The new sales and marketing strategy targets large integrated delivery networks instead of individual facilities. This strategy requires fewer, but more experienced and technically knowledgeable sales personnel to interact with executive management, laboratory and medical directors. The Company incurred severance expenses related to staff reductions during the nine months ended September 30, 2016 which did not recur during the same period of 2017.

The Company renegotiated or eliminated several consulting arrangements targeted at improving market penetration or identifying marketing or distribution partners during the first half of 2016. The result is a reduction of 47% in professional service fees. General consulting services (\$190,176 (2016: \$295,299)) and marketing services (\$161 (2016: \$51,246)) accounted for the savings for the nine months ended September 30, 2017.

The legal settlement with ChubeWorkx Guernsey, Ltd (“ChubeWorkx”), signed on August 11, 2016, requires the Company to pay a 5% royalty on adjusted gross sales to ChubeWorkx on a quarterly basis. During the nine months ended September 30, 2017, this royalty totaled \$128,109 (2016: \$117,949).

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

Research and Development

Research and development expenses for the nine months ended September 30, 2017 totaled \$952,724, which was a 2% increase as compared to \$932,858 for the nine months ended September 30, 2016.

The table below summarizes our research and development expenses for the nine months ended September 30, 2017 and 2016 as well as the percentage of change year-over-year:

Description	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Percent Change
Personnel Costs	\$ 727,206	\$ 539,810	35 %
Clinical Trial Costs	2,453	160,405	(98) %
Professional Service Costs	89,541	96,515	(7) %
Other Research and Development Costs	133,524	136,128	(2) %

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

Total Research and Development Expenses	\$	952,724	\$	932,858	2	%
---	----	---------	----	---------	---	---

Personnel costs increased 35% during the nine months ended September 30, 2017 as compared to the same period of 2016. This increase was a result of the transfer of Dr. Akers' salary and benefits from the General and Administrative

41

department to Research and Development as he assumed his new responsibilities for the Company. In addition, employee benefit expenses (\$72,026 (2016: \$45,052)) also contributed to the increase.

Clinical trial costs decreased 98% during the nine months ended September 30, 2017 as compared to the same period of 2016. The Company performed two clinical trials during the nine months ended September 30, 2016, one to test the effectiveness of the PIFA Chlamydia assay and one for the KetoChek™ health and wellness product. Both studies were completed during 2016 and no significant expense was incurred during the nine months ended September 30, 2017.

A reduction in general consulting services (\$30,503 (2016: \$57,651)) was offset by an increase in engineering and product design fees (\$56,164 (\$36,593)) for the nine months ended September 30, 2017 resulting in a 7% decline in professional service fees.

Moderate decreases in several expense categories were offset by increases in internal resource utilization (\$17,110 (2016: \$6,976)) and travel expenses (\$28,875 (2016 \$11,050)) to account for the 2% decrease in other research and development expenses.

The following table illustrates research and development costs by project for the nine months ended September 30, 2017 and 2016, respectively:

Project	2017	2016
Asthma/Ph	\$ 52,368	\$ —
Breath Alcohol	6,885	1,381
Chlamydia Trachomatis	182,825	10,685
CHUBE	—	22,307
Heparin/PF4	57,180	72,823
HIV	—	16,885
Ketone	7,154	2,125
KetoChek/OxiChek	284,278	365,177
Lithium	—	117,871
METRON	1,098	2,507
Other Projects	59,688	101,659
Pulmo Health	11,361	6,126
SeraSTAT	5,610	—
Sonicator OQ	—	5,447
Tri-Cholesterol	283,685	117,903
VIVO	592	89,962
Total R&D Expenses:	\$ 952,724	\$ 932,858
Other Income and Expenses		

Other income, net of expense for the nine months ended September 30, 2017 totaled \$15,468, which was a 32% decrease as compared to \$22,792 for the nine months ended September 30, 2016.

The table below summarizes our other income and expenses for the nine months ended September 30, 2017 and 2016 as well as the percentage of change year-over-year:

Description	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Percent Change	
Currency Translation Gain/(Loss)	\$ 6,172	\$ (1,189)	619	%
Realized Gain on Investments	3,375	3,421	(1	)%
Interest and Dividends	5,921	20,560	(71	)%
Other Income	—	—	—	%

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

Total Other Income, Net of Expenses	\$	15,468	\$	22,792	(32	)%
42						

Gains and losses associated with foreign currency transactions increased by 619% during the nine months ended September 30, 2017 as compared to the same period of 2016, primarily a result of the increased strength of the US Dollar compared to the British Pound during the three quarters of 2017.

Realized gains, interest and dividend income declined to \$9,296 (2016: \$23,981). The Company's available capital for investment activities was limited during the nine months ended September 30, 2017 resulting in the decline in investment income.

Summary of Statements of Operations for the Years Ended December 31, 2016 and 2015

Revenue

The Company's total revenue for the year ended December 31, 2016 was \$2,960,912, a 40% increase compared to the same period in 2015. The table below presents a summary of our sales by product line:

Product Line	Year Ended December 31, 2016	Year Ended December 31, 2015	Percent Change
MicroParticle Catalyzed Biosensor ("MPC")	\$ 282,516	\$ 296,328	(5)%
Particle ImmunoFiltration Assay ("PIFA")	2,577,148	1,391,017	85%
Other	97,499	107,149	(9)%
Product Revenue Total	\$ 2,957,162	\$ 1,794,494	65%
License Fees	3,750	320,556	(99)%
Total Revenue	\$ 2,960,912	\$ 2,115,050	40%

Product revenue increased by 65% to \$2,957,162 (2015: \$1,794,494) during the year ended December 31, 2016 driven primarily by a price increase for our PIFA Heparin/PF4 Rapid Assay products. Licensing revenue declined by 99% to \$3,750 (\$320,556), the result of the loss of licensing revenue from Chube as a result of the termination of the distribution agreement for the Company's BreathScan Alcohol Breathalyzers that occurred in the second quarter of 2015.

The Company's MPC product sales declined by 5% to \$282,516 (2015: \$296,328) during the year ended December 31, 2016. A distributor's initial stocking order of approximately \$144,000 for the Company's BreathScan Alcohol Breathalyzer products in Great Britain was included for the year ended December 31, 2015 but not repeated in 2016. Net of this significant order, MPC product sales increased 85% year-over-year. The Company's new BreathScan Lync and BreathScan OxiChek™ products and renewed interest in the Company's BreathScan Alcohol Breathalyzers, both domestically and internationally, contributed to the increase for the year ended December 31, 2016.

The Company's total PIFA sales increased during the year ended December 31, 2016 by 85% to \$2,577,148 (2015: \$1,391,017). The increase is due primarily to two events; first, the implementation of a significant price increase for the product line and second, the fulfillment during the year of approximately 20% of the \$2.5 million order from Novotek, our exclusive distributor for PIFA Heparin/PF4 Rapid Assay products in the People's Republic of China.

The Company's dedicated technical sales account executives are supporting over 300 sales representatives of Akers' U.S. distribution partners, Cardinal Health ("Cardinal Health"), Fisher HealthCare ("Fisher Healthcare") and Typenex Medical, LLC ("Typenex"). The Company's relationship-building initiative with our partners has delivered a measurable increase in product trials and adoptions. Domestic sales for the year ended December 31, 2016 of our distributors, Cardinal Health and Fisher HealthCare, accounted for \$1,820,186 of the total PIFA Heparin/PF4 Rapid Assay sales as compared to \$1,213,006 for the same period of 2015 and individually represented 37% and 22% of such sales, respectively.

The Company's international sales of its PIFA Heparin/PF4 Rapid Assay products totaled \$493,850 (2015: \$-) during the year ended December 31, 2016 primarily as a result of the partial fulfillment of a \$2.5 million order from

NovoTek. Although the product has been approved for use in China by the China Food and Drug Administration, each province in which it is sold must establish reimbursement rates for the medical facilities that utilize the test. NovoTek is diligently working through this provincial approval process and is projecting reimbursement rate approvals in several provinces during 2017 which is expected to allow for the release of and payment for further products in line with user demand.

Other operating revenue decreased by 9% to \$97,499 (2015: \$107,149) for the year ended December 31, 2016 due in a major part to a decline in the sale of miscellaneous components to \$42,570 (2015: \$50,612).

The Company's exclusive License and Supply Agreement with Chube for the Company's proprietary breathalyzer product was cancelled by both parties on May 7, 2015. As a result of this event, and per the terms of the original agreement, the Company recognized the remaining \$166,667 of deferred revenue in the statement of operations and comprehensive income for the year ended December 31, 2015. The Company is now able to solicit business outside the United States for its alcohol breathalyzer products and has begun to receive and ship orders.

Licensing fee revenue declined to \$3,750 (2015: \$320,556). The decline is associated with the cancellation of the Company's exclusive License and Supply Agreement with Chube as described above.

Cost of sales for the year ended December 31, 2016 totaled \$1,083,087 (2015: \$950,792) on the increased revenue during the year ended December 31, 2016. Direct cost of sales decreased to 26% (2015: 43%) and indirect cost of sales decreased to 21% (2015: 24%) of product revenue for year ended December 31, 2016. Overall, cost of sales, as a percentage of product revenue, was 37% and 53% for the years ended December 31, 2016 and 2015.

Direct costs associated with the MPC products remained constant at 30% (2015: 30%) and PIFA products decreased to 9% (2015: 11%) related to the increased use of sub-contractors for the assembly of components.

Indirect cost of sales for the year ended December 31, 2016 totaled \$634,848 (2015: \$425,609) which represented 21% (2015: 24%) of product revenue. Costs associated with personnel, consumable supplies other general production declined while a project to identify and discard expired, stale and obsolete inventory resulted in a significant increase in expenses related to slippage and obsolescence. In addition, the percentage change is affected by the fixed cost nature of many of the components in this category.

Akers' gross profit margin, as a percentage of revenue, increased to 63% for the year ended December 31, 2016 as compared to 55% in 2015 for the reasons described above.

General and Administrative Expenses

General and administrative expenses in the year ended December 31, 2016 totaled \$3,008,811, which was a 25% decrease as compared to \$4,029,516 for the year ended December 31, 2015. The table below summarizes our general and administrative expenses for the years ended December 31, 2016 and 2015 as well as the percentage of change year-over-year:

Description	Year Ended December 31, 2016	Year Ended December 31, 2015	Percent Change
Personnel Costs	\$ 886,294	\$ 902,431	(2) %
Professional Service Costs	885,746	1,233,126	(28) %
Stock Market & Investor Relations Costs	441,453	572,161	(23) %
Other General and Administrative Costs	795,318	1,321,798	(40) %
Total General and Administrative Costs	\$ 3,008,811	\$ 4,029,516	(25) %

Several specific categories of expense decreased significantly during the year ended December 31, 2016. Below is a summary of these categories:

Description	Year Ended December 31, 2016	Year Ended December 31, 2015	Percent Change
Professional Services	\$ 885,746	\$ 1,233,136	(28) %
Stock Market & Investor Relations	441,453	572,161	(23) %
Travel Costs	118,980	268,201	(56) %

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

Total	\$	1,446,179	\$	2,073,488	(30	)%
-------	----	-----------	----	-----------	-----	----

Professional services included significant decreases in employment agency fees (\$409 (2015: \$237,553)), general consulting services (\$73,405 (2015: \$125,168)) and legal fees (\$613,159 (2015 \$736,745)) which were offset by an increase in accounting and audit expenses (\$182,396 ((2015: \$133,660)) during the year ended December 31, 2016.

The Company recognized cost savings in all of its stock market and investor relations categories. These include consulting, investor relations, stock exchange fees and transfer agent fees.

Travel to China in support of NovoTek and Hainan Savy-Akers Biosciences (“Savy-Akers”), our Chinese joint venture, were consolidated resulting in two (2) extended trips during the year ended December 31, 2016. During 2015, the Company made several trips to assist NovoTek in gaining government approvals and developing the market for the Company’s PIFA Heparin/PF4 Rapid Assay product.

Sales and Marketing Expenses

Sales and marketing expenses in the year ended December 31, 2016 totaled \$2,137,282, which was a 16% decrease as compared to \$2,543,286 for the year ended 2015. The table below summarizes our sales and marketing expenses for the years ended December 31, 2016 and 2015 as well as the percentage of change year-over-year:

Description	Year Ended December 31, 2016	Year Ended December 31, 2015	Percent Change
Personnel Costs	\$ 1,129,722	\$ 1,359,460	(17)%
Professional Service Costs	441,632	751,220	(41)%
Royalties and Commission Costs	225,159	158,347	42%
Other Sales and Marketing Costs	340,769	274,259	24%
Total Sales and Marketing Costs	\$ 2,137,282	\$ 2,543,286	(16)%

Personnel costs decreased in the year ended December 31, 2016 due to a revision of the sales strategy to target large integrated delivery networks (“IDNs”) which require fewer, but more experienced, area business directors. This was accomplished by replacing the executive sales staff with a Vice President for Global Marketing and a Vice President of United States Sales. The strategy established five (5) areas, each with an Area Business Director (“ABDs”), however, attrition during the year resulted in the loss of three (3) ABDs and the strategy was revised to use pay-for-performance based Independent Manufacturing Representatives (“IMRs”) in-lieu of replacing staff.

The decrease in the use of contracted marketing services firms (\$51,246 (2015: \$225,064)) and general sales consultants (\$351,459 (2015: \$525,938)) resulted in a 41% decrease in professional service costs. The Company has refocused its sales and marketing strategy, concentrating on the development of relationships with Independent Manufacturing Representatives that are paid for performance versus the use of contracted sales groups paid fixed monthly fees.

Royalty and commission costs increased as a result of outside sales commissions (\$71,305 (2015: \$66,436)), due to increased sales of the PIFA products, both domestically and internationally, and royalty expenses (\$153,854 (2015: \$91,910)) during the year ended December 31, 2016.

Other sales and marketing costs increased primarily due to technology (\$53,312 (2015: \$20,261)), sponsorships (\$10,500 (2015: \$-)) and travel (\$182,420 (2015: \$145,688)) expenses and was partially offset by decreases in advertising and promotional materials expenses (\$5,080 (2015: \$42,323)).

Research and Development

Research and development expenses in the year ended December 31, 2016 totaled \$1,188,868, which was a 15% decrease as compared to \$1,406,895 for the year ended 2015. The table below summarizes our research and development expenses for the years ended December 31, 2016 and 2015 as well as the percentage of change year-over-year:

Description	Year Ended December 31, 2016	Year Ended December 31, 2015	Percent Change
-------------	---------------------------------	---------------------------------	-------------------

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

Personnel Costs	\$	745,326	\$	699,595	7	%
Professional Service Costs		113,807		504,800	(77	)%
Clinical Trial Costs		160,405		41,586	286	%
Other Research and Development Costs		169,330		160,914	5	%
Total Research and Development Costs	\$	1,188,868	\$	1,406,895	(15	)%

45

Personnel costs increased 7% during the year ended December 31, 2016 as compared to the same period of 2015 as a result of the transfer to this department of Dr. Akers from the General and Administrative department effective April 25, 2016 and the employment of a new Director of Quality Assurance.

The Company had two clinical trials in-process during the year ended December 31, 2016 in respect of the Company's rapid chlamydia assay and Diabetic Ketoacidosis breath test resulting in a significant increase in costs associated with these programs. The trials are collecting data to support submissions to the U.S. Food and Drug Administration for 510(k) approvals and to support the clinical effectiveness of the products.

Professional service costs declined 77% during the year ended December 31, 2016. During the year ended December 31, 2015, the Company was expending funds for the engineering and design of the BreathScan Lync™ reader and cartridge being used with the new Health and Wellness MPC products. These design projects are now complete.

Increase in supplies (\$52,317 (2015: \$45,235)), seminars and professional development (\$26,849 (2015: \$1,980)) waste disposal (\$19,322 (2015: \$15,082)) and travel expenses (\$29,561 (\$2015: 9,739)) was offset by a reduction in the utilization of inventory resources for development and testing (\$8,595 (2015: \$46,590)) that resulted in an increase of 5% for other research and development costs during the year ended December 31, 2016.

The following table illustrates research and development costs by project for the years ended December 31, 2016 and 2015, respectively.

	2016	2015
Asthma/pH	\$ —	\$ 4,917
BreathScan	1,483	110,609
Chlamydia Trachomatis	35,808	134,362
CHUBE	—	397
H/PF4	104,436	98,876
HIV	—	150,543
Diabetic Ketoacidosis	3,098	72,757
KetoChek/OxiChek	584,585	252,462
Lithium	—	41,086
Metron	5,832	77,796
Other Projects	144,457	156,379
Pulmo Health	22,069	18,283
Sonicator OQ	—	886
Troponin	—	127,095
Tri Cholesterol	281,884	96,271
VIVO	5,216	64,176
Total R&D Expenses:	\$ 1,188,868	\$ 1,406,895
(Reversal of Allowance for) Bad Debt Expense — Related Party		

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

Other Income and Expense

Other income and expense decreased for the year ended December 31, 2016 to \$25,097 from \$100,973 for the same period in 2015. The table below summarizes our other income and expenses for the years ended December 31, 2016 and 2015 as well as the percentage of change year-over-year:

Description	Year Ended December 31, 2016	Year Ended December 31, 2015	Percent Change	
Currency Translation (Gain)/Loss	\$ (3,398)	\$ 7,535	145	%
Dividend on Series A Preferred Stock	—	—	—	%
Investment (Gain)/Loss	85	6,512	99	%
Interest and Dividends	(21,784)	(108,968)	(80)	)%
Other Extraordinary Income	—	(6,052)	(100)	)%
Total Other (Income) and Expense	\$ (25,097)	\$ (100,973)	(75)	)%
Income Taxes				

During 2015, the Company was approved by the State of New Jersey to sell a portion of its state tax benefits that existed as of December 31, 2014, pursuant to the Technology Tax Certificate Transfer Program. The Company received net proceeds of \$269,344 for the year ended December 31, 2015 as a result of the sale of the tax benefits. The Company, anticipating profitability for 2016 at the June 30, 2016 filing deadline, did not participate in the program during the year ended December 31, 2016.

As of December 31, 2016 and 2015, the Company had Federal net operating loss carry forwards of approximately \$60,100,000 and \$58,000,000, respectively, expiring through the year ending December 31, 2036. As of December 31, 2016 and 2015, the Company had New Jersey state net operating loss carry forwards of approximately \$9,400,000 and \$7,200,000, respectively, expiring the year ending December 31, 2023.

The principal components of deferred tax assets and valuation allowance as of December 31, 2016 and December 31, 2015 are as follows:

Deferred Tax Assets

	Year Ended December 31, 2016	2015
Reserves and other	\$ 865,000	\$ 2,506,000
Net operating loss carry-forwards	\$ 21,618,000	\$ 20,728,000
Valuation Allowance	\$ (22,483,000)	\$ (23,234,000)
Net	\$ —	\$ —

The valuation allowance for deferred tax assets as of December 31, 2016 and 2015 was \$22,483,000 and \$23,234,000. The change in the total valuation for the years ended December 31, 2016 and 2015 were a decrease of \$751,000 and an increases of \$3,795,104. 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.

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

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, 2016 and December 31, 2015 are as follows.

Tax Rates & Benefits

	Year Ended December 31,			
	2016		2015	
Statutory U.S. Federal Income Tax Rate	(35.0	)%	(35.0	)%
New Jersey State income taxes, net of U.S.				
Federal tax effect	(6.0	)%	(6.0	)%
Benefit from sale of New Jersey NOL	0.0	%	(2.9	)%
Change in Valuation Allowance	41.0	%	41.0	%
Net	0.0	%	(2.9	)%

Liquidity and Capital Resources

For the nine months ended September 30, 2017 and 2016, the Company generated a net loss attributable to shareholders of \$3,193,571 and \$2,207,707, respectively. For the years ended December 31, 2016 and 2015, the Company generated a net loss attributable to shareholders of \$3,303,538 and \$9,311,913, respectively. As of September 30, 2017 and December 31, 2016, the Company has an accumulated deficit of \$100,673,108 and \$94,479,537 and had cash and equivalents totaling \$145,311 and \$72,700, respectively. As of December 31, 2016 and 2015, the Company has an accumulated deficit of \$97,479,537 and \$94,175,999 and had cash and cash equivalents totaling \$72,700 and \$402,059, respectively. The Company had marketable securities of \$50,001 and \$4,025,104 available as of December 31, 2016 and 2015.

Currently, our primary focus is to expand the domestic and international distribution of our PIFA Heparin/PF4 rapid assays.

The Company's secondary focus is fully commercializing the health and wellness product line linked to smartphones and tablets. The Company continues commercialization tasks for its PIFA PLUSS® Infectious Disease single-use assays, BreathScan® DKA, and Breath PulmoHealth products, including advancement of the steps required for FDA clearance or CE marking in the EU where necessary.

The Company continues to expand the global distribution of our PIFA Heparin/PF4 rapid assays. The Company's future and focus resides in preparing for the launch of our health and wellness product line linked to smartphones and tablets and the Company's rapid manual point-of-care chlamydia assay.

Substantial doubt exists about the Company's ability to continue as a going concern within one year after the financial statements are issued. The Company has identified three conditions or events that support this determination:

The Company's current working capital position

Negotiations are underway with multiple customers for the Company's products and are anticipated to be completed during the three months ending March 31, 2018. All parties are confident that a solution can be achieved but a significant delay will impact revenue projections.

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

Please refer to Note 3 in the September 30, 2017 unaudited financial statement footnotes, Management Plan, of the Financial Statements for the Company's plans to address the going concern.

We expect that our primary expenditures will be to continue development of our health and wellness line, Tri-cholesterol test, PIFA Chlamydia assay and PIFA PLUS[®] Infectious Disease single-use assays products, enrolling patients in clinical trials to support performance claims, generating studies in peer-reviewed journals to support product marketing, and provide data for the FDA 510(k) clearance/CE certifications processes when required. We will also continue to support commercialization and marketing activities of commercialized products. Based upon our experience, clinical trial and related regulatory expenses can be significant costs. Steps to achieve commercialization of emerging products

will be an ongoing and evolving process with expected improvements and possible subsequent generations being evaluated for commercialized and emerging tests. Should we be unable to achieve FDA clearance for products that require such regulatory “approval”, develop performance characteristics for rapid tests that satisfy market needs, or generate sufficient revenue from commercialized products, we would need to rely on other business or product opportunities to generate revenue and costs that we have incurred for the patents may be deemed impaired.

Capital expenditures for the nine months ended September 30, 2017 were \$37,191 (2016: \$88,023). Capital expenditures, primarily for production and laboratory costs for the year ending December 31, 2017 are expected to be approximately \$50,000. As per the Company’s lease agreement, the owner of the facility will be handling the majority of facility upgrades, and we anticipate financing any production and laboratory capital expenditures through working capital. Capital expenditures, primarily for production, laboratory and facility improvement costs for the year ending December 31, 2016 totaled \$123,301 (2015: \$112,951). As per the Company’s lease agreement, the owner of the facility will be handling the majority of facility upgrades, and we anticipate financing any production and laboratory capital expenditures through working capital.

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

We lease our manufacturing facility which also contains our administrative offices. Our current lease was executed January 1, 2013 and is effective through December 31, 2019. The Company has leased this property from the current owner since 1997.

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

Due to recent market events that have adversely affected all industries and the economy as a whole, management has placed increased emphasis on monitoring the risks associated with the current environment, particularly the recoverability of current assets, the fair value of assets, and the Company’s liquidity. At this point in time, there has not been a material impact on the Company’s assets and liquidity. Management will continue to monitor the risks associated with the current environment and their impact on the Company’s results.

The table below summarizes our cash flows for the nine months ended September 30, 2017 and 2016 as well as the percentage of change year-over-year:

Description	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016	Percent Change	
Cash at beginning of period	\$ 72,700	\$ 402,059	(82	)%
Loss from operations	(3,193,571)	(2,207,707)	(45	)%
Adjustments				
Non-Operating Gains	—	—	—	%
Non-Cash Activities	266,881	(846,749)	129	%
Cash Used in Operating Activities				
Cash Consumed by Operating Activities	(935,622)	(754,781)	(12	)%
Cash Contributed by Operating Activities	207,454	275,588	(50	)%
Cash Flows from Investing Activities				
Cash Consumed by Investing Activities	(2,746,339)	(125,383)	(2,090	)%
Cash Contributed by Investing Activities	2,749,119	3,452,833	(20	)%
Cash Flows from Financing Activities				

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

Cash Consumed by Financing Activities	—	—	—	%
Cash Contributed by Financing Activities	3,714,511	—	100	%
Cash at end of period	\$ 135,133	\$ 195,860	(31	)%

49

The Company's net cash provided by investing and financing activities totaled \$6,463,630 during the nine months ended September 30, 2017. Cash of \$2,746,339 was consumed by capital expenditures and the purchase of marketable securities. Proceeds from the sale of marketable securities contributed cash of \$2,749,119 for the period ended September 30, 2017.

The Company's net cash provided by investing and financing activities totaled \$3,452,833 during the nine months ended September 30, 2016. Cash of \$125,383 was consumed by capital expenditures and the purchase of marketable securities. Proceeds from the sale of marketable securities contributed cash of \$3,452,833 for the period ended September 30, 2016.

Our net cash consumed by operating activities totaled \$3,654,858 during the nine months ended September 30, 2017. Cash was consumed by the loss of \$3,193,571 plus non-cash adjustments of \$182,866 for depreciation and amortization of non-current assets, \$46,239 for allowances for doubtful accounts, \$15,784 for amortization of deferred compensation, \$14,502 for share based compensation, \$2,183 for options issued for services and \$5,455 for restricted stock issued for services less and \$148 for accrued income on marketable securities. For the nine months ended September 30, 2017, decreases in deposits and other receivables of \$2,034, prepaid expense of \$68,798, prepaid expense — related parties of \$38,438 and an increase in trade and other payables of \$85,684 and deferred revenue of \$12,500 provided cash, primarily related to routine changes in operating activities. A net increase in trade receivables of \$570,065, trade receivables — related parties of \$93,109, inventories of \$49,346 and other assets of \$9,280 and a decrease in trade and other payables — related party of \$213,822 consumed cash from operating activities.

Our net cash consumed by operating activities totaled \$3,533,649 during the nine months ended September 30, 2016. Cash was consumed by the loss of \$2,207,707 plus non-cash adjustments of \$221,946 for depreciation and amortization of non-current assets, \$146,196 for allowances for doubtful accounts, \$24,834 for amortization of deferred compensation, \$22,828 for share based compensation, \$23,676 for options issued for services and \$13,380 for accrued income on marketable securities less \$1,299,609 for the reversal of a bad debt allowance. For the nine months ended September 30, 2016, decreases in deposits and other receivables of \$65,855, prepaid expense of \$91,706, prepaid expense — related party of \$58,974 and an increase in trade and other payables — related party of \$59,673 provided cash, primarily related to routine changes in operating activities. A net increase in trade receivables of \$275,541 and inventories of \$60,862 and a decrease in trade and other payables of \$418,998 consumed cash from operating activities.

The Company's net cash consumed by operating activities in the year ended December 31, 2016 totaled \$4,173,148, which was a 19% decrease as compared to \$5,132,343 for the year ended December 31, 2015. The table below summarizes our net cash consumed for the years ended December 31, 2016 and 2015 as well as the percentage of change year-over-year:

Description	Year Ended December 31, 2016	Year Ended December 31, 2015	Percent Change	
Loss from Operations	\$ (3,303,538)	\$ (9,311,913)	65	%
Adjustments				
Non-Operating Gains	(1,153,413)	(6,052)	(18,958	)%
Non-Cash Activities	414,545	3,331,291	88	%
Cash Used in Operating Activities				
Cash Consumed by Operating Activities	(531,220)	(663,010)	20	%
Cash Contributed by Operating Activities	400,478	1,517,341	(74	)%
Net Cash Used in Operating Activities	\$ (4,173,148)	\$ (5,132,343)	19	%

For the year ended December 31, 2016, cash was consumed by the loss of \$3,303,538 and non-operating gains of \$1,153,413 offset by a non-cash adjustment of \$14,244 for accrued interest and dividends, \$286,162 for depreciation, amortization of non-current assets, \$32,333 for a reserve for obsolete inventory, \$30,153 for amortization of deferred compensation and \$51,653 for non-cash share based compensation and services. Decreases in deposits and other

receivables (\$71,795), prepaid expenses (\$17,689), prepaid expenses — related party of (\$76,927) and an increase in trade and other payables — related party (\$234,067) provided cash. Increases in trade receivables (\$138,272), trade receivables — related party (\$380), inventories (\$187,200) and a decrease in trade and other payables (\$205,368) consumed cash. The decrease in net cash used in operating activities was related to improvements to the Company's budgeting process, termination of several consulting agreements and a significant reduction in legal expenses.

For the year ended December 31, 2015, cash was consumed by the loss of \$9,311,913 and non-operating gains of \$6,052 offset by a non-cash adjustment of \$4,199 for accrued interest and dividends, \$766,471 for depreciation, amortization and impairment of non-current assets, \$2,163,609 for allowances for doubtful accounts and \$397,012 for non-cash share based compensation and services. Decreases in trade receivables (\$513,583), trade receivables — related party (\$176,157) and an increase in trade and other payables (\$827,601) provided cash. Increases in other receivables (\$54,142), inventories (\$226,538), other assets (\$76,774) and a decrease in deferred revenue — related party (\$305,556) consumed cash. The increase in net cash used in operating activities was related to routine changes in operating activities.

Critical Accounting Policies

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

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

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

Trade Receivables, Trade Receivables — Related Party and Allowance for Doubtful Accounts

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

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

Fair Value Measurement — Marketable Securities

The framework for measuring fair value provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active

markets for identical assets or liabilities (level 1) and the lowest priority to unobservable inputs (level 3). The three levels of the fair value hierarchy under FASB ASC 820 are described as follows:

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

Level 2 Inputs to the valuation methodology include

- quoted prices for similar assets or liabilities in active markets;
- quoted prices for identical or similar assets or liabilities in inactive markets;
- inputs other than quoted prices that are observable for the asset or liability;
- inputs that are derived principally from or corroborated by observable market data by correlation or other means.

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

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

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

Intangible Assets

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 September 30, 2017, the Company has eleven patents from the United States Patent Office in effect (9,383,368; 7,896,167; 8,097,171; 8,003,061; 8,425,859; 8,871,521; 8,808,639; D691,056; D691,057; D691,058 and D786,872). Other patents are in effect in Australia through the Design Registry (348,310; 348,311 and 348,312), European Union Patents 1793906, 2684025, 002216895-0001; 002216895-0002; 002216895-0003; 3459700-0001 and 3459395-001), United Kingdom and France (2684025), Germany (602012021524.0), Spain (E12755523), China (2016305495829), in Hong Kong (HK11004006) and in Japan (1,515,170; 4,885,134; 4,931,821 5,775,790, and 6023096). Patents are in the national phase of prosecution in many Patent Cooperation Treaty participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the US, European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

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

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

Long-Lived Assets

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Cost includes expenditure that is directly attributable to the acquisition of the asset. When parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment. Gains and losses on disposal of an item of property, plant and

equipment are determined by comparing the proceeds from disposal with the carrying amount of property, plant and equipment and are recognized net within “other income” in profit or loss.

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 value these investments using the cost method.

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

Revenue Recognition

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

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

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

Stock-based Compensation

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

Recently Issued and Adopted Accounting Pronouncements

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

Quantitative and Qualitative Disclosure About Market Risk

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

Interest Rates

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

Off-Balance Sheet Arrangements

We have no significant known off balance sheet arrangements.

BUSINESS

Overview

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

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

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

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

- cost pressures/efficiency of healthcare delivery;
- need for fast, easy to use, accurate at-home tests for individuals to monitor their personal health and wellness;
- need for affordable mass screening tests for key infectious diseases, cardiac conditions, and metabolic markers; and
- public health needs in developing countries lacking basic health infrastructure.

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

Market Overview

Worldwide, healthcare professionals use laboratory tests to support their clinical diagnosis and treatment decisions. According to a Markets and Markets report, In-Vitro Diagnostic (IVD) Market (Applications, End-users & Types) Trends & Global Forecasts (Major & Emerging Markets — G7, Japan & BRIC) (2011 – 2016), published in January 2012 (the "IVD Market Report"), the use of such tests continues to grow as a result of increased patient awareness, patient self-testing and the aging baby boomer population across the globe. Other major drivers for the growth of the in vitro diagnostic ("IVD") industry is a rise in the number of diseases like respiratory and hospital-acquired infections and a rise in the chronic diseases such as diabetes, hypertension, cardiovascular diseases, and cancer. Both an increasing understanding of the molecular processes underlying many disease states and the opportunity for clinicians to quickly incorporate that targeted information into treatment decisions (e.g. companion testing). According to an article published on in vitro diagnostics by Medical Device and Diagnostic Industry ("MDDI") online in March 2013, in the

past, the in vitro diagnostics industry has focused on developing tests that require significant time, skill, and often costly, specialized equipment. Patient specimens often had to be collected remotely and processed in a central laboratory with test results sent to a physician at a later date. This general protocol is not particularly well-adapted to the practice of medicine in a cost-effective, timely manner. The pressures on public health budgets and falling profits among third party payors such as insurers, necessitates an alternative approach to disease management. In addition, there has been steady growth of the retail health clinic and urgent care center markets.

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

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

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

Strategy

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

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

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

- Clinical Laboratories;
- Physicians' Office and Urgent Care Clinics;
- Retail;
- Nutraceutical Suppliers; and
- Health and Fitness.

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

Technology Overview

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

Testing Platform Technologies

MPC Biosensor Technology

MicroParticle Catalyzed Biosensor (“MPC Biosensor”) Technology permits the rapid identification of medical conditions through biomarkers in exhaled breath. MPC Biosensor-based products contain microparticles that change color to indicate a positive test result. The microparticles are coated with recently discovered agents that both decrease the time to result and exhibit a more defined color change when appropriate. MPC Biosensor-based products are packaged in small, disposable cartridges through which test subjects can easily blow for several seconds. Breath KetoChek has one U.S. and two international patents granted. In addition, Akers also holds three US, three Australian and three European Community Design patents for Color Comparison Card technology that users can utilize to interpret detector results.

Particle ImmunoFiltration Assay (PIFA®) Technology

PIFA® technology is an accurate, rapid, immunoassay (a procedure for detecting or measuring specific proteins or other substances through their properties as antigens or antibodies) method based on the selective filtration of dyed microparticles coated with antigen or antibody. The microparticles are combined with a test sample (whole blood, serum, urine or saliva) within a self-contained device. If a patient tests positive for the antibody or antigen, a binding event will occur and the dyed microparticles will be trapped by a filter within the device. As a result, the test window will be void of any color. Conversely, if the patient tests negative, the dyed microparticles will flow freely into the test window. Specific to the PIFA Heparin tests, the Company has two international patents and one US patent granted in force.

SMC Technology

Synthetic Macrocyclic Complex (“SMC”) Technology is a colorimetric testing methodology that pairs a proprietary reagent (a substance or mixture for use in chemical analysis or other reactions) with a hand-held, photometric reader that determines the quantitative level of a therapeutic drug in a patient’s blood sample. The technology also permits the use of whole blood samples collected from a simple finger stick, making products that use this technology extremely flexible within the healthcare delivery system.

Rapid Enzymatic Assay

Rapid Enzymatic Assay (“REA”) technology enables the rapid detection of metabolites in blood and urine in assay formats that are easy-to-use and deliver quantitative or semi-quantitative results. Products that employ REA technology are primarily intended for pharmaceutical, nutritional and over-the-counter (“OTC”) markets. Akers has three U.S. patents for this technology covering our Tri-Cholesterol “Check” test.

Sample Preparation Technology

Rapid Blood Cell Separation Technology

Akers’ Rapid Blood Cell Separation (“Separator”) Technology, marketed under the brand name seraSTAT®, further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically. Conventional methods of blood cell separation are labor-intensive and time-consuming, typically involving blood collection and laboratory personnel, as well as electrically-powered centrifuges and other specialized equipment. The disposable Separator device requires only a small-volume blood sample obtained from a time and cost-efficient finger stick procedure or through a venous blood draw. Akers has obtained the appropriate US FDA regulatory clearances for seraSTAT® as a stand-alone device and the technology is currently integrated into PIFA PLUSS PF4 devices, and will be utilized in the infectious disease products currently under development. The

seraSTAT® Rapid Blood Cell Separation Technology is currently protected by two U.S. patents and three international patents.

Product Portfolio

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

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

Akers designed its products based on single-use assay platforms with straightforward test procedures that can be completed in minutes. In the U.S. some of the Company's clinical laboratory products and those with medical intended uses generally require "prescription use" Federal Drug Administration ("FDA") 510(k) clearance prior to product marketing given that they will be ordered or used by medical practitioners in the course of his or her professional practice. Despite this categorization, Akers' professional use products are still designed for ease of use, can be utilized near or at the point-of-care, and do not require the use of expensive equipment or a highly trained or specialized staff. As a result, an individual's current health status can rapidly be incorporated into diagnostic and treatment decisions, improving the overall efficiency of the healthcare experience for the patient, and ultimately the payor. In addition, in the developing world, the portability and ease-of-use of such point-of-care tests can serve to drastically improve the level of disease screening and subsequent patient care. We believe the benefits of our technology platforms are therefore well-suited to the diagnostic demands of countries in the developing world that seek to deliver modern medical diagnosis with limited medical infrastructure. In addition, some of our products have received FDA 510(k) clearance for over-the-counter ("OTC") use. Other self-tests deliver personal health information of a non-medical nature, on-demand, and are not FDA regulated; these products are still manufactured in compliance with its ISO 13485 quality management system ("QMS-Compliant"). Akers believes that all its technology platforms and products address the needs of the evolving healthcare delivery system that is moving patient care closer to or in the home.

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

Our marketed and emerging products include:

Product	Platform	Marketed/Pipeline	Not FDA-regulated; QMS-Compliant Only	FDA Clearance Required <i>Prescription Use/OTC</i>	FDA Clearance Status Obtained/Needed	Description
BreathScan™	MPC	Marketed		OTC	Obtained	Disposable breath alcohol detector
BreathScan® PRO	MPC	Marketed		OTC	Obtained	Quantitative breath alcohol detection system
Breath Diabetic Ketoacidosis®	MPC	Pipeline		Prescription Use	Needed	Disposable breath ketone device for diabetic monitoring
METRON®	MPC	Marketed		Health and wellness	n/a	Disposable breath ketone device to

Breath PulmoHealth “Check”®	MPC	Pipeline	Prescription Use	Needed	monitor ketosis A suite of breath tests for biomarkers indicating asthma, chronic obstructive pulmonary disease (COPD), and lung cancer
BreathScan Lync	MPC	Marketed	Health and wellness	n/a	Non-invasive, quantitative measurement of biological markers for health and wellness

Product	Platform	Market/Pipeline	Not FDA-regulated; QMS-Compliant Only	FDA Clearance Required <i>Prescription Use/OTC</i>	FDA Clearance Status Obtained/Needed	Description
PIFA® Heparin/PF4 & PIFA PLUS® PF4	PIFA	Marketed		Prescription Use	Obtained	Rapid tests for Heparin/PF4 antibodies to detect an allergy to the widely used blood thinner, Heparin
PIFA PLUS® Chlamydia	PIFA	Pipeline		Prescription Use	Needed	Rapid tests for the most prevalent sexually transmitted disease
seraSTAT®	seraStat	Marketed		Prescription Use	Obtained	Rapid Blood Cell Separator, marketed under the brand name seraSTAT®, further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically.
Tri-Cholesterol “Check”®	REA	Marketed		OTC	Obtained	Rapid test for Total and high density lipoprotein cholesterol and estimates low density lipo protein
BreathScan OxiChek	MPC	Marketed		Health and wellness	n/a	Breath test for oxidative stress using the Lync reader and digital app
BreathScan KetoChek	MPC	Pipeline		Health and wellness	n/a	Breath test for ketosis using the Lync reader and digital app

MPC Biosensor Technology

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

Breath Alcohol Franchise

BreathScan® originated the disposable breath alcohol detector category and was the first single-use breathalyzer to obtain the FDA 510(k) clearance in 2006 for Over-the-Counter use required to facilitate sales to U.S. consumers; CE certification is not required to market the product in the EU because BreathScan® results are not used to diagnose any medical conditions. The Company’s breath alcohol detector technology was granted an Australian Standard certification trademark, which cleared the commercial pathway for product sales in Australia, New Zealand, and South Africa.

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

The Company's proprietary breath alcohol detection technology is paired with the quantitative precision of an electronic analyzer in the BreathScan® PRO alcohol detection system. As with all BreathScan® products, the test subject exhales into a specially calibrated, BreathScan® PRO detector. The testing coordinator then inserts the used detector into the BreathScan® PRO Digital Analyzer (the "Analyzer"). After two minutes, the Analyzer's sophisticated optics calculate the subject's BAC; the detectable range spans from 0.00% to .15% BAC. Unlike other electronic breathalyzers, BreathScan® PRO never requires recalibration so it is in "ready" mode at all times. In 2011, the Company received FDA over-the-counter clearance for the system, providing a commercialization path in the U.S. for use by trained

professionals, including those in civil and military law enforcement, and the general public; in addition, the CE-Mark was affixed to the alcohol detection system for professional use. Finally, the .02 Breath Alcohol Detection System has been approved to the Conforming Products List by the U.S. Department of Transportation, and may be sold as a compliance tool to the transportation industry.

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

Other Emerging MPC Platform Products

The Company's MPC Biosensor technology is being applied to the development of products that serve the nutraceutical, fitness, and weight loss marketplaces. As a category, these disposable screening tests are exempt from FDA 510(k) premarket clearances. Biomarkers related to various metabolic processes can be measured in breath condensate. As a result, Akers has used its proprietary, easy-to-use platform to design disposable breath devices that measure ketone (acid) production associated with fat-burning (METRON® and KetoChek) and oxidative stress levels that relate to cellular damage and the development of many preventable diseases (OxiChek). The Company believes that personalized health and wellness – and eventually personalized medicine – will become an increasingly significant market. The Company is positioning its tests for fitness, weight loss and oxidative stress for this market by designing a more consumer-focused reagent device, and linking this device to an application for smartphones and tablets that can not only produce a result, but also track progress over time. Initial marketing activities have commenced for these products and the Company is preparing for commercialization. The Company is currently assessing distribution opportunities with companies specializing in weight loss and/or mass distribution through health-related multilevel marketing organizations. Since devices with claims related to weight loss or nutrition are exempt from FDA oversight, a clinical program to support 510(k) submission is not required for any of these products. Given the non-medical intended use, the Company does not believe products will be required to hold a CE-mark prior to marketing in the EU.

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

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

- over 300 million people worldwide are living with asthma and up to 18% of a country's population are undiagnosed asthmatics;
- 210 million individuals are being treated for COPD but each of the 1 billion smokers worldwide are at risk for the disease; and

- more than 1.6 million people worldwide receive the diagnosis of lung cancer annually with many more victims expected as 80% of all lung cancers can be attributed to smoking.

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

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

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

PIFA® Technology

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

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

The PIFA® Heparin/PF4 Rapid Assay improves the standard of care in HIT-testing with its result delivered in less than five minutes after the patient sample has been prepared. Traditional methods required the use of expensive equipment, specialized laboratory personnel and hours of technician time to complete the 20+ assay test procedure in-house. Clinicians were subjected to a 24-to-72 hour turnaround time if the HIT-antibody determination was outsourced to a reference laboratory. Especially in the latter scenario, the patient information obtained is retrospective in nature as the HIT-antibody result cannot be factored into time-sensitive diagnostic and treatment decisions.

The Company has also introduced PIFA PLUSS® PF4 to U.S. hospitals to further improve the rate at which healthcare professionals can obtain a HIT-antibody result. This PIFA® line extension merges the ease-of-use of the PIFA testing platform with Akers’ recently patented Rapid Blood Cell Separation Technology, marketed under the brand name seraSTAT®. The marriage of these two technologies condenses the sample preparation and analysis procedures as the precise micro-volume of a seraSTAT® -prepared patient specimen is delivered directly into the PIFA® cassette for immediate testing. This eliminates an additional one-hour of sample processing time and the need for healthcare personnel to have access to a centrifuge to separate the liquid fraction of blood from the cellular fraction. As a result, HIT-testing can be initiated and completed at or near the point-of-care, especially in emergency and critical care departments where time-efficient diagnostic results can drastically improve patient outcomes.

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

Other PIFA® Platform Assays in development

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

- Chlamydia
- Troponin I
- ABOD Battlefield Blood Transfusion Card

REA Technology

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

Tri-Cholesterol "Check" has the appropriate U.S. FDA market clearances and is also CE-marked for sale in the European Union. At present, the Company's Tri-Cholesterol "Check" business strategy is to focus on distribution activities to the OTC and walk-in clinic markets in the U.S. and Europe through strategic alliances, such as Alere in the U.S.

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

Sample Preparation Technology

Rapid Blood Cell Separation Technology

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

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

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

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

Competition

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

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

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

- respond to new technologies or technical standards;
- devote resources to the development, production, promotion, support and sale of products;
- acquire other companies to gain new technologies or products that may displace our product lines;
- react to changing customer requirements and expectations;
- manufacture, market and sell products; and
- deliver a broad range of competitive products at lower prices.

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

How we Generate Revenue

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

Our Current Target Markets

Regarding the Company's test for the heparin drug allergy, the testing market largely resides within the clinical hospital laboratories of medical facilities. In the U.S., the Company accesses decision makers within these institutions through profiling by its highly trained technical sales team and collaborative prospecting with distributor sales representatives. Internationally, Akers provides comprehensive training to its distributor partners which will enable them to implement the same selling and technical training strategies.

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

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

Manufacturing and Suppliers

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

We use a diverse and broad range of raw materials in the manufacturing of our products. We purchase all of our raw materials and select items, such as packaging, from external suppliers. In addition, we purchase some supplies from single sources for reasons of proprietary know-how, quality assurance, sole source availability, or due to regulatory qualification requirements. U.S. medical device manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products are known as current good manufacturing practices ("cGMP's"). cGMP requirements for devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. To date, we have not experienced any significant difficulty locating and obtaining the materials necessary to fulfill our production requirements.

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

Distribution

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

With respect to the Company's breath alcohol franchise, historically Akers focused its commercial attention within the on-the-job safety/human resources sector. Access was and currently is largely achieved through designated BreathScan® distributors and limited arrangements in which the Company serves in an OEM capacity.

Our dedicated technical sales force works in tandem with distributor sales representatives to uncover opportunities in the clinical laboratory marketplace. The Company facilitates direct sales for hospitals that prefer to purchase direct from the manufacturer.

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

In select European countries and Australia we have distribution relationships with specialized sales and marketing organizations for some of our products. We do not have a strong presence in many emerging markets, but are seeking to enter into agreements to enable us to enter other international markets in the current fiscal year.

During the year ended December 31, 2016 sales to Cardinal Health and Fisher Healthcare accounted for a significant part of the Company's product revenue. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

Joint Venture

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

Intellectual Property

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

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

The following table summarizes the U.S. and international utility patents that currently protect Akers intellectual property; the core and emerging products to which they relate are also noted:

Description	Jurisdiction	Utility Patent No.	Type of Protection	Expiration Date	Product(s) To Which They Relate
breath ketone detector	US	8,871,521	Manufacture	3/8/2031	Breath KetoChek®
breath ketone detector	Japan	6023906	Manufacture	3/8/2032	Breath KetoChek®
breath ketone detector	European Union	2684025	Manufacture	3/8/2032	Breath KetoChek®
blood separator and method of separating fluid fraction from whole blood	US	7,896,167	Manufacture	9/7/2026	seraSTAT®; PIFA PLUSS® PF4; PIFA PLUSS® Infectious Diseases Rapid Assays
blood separator and method of separating fluid fraction from whole blood	US	8,097,171	Manufacture	8/5/2025	seraSTAT®; rapid blood cell separator also integrated into PIFA PLUSS® PF4 and PIFA PLUSS® Infectious Diseases Rapid Assays
blood separator and method of separating fluid fraction from whole blood	Japan	4,885,134	Manufacture	8/5/2025	seraSTAT®; rapid blood cell separator also integrated into PIFA PLUSS® PF4 and PIFA PLUSS® Infectious Diseases Rapid Assays
blood cell separator	European Union	1793906	Manufacture	8/5/2025	seraSTAT®; rapid blood cell separator also

					integrated into PIFA PLUSS® PF4 and PIFA PLUSS® Infectious Diseases Rapid Assays
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

65

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

Description	Jurisdiction	Utility Patent No.	Type of Protection	Expiration Date	Product(s) To Which They Relate
methods and kits for detecting heparin/platelet factor 4 antibodies	Japan	4,931,821	Manufacture	10/4/2025	PIFA® Heparin/PF4 Rapid Assay; PIFA PLUS® PF4
Methods and kits for detecting heparin platelet factor 4 antibodies	Japan	577579	Manufacture	10/4/2025	PIFA® Heparin/PF4 Rapid Assay; PIFA PLUS® PF4
test strip card	US	8,003,061	Manufacture	5/6/2024	Tri-Cholesterol “Check”®
test strip card	US	8,425,859	Manufacture	5/6/2024	Tri-Cholesterol “Check”®
test strip card	US	8,808,639	Manufacture	5/6/2024	Tri-Cholesterol “Check”®

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

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

Government Regulations

FDA Approval/Clearance Requirements

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

The FDA decides whether a device line must undergo either the 510(k) clearance or Premarket approval (“PMA”). PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. The PMA approval process is based on statutory criteria. These criteria include the level of risk that the agency perceives is associated with the device and a determination whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either Class I or II, which requires the manufacturer to submit a premarket notification (“PMN”) requesting 510(k) clearance, unless an exemption applies. The PMN must demonstrate that the proposed device is “substantially equivalent” in intended use and in safety and effectiveness to a legally marketed predicate device, which is a pre-existing medical device to which equivalence can be drawn, that is either in Class I, Class II, or is a Class III device that was in commercial distribution before May 28,

1976, for which the FDA has not yet called for submission of a PMA application.

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

Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) PMN procedure. Pursuant to the Medical Device User Fee and Modernization Act of 2002, or MDUFMA, as of October 2002 unless a specific exemption applies, 510(k) PMN submissions are subject to user fees. Certain Class II devices are exempt from this premarket review process. A majority of our products, encompassing all of our significant product lines, are Class II devices.

Class III devices are those devices which have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices almost always require formal clinical studies to demonstrate safety and effectiveness and must be approved through the premarket approval process described below. Premarket approval applications (and supplemental premarket approval applications) are subject to significantly higher user fees under MDUFMA than are 510(k) PMNs. None of our products are Class III devices.

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

Pervasive and Continuing FDA Regulation

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

Health Care Fraud and Abuse

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

to the federal anti-kickback law, many states have their own kickback laws. Often, these state laws closely follow the language of the federal law. Some state anti-kickback laws apply regardless of whether a federal health care program payment is involved. Federal and state anti-kickback laws may affect our sales, marketing and promotional activities, and relationship with health care providers or laboratory professionals by limiting the kinds of arrangements we may have with hospitals and others in a position to purchase or recommend our products.

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

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

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

Foreign Regulation

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

Third-Party Reimbursement

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

CMS, the federal agency responsible for administering the Medicare program, along with its contractors establishes coverage and reimbursement policies for the Medicare program. In addition, private payors often follow the coverage

and reimbursement policies of Medicare. We cannot assure you that government or private third-party payors will cover and reimburse the procedures using our products in whole or in part in the future or that payment rates will be adequate.

In general, Medicare will cover a medical product or procedure when the product or procedure is reasonable and necessary for the diagnosis or treatment of an illness or injury. Even if the medical product or procedure is considered medically necessary and coverage is available, Medicare may place restrictions on the circumstances where it provides coverage. For some of our products, our success in non-U.S. markets may depend upon the availability of coverage and reimbursement from the third-party payors through which health care providers are paid in those markets. Health care

payment systems in non-U.S. markets vary significantly by country, and include single-payor, government managed systems as well as systems in which private payors and government-managed systems exist, side-by-side. For some of our products, our ability to achieve market acceptance or significant sales volume in international markets may be dependent on the availability of reimbursement for our products under health care payment systems in such markets. There can be no assurance that reimbursement for our products, will be obtained or that such reimbursement will be adequate.

Other U.S. Regulation

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

Available information

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

Employees

We currently employ 28 full-time equivalent employees, contractors or consultants, which include 11 in research and development, 4 in general and administrative, 4 in sales and marketing and 9 in direct and indirect manufacturing. None of our employees are represented by a labor union or are a party to a collective bargaining agreement. We believe that we have good relations with our employees.

Properties

Our corporate headquarters which houses our research and development, engineering, manufacturing, operations and support personnel, is located in Thorofare, New Jersey, in an office consisting of a total of 12,500 square feet. For the past eleven years, the Company has leased this facility at this location. The current lease term is effective from January 1, 2013 through December 31, 2019 with an annual rent of \$132,000.

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.

Legal Proceedings

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

On August 17, 2016, the Company entered into a Settlement Deed (the “Settlement Agreement”) by and among the Company, ChubeWorkx Guernsey Limited (“Chube”), Thirty Six Strategies, LLC (“36S”), Gavin Moran (“Mr. Moran”) and Frank Runge (“Mr. Runge”) (each, a “Party” and, collectively, the “Parties”) to resolve disputes related to (i) the Company’s claims brought against Chube in United States District Court, District of New Jersey for outstanding amounts due to the Company pursuant to that certain promissory note (the “Note”) issued in favor of Chube on December 31, 2014

(“Dispute 1”); (ii) various claims brought by Chube against the Company brought in The High Court of Justice, Queen’s Bench Division Commercial Court, Royal Courts of Justice, United Kingdom arising out that certain Licensing and Supply Agreement, as amended (the “License Agreement”), pursuant to which Chube was granted a worldwide, exclusive license to import, offer for sale, sell, distribute, use, promote or label certain products using the Company’s intellectual property (“Dispute 2”) and (iii) various claims brought by the Company against 36S, Mr. Moran and Mr. Runge in the United States District Court, District of New Jersey, related to that certain Distribution Agreement entered into by and between the Company and 36S on October 5, 2015 (“Dispute 3” and, together with Dispute 1 and Dispute 2, the “Disputes”).

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

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

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

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

Pulse subsequently filed an Amended Complaint, in which Pulse seeks not less than \$500,000 in damages and, among other items, an injunction prohibiting the Company from manufacture, use and sale of the OxiChek product. The Company answered the Amended Complaint on May 11, 2017. Discovery has commenced and is scheduled to conclude on January 22, 2018. The Court has set the trial date for July 17, 2018.

The Company intends to establish a rigorous defense of all claims. As the case has not progressed beyond initial motion practice and early discovery, the Company is unable to assess the potential outcome, no accrual for losses was made as of September 30, 2017. All legal fees were expensed as and when incurred.

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

MANAGEMENT

Executive Officers and Directors

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

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

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

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

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

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

Raymond F. Akers Jr., Ph.D., age 59, has been Executive Chairman of the Board since August 10, 2017, served as Vice Chairman from April 2016 through August 2017, and served as Executive Chairman from December 31, 2009 through April 2016. Dr. Akers was appointed Secretary on August 5, 2013. Dr. Akers founded the Company in 1989. He has over 25 years of experience in the diagnostics industry having co-founded Drug Screening Systems, Inc., a publicly listed company, in 1987, and Akers Medical Technology Inc. in 1984. He was Chief Executive Officer and vice president of research and development of Drug Screening Systems, Inc. until the sale of that company in 1989 and served as President and Chief Executive Officer of Akers Medical Technology Inc. until 1987.

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

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

Gary M. Rauch, age 61, has over 40 years of experience in accounting, financial and information systems consulting, discrete manufacturing, distribution and administration. Mr. Rauch has been the Company's Controller then Vice President, Finance since March, 2010 and was appointed Treasurer on August 5, 2013. Mr. Rauch also founded DataSys Solutions, LLC in 2004 and is currently the managing member. DataSys Solutions LLC specializes in financial and information systems consulting and technical support services. From July, 2002 through March, 2010, Mr. Rauch was the controller for Cold Star, Inc., a manufacturer of dairy dispensing equipment and a dairy products

distributor. Mr. Rauch also worked for six years as consulting manager with Deloitte & Touche providing financial system selection, development and implementation services for their small to middle market clients.

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

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

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

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

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

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

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

Christopher C. Schreiber, age 52, combines over 30 years of experience in the securities industry. As the Managing Director of Capital Markets at Taglich Brothers, Inc., Mr. Schreiber builds upon his extensive background in capital markets, deal structures, and syndications. Prior to his time at Taglich Brothers, he was a member of the board of directors of Paulson Investment Company, a 40-year-old full service Investment Banking firm. In addition, Mr. Schreiber serves as 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.

Chubeworkx Purchase Agreement/Voting Agreement

On June 19, 2013, the Company and Chubeworkx entered into a purchase agreement (the “Chubeworkx Purchase Agreement”) pursuant to which Chubeworkx purchased 512,820 of the Company’s common stock for an aggregate purchase price of \$1,600,000. As further consideration to induce Chubeworkx to enter into the Chubeworkx Purchase

Agreement, the Company, Chubeworkx and Mr. Tom Knox entered into a voting agreement (the “Voting Agreement”) whereby Mr. Knox and Chubeworkx agreed to vote their respective shares pursuant to the terms of the Voting Agreement. Amongst other things, the Company, Mr. Knox and Chubeworkx agreed as follows:

- (i) to take all other actions necessary to ensure that at all times, (a) the size of the Board shall be a maximum of five (5) directors and (b) the Company’s organizational documents specify that each director has equal rights to each other director;
- (ii) on all matters relating to the election of one or more directors of the Company, each of Mr. Knox and Chubeworkx shall vote at regular or special meetings of shareholders and so long as each maintains ten percent (10%) or more of the voting rights with respect to the Company shall be entitled to designate their own directors (each a “Designee and together the “Designees”); and
- (iii) Mr. Knox shall vote at a regular or special meeting of stockholders (or by written consent) all of the shares held by him, and the Company and Mr. Knox shall otherwise take all actions necessary to ensure that at all times up to the time which is immediately prior to the consummation of this offering, the unanimous approval of the board of directors of the Company shall be required for any issuance by the Company of any new shares of capital stock of the Company or any instruments convertible into shares of capital stock of the Company (including any such issuance of shares of capital stock of the Company in connection with this offering, including without limitation voting in favor of any amendment to the Certificate of Incorporation or Bylaws, as necessary.

Although Mr. Knox is no longer a member of the Board, the Voting Agreement remains in place.

Family Relationships

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

Board Composition and Committees and Director Independence

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

The directors will serve until our next annual meeting and until their successors are duly elected and qualified. The Company defines “independent” as that term is defined in Rule 5605(a)(2) of the Nasdaq listing standards.

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

Board Committees

The Company has established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each committee has its own charter, which is available on our website at www.akersbio.com. Information contained on our website is not incorporated herein by reference.

Audit Committee

We have a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act of 1934, as amended (the “Exchange Act”). The members of our Audit Committee are Mr. White,

Mr. Tarbox and Mr. Schreiber. Each of these Committee members is “independent” within the meaning of Rule 10A-3 under the Exchange Act and the Nasdaq Stock Market Rules. Our board has determined that Mr. White is an “audit committee financial expert”, as such term is defined in Item 407(d)(5) of Regulation S-K. Mr. White serves as Chairman of our Audit Committee.

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

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

Compensation Committee

The members of our Compensation Committee are Mr. Bill J. White, Mr. Richard C. Tarbox and Mr. Christopher C. Schreiber. Each such member is “independent” within the meaning of the Nasdaq Stock Market Rules. In addition, each member of our Compensation Committee qualifies as a “non-employee director” under Rule 16b-3 of the Exchange Act. Our Compensation Committee assists the board of directors in the discharge of its responsibilities relating to the compensation of the board of directors and our executive officers. Mr. Schreiber will serve as Chairman of our Compensation Committee.

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

- reviewing and approving on an annual basis the corporate goals and objectives with respect to compensation for our Chief Executive Officer;
- reviewing, approving and recommending to our board of directors on an annual basis the evaluation process and compensation structure for our other executive officers;
- determining the need for an the appropriateness of employment agreements and change in control agreements for each of our executive officers and any other officers recommended by the Chief Executive Officer or board of directors;

- providing oversight of management's decisions concerning the performance and compensation of other company officers, employees, consultants and advisors;
- reviewing our incentive compensation and other equity-based plans and recommending changes in such plans to our board of directors as needed, and exercising all the authority of our board of directors with respect to the administration of such plans;
- reviewing and recommending to our board of directors the compensation of independent directors, including incentive and equity-based compensation; and
- selecting, retaining and terminating such compensation consultants, outside counsel or other advisors as it deems necessary or appropriate.

Nominating and Corporate Governance Committee

The members of our Nominating and Corporate Governance Committee are Mr. Bill J. White, Mr. Richard C. Tarbox and Mr. Christopher C. Schreiber. Each such member is “independent” within the meaning of the Nasdaq Stock Market Rules. The purpose of the Nominating and Corporate Governance Committee is to recommend to the board nominees for election as directors and persons to be elected to fill any vacancies on the board, develop and recommend a set of corporate governance principles and oversee the performance of the board. Mr. Tarbox serves as Chairman of our Nominating and Corporate Governance Committee.

The Committee’s responsibilities include:

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

The Nominating and Corporate Governance Committee may delegate any of its responsibilities to subcommittees as it deems appropriate. The Nominating and Corporate Governance Committee is authorized to retain independent legal and other advisors, and conduct or authorize investigations into any matter within the scope of its duties.

Management-Non-Executive Director Compensation

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

Code of Ethics

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,

75

- 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.

Involvement in Certain 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.

EXECUTIVE COMPENSATION

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 2016, 2015 and 2014.

Name and Principal Position	Year	Salary \$	Cash Bonus \$	Stock Awards \$	Option Awards \$	All Other \$	Total \$
Raymond F Akers, Jr PhD Former Executive Chairman Secretary, Chief Scientific Director	2016	269,231	—	—	—	7,800 (1)	277,031
	2015	397,450	—	256,900	—	7,800 (1)	662,150
	2014	394,231	—	—	124,270	7,800 (1)	526,301
John J. Gormally(2) Chief Executive Officer	2016	248,500	—	54,725	—	7,800 (3)	311,025
	2015	24,038	—	—	—	650 (3)	24,688
Gary M Rauch Vice President, Finance and Treasurer	2016	95,000	—	—	—	—	95,000
	2015	95,000	—	27,675	—	—	122,675
	2014	78,414	—	—	46,601	11,250 (4)	138,765

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

(2) Mr. Gormally was appointed as Chief Executive Officer on November 16, 2015.

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

(4) Mr. Rauch became an employee of the Company effective February 2, 2014. Prior to this date, Mr. Rauch was paid a fee pursuant to his consultant agreement. Fees paid to Mr. Rauch for his pre-employment period are recorded as other compensation.

Employment Agreements

On December 2, 2015, the Company and John J. Gormally finalized the terms of his employment and entered into an employment agreement (the “Employment Agreement”), pursuant to which Mr. Gormally will serve as the Company’s Chief Executive Officer. Mr. Gormally shall have such duties, responsibilities and authority as are commensurate and consistent with the position of Chief Executive Officer of a public company.

The Company shall pay Mr. Gormally a salary at a rate of Two Hundred Fifty Thousand and 00/100 Dollars (\$250,000) per year (the “Base Salary”). On January 31, 2017, pursuant to the terms of the Employment Agreement, the Board adjusted Mr. Gormally’s salary to Three Hundred Twenty-Five Thousand and 00/100 Dollars (\$325,000) effective as of January 1, 2017. In addition, subject to the discretion of the Company’s Compensation Committee and the Board, provided that the Employment Agreement has not been terminated, Mr. Gormally shall be eligible for an annual performance-based cash bonus of up to 100% of the Base Salary (the “Cash Incentive Bonus”). Mr. Gormally shall receive certain grants of the Company’s restricted common stock (each an “Incentive Award” and together with the Cash Incentive Bonus, the “Incentive Compensation”) on a bi-annual basis, with such awards expected to be made on or about February 15 and August 15 of each year, under the Company’s Amended and Restated 2013 Incentive Stock and Award Plan. Each Incentive Award will vest or has vested as follows: (i) 1/3 vested on the date of grant; (ii) 1/3 vest

on the first anniversary of the date of grant and (iii) 1/3 shall vest on the second anniversary of the date of grant. The Incentive Awards will be made within the following ranges, in the aggregate, for each such year: (i) for 2016, up to 140,000 shares of restricted common stock, but no less than 27,500 shares of restricted common stock; (ii) for 2017, up to 125,000 shares of restricted common stock, but no less than 25,000 shares of restricted common stock; (iii) for 2018, up to 125,000 shares of restricted common stock, but no less than 25,000 shares of restricted common stock; (iv) for 2019, up to 125,000 shares of restricted common stock, but no less than 25,000 shares of restricted common stock; and (v) for 2020, up to 125,000 shares of restricted common stock, but no less than 25,000 shares of restricted common stock.

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

Stock Awards

Name (a)	Number of Securities Underlying Unexercised Options (#) (b)	Number of Securities Underlying Unexercised Options (#) (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#) (d)	Option Exercise Price (\$) (e)	Option Expiration Date (f)	Number of Shares or Units of Stock That Have Not Vested (g)	Market Value of Shares or Units of Stock That Have Not Vested (\$) (h)	Equity Incentive Plan Awards: Number of Shares, Units or Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Rights That Have Not Vested (\$) (j)
Raymond F. Akers Jr. Director, Secretary	40,000 ₍₁₎	0	0	5.50	06/30/2019	0	0	0	0
John J. Gormally Chief Executive Officer	0	0	0	0	n/a	18,666	35,465	0	0
Gary Rauch VP of Finance	15,000	0	0	5.50	06/30/2019	0	0	0	0
Thomas Knox, Non-Executive Chairman	20,000	0	0	5.50	06/30/2019	0	0	0	0

Robert E. Andrews Director	0	0	0	0	n/a	0	0	0	0
Brandon Knox, Director	20,000	0	0	5.50	06/30/2019	0	0	0	0
Dr. Raza Bokhari	0	0	0	0	n/a	0	0	0	0

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

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

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, 2016.

Name	Fees earned or paid in cash (\$)	Stock Awards (\$)	Option Awards (\$)	Non-equity incentive plan compensation (\$)	All other compensation (\$)	Total (\$)
Raymond Akers, Jr.(1)	0	0	0	0	0	0
Thomas Knox(2)	0	0	0	0	0	0
Brandon Knox(3)	0	0	0	0	0	0
Robert E. Andrews(4)	0	0	0	0	0	0
Dr. Raza Bokhari(5)	0	0	0	0	0	0

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

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

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

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

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

Compensation-Setting Process/Role of Our Compensation Committee

The Compensation Committee has responsibility for the Company's compensation practices with appropriate approval and general oversight from the Board. This responsibility includes the determination of compensation levels and awards provided to the named executive officers. The Compensation Committee provides a recommendation for the performance review and any compensation adjustments to the Board for approval. Grants of equity-based compensation are approved by the Compensation Committee in accordance with the Company's stock incentive and award plan established by the Compensation Committee.

Base Salary

We provide base salary as a fixed source of compensation for our executive officers, allowing them a degree of certainty when having a meaningful portion of their compensation "at risk" in the form of equity awards covering the shares of a Company for whose shares there has been limited liquidity to date. The Board recognizes the importance of base salaries as an element of compensation that helps to attract highly qualified executive talent.

Base salaries for our executive officers were established primarily based on individual negotiations with the executive officers when they joined us and reflect the scope of their anticipated responsibilities, the individual experience they bring, the Board members' experiences and knowledge in compensating similarly situated individuals at other

companies, our then-current cash constraints and a general sense of internal pay equity among our executive officers and key personnel.

The Compensation Committee does not apply specific formulas in determining base salary increases. Actual base salaries may differ from the competitive market rates target as a result of various other factors including relative depth of experience, prior individual performance and expected future contributions, internal pay equity considerations within our Company and the degree of difficulty in replacing the individual.

Outstanding Equity Awards at Fiscal Year-End 2016

There were no outstanding equity awards at Fiscal Year-End 2016.

Compensation Risk Assessment

In connection with this offering, our board of directors expects to review the potential risks associated with the structure and design of our various compensation plans, including a comprehensive review of the material compensation plans and programs for all employees. Our material plans and programs operate within our larger corporate governance and review structure that serves and supports risk mitigation.

Employee Stock Incentive Plans

Effective August 7, 2017, the shareholders of the “Company, upon the recommendation of the Board of the Company, approved and adopted the Akers Biosciences, Inc. 2017 Equity Incentive Plan (the “Plan”). The Plan provides for the issuance of up to 1,350,000 shares of the Company’s common stock, no par value per share (the “Common Stock”), through the grant of non-qualified options (the “Non-qualified Options”), incentive options (the “Incentive Options” and together with the Non-qualified Options, the “Options”), restricted stock (the “Restricted Stock”) and unrestricted stock to directors, officers, consultants, attorneys, advisors and employees.

The Board will initially administer the Plan. The Compensation Committee of the Board will recommend to the Board the employees and non-employees who receive awards, the number of shares covered thereby, and, subject to the terms and limitations expressly set forth in the Plan, the terms, conditions and other provisions of the grants. The Board intends to appoint the Compensation Committee of the Board to administer the Plan at such time as the newly elected directors comprising the Compensation Committee of the Board are prepared to administer the Plan.

Options are subject to the following conditions:

- (i) The Board or committee administering the Plan (the “Committee”) determines the strike price of Incentive Options at the time the Incentive Options are granted. The assigned strike price must be no less than 100% of the Fair Market Value (as defined in the Plan) of the Common Stock. In the event that the recipient is a Ten Percent Owner (as defined in the Plan), the strike price must be no less than 110% of the Fair Market Value of the Company.
- (ii) The strike price of each Option will be at least 100% of the Fair Market Value of such share of the Company’s Common Stock on the date the Non-qualified Option is granted.
- (iii) The Committee fixes the term of Options, provided that Options may not be exercisable more than ten years from the date the Option is granted, and provided further that Incentive Options granted to a Ten Percent Owner may not be exercisable more than five years from the date the Incentive Option is granted.
- (iv) The Committee may designate the vesting period of Options. The vesting period accelerates upon the consummation of a Sale Event (as defined in the Plan).
- (v) Options are not transferable and Options are exercisable only by the Options’ recipient, except upon the recipient’s death.
- (vi) Incentive Options may not be issued in an amount or manner where the amount of Incentive Options exercisable in one year entitles the holder to Common Stock of the Company with an aggregate Fair Market value of greater than \$100,000.

Awards of Restricted Stock are subject to the following conditions:

- (i) The Committee grants Restricted Stock and determines the restrictions on each Restricted Stock Award (as defined in the Plan). Upon the grant of a Restricted Stock Award and the payment of any applicable purchase price, grantee is considered the record owner of the Restricted Stock and entitled to vote the Restricted Stock if such

Restricted Stock is entitled to voting rights.

- (ii) Restricted Stock may not be delivered to the grantee until the Restricted Stock has vested.
- (iii) Restricted Stock may not be sold, assigned, transferred, pledged or otherwise encumbered or disposed of except as provided in the Plan or in the Award Agreement (as defined in the Plan).

Issuances made pursuant to the Plan

On October 17, 2017, pursuant to the Plan, the Board issued (i) John J. Gormally, the Company's CEO, 150,000 shares of Restricted Stock, (ii) Gary Rauch, the Company's CFO, 36,277 shares of Restricted Stock, (iii) 58,043 shares of Restricted Stock to a current employee of the Company and (iv) 50,787 shares of Restricted Stock to a former employee of the Company, for a total of 295,107 shares of Restricted stock.

As of December 4, 2017, under the Plan, the Company has issued 295,107 shares of Restricted Stock and has 1,054,893 shares of Common Stock available for issuance.

The above description of the Plan does not purport to be complete and is qualified in its entirety by reference to the full text of the Plan, which is attached as Exhibit 10.1 to this Current Report on Form 8-K is incorporated by reference herein.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

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:

On June 19, 2012, the Company entered into a 3-year exclusive License & Supply Agreement with ChubeWorkx for the purchase and distribution of Akers' proprietary breathalyzers outside North America. ChubeWorkx paid a licensing fee of \$1,000,000 which was recognized over the term of the agreement through September 30, 2015.

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

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

Under the terms of the Settlement Agreement, the Company recovered the full outstanding principal amount in the current fiscal year in the form of \$750,000 of BreathScan® Alcohol Detector products — which the Company intends to subsequently sell — and the balance of \$549,609 as prepaid royalty. The goods were received in August, 2016. Akers' established an allowance for this doubtful note in the Company's financial statements for the year ended December 31, 2015. As a result of the Settlement Agreement, the Company reversed the allowance for doubtful note in the amount of \$1,299,609 which is included in the Condensed Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2016.

In addition to addressing the promissory note described above, the Settlement Agreement also allows the Company to market and sell all of the Company's breath technology tests worldwide, unencumbered by any past/future claims by ChubeWorkx under the Licensing Agreement (entered into with ChubeWorkx in 2012 and subsequently amended in 2013). Under the terms of the Settlement Agreement, ChubeWorkx no longer holds any rights pertaining to Akers' BreathScan® technology, which serves as the basis for a number of commercialized products including BreathScan® Alcohol Detector and BreathScan OxiChek™; and a number of products in development.

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 \$153,854 for the year ended December 31, 2016 which are included in sales and marketing expenses — related party on the Consolidated Statement of Operations and Comprehensive Loss.

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

the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other equipment; and 3) the grant of voting proxy by ChubeWorkx to the Company which allows the Company to vote ChubeWorkx's shares for corporate formalities under certain conditions.

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

The Company began purchasing manufacturing molds, plastic components and the assembled BreathScan Lync device through Hainan and its related parties during the year ended December 31, 2016 (Note 11). The Company purchased a total of \$207,135 during the year ended December 31, 2016 from this related party. As of December 31, 2016, the Company owed the three companies \$164,049 which is included in trade and other payables — related party on the Consolidated Balance Sheet.

Trade receivables — related party as of December 31, 2016 and 2015 were \$31,892 and \$31,512. The amounts due are non-interest bearing, unsecured and generally have a term of 30-90 days (Note 5). This receivable is past due and management deemed it fully collectable.

Product revenue — related party for the year ended December 31, 2016 and 2015 were \$380 and \$36,512. The revenue was the result of sales to Hainan.

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.

Pursuant to the Settlement Agreement, all of the Disputes have been settled and all of the proceedings related to such have been dismissed. For more detailed information related to the Settlement Agreement See — Item 3, Legal Proceedings and Note 18 to the Company's audited financial statements.

On March 9, 2015, the Company contributed capital of \$64,675 in Hainan Savy Akers Biosciences, Ltd., a company incorporated in the People's Republic of China, resulting in a 19.9% ownership interest. The contribution was adjusted downward to \$64,091 on April 8, 2015; the net effect of the currency conversion when the contribution was processed in Hainan. Mr. Thomas Knox, a member of the Company's Board of Directors, is also an investor in the joint venture.

Indemnification of our Directors and Officers

Section 14A:2-7(3) of the New Jersey Business Corporation Act permits a corporation to provide in its certificate of incorporation that a director or officer shall not be personally liable, or shall be liable only to the extent therein provided, to the corporation or its shareholders for damages for breach of any duty owed to the corporation or its shareholders, except that such provision shall not relieve a director or officer from liability for any breach of duty based upon an act or omission (a) in breach of such person's duty of loyalty to the corporation or its shareholders, (b) not in good faith or involving a knowing violation of law or (c) resulting in receipt by such person of an improper personal benefit. Akers Biosciences, Inc.'s certificate of incorporation provides for such limitation of liability.

Section 14A:3-5 of the New Jersey Business Corporation Act empowers a corporation to indemnify any current or former director or officer made a party to a proceeding because he or she is or was a director or officer against liability incurred in the proceeding; provided that such director or officer acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal proceeding, such director or officer had no reasonable cause to believe his conduct was unlawful.

Akers Biosciences, Inc.'s certificate of incorporation provides that the corporation must indemnify its directors and officers to the fullest extent authorized by law. Akers Biosciences, Inc. is also expressly required to advance certain expenses to its directors and officers. Akers Biosciences, Inc. believes that these indemnification provisions are useful to attract and retain qualified directors and executive officers.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Policy on Future Related Party Transactions

All future transactions between us and our officers, directors, principal stockholders and their affiliates will be approved by the audit committee, or a similar committee consisting of entirely independent directors, according to the terms of our Code of Business Conduct and our Related Party Transaction Policies and Procedures.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth, as of November 20, 2017, 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 November 20, 2017. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all shares of common stock shown that they beneficially own, subject to community property laws where applicable.

Our calculation of the percentage of beneficial ownership is based on 9,920,552 shares of our common stock issued and outstanding as of November 20, 2017.

Common stock subject to stock options currently exercisable or exercisable within 60 days of November 20, 2017, are deemed to be outstanding for computing the percentage ownership of the person holding these securities and the percentage ownership of any group of which the holder is a member but are not deemed outstanding for computing the percentage of any other person.

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

Name of Beneficial Owner:	Shares Beneficially Owned as of November 20, 2017	Percentage of Ownership as of November 20, 2017	
5% Stockholders:			
Empery Asset Management, LP	724,200	7.30	%
Hudson Bay Master Fund, LTD	632,000	6.37	%
Chubeworkx Guernsey Limited ⁽¹⁾	512,820	5.17	%
Named Executive Officers and Directors:*			
Raymond F. Akers, Jr. Phd ⁽²⁾	—	—	%
Bill J. White	—	—	%
Richard C. Tarbox III	—	—	%
Christopher C. Schreiber	—	—	%
John J. Gormally	180,000	1.81	%
Gary M. Rauch ⁽³⁾	78,777	0.79	%

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

All executive officers and directors as a group (6 persons)	258,777	2.60	%
---	---------	------	---

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

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

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

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

Changes in Control

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

The following table shows information with respect this plan as of the fiscal year ended December 31, 2016.

Equity Compensation Plan Information

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average Exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	—	\$ —	—
Equity compensation plans not approved by security holders	259,000	\$ 4.23	13,292
Total	259,000	\$ 4.23	13,292

DESCRIPTION OF SECURITIES

General

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the bylaws that were filed with the Securities and Exchange Commission as exhibits to the registration statement of which this prospectus forms a part.

Our authorized capital stock consists of 550,000,000 shares, of which 500,000,000 are common stock, without par value, and 50,000,000 are preferred stock, without par value. As of November 20, 2017 we had issued and outstanding 9,920,552 shares of common stock and no preferred stock.

Common Stock

Voting Rights

Each Stockholder has one vote for each share of common stock held on all matters submitted to a vote of stockholders. A shareholder may vote in person or by proxy. Elections of directors are determined by a plurality of the votes cast and all other matters are decided by a majority of the votes cast by those Shareholders entitled to vote and present in person or by proxy.

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all of our directors. Our amended and restated certificate of incorporation and bylaws provide that stockholder actions may be effected at a duly called meeting of stockholders or pursuant to written consent of the majority of shareholders. A special meeting of stockholders may be called by the President, Chief Executive Officer or the Board of Directors pursuant to a resolution approved by the majority of the Board of Directors.

Dividend Rights

The holders of outstanding shares of common stock are entitled to receive dividends out of funds legally available at the times and in the amounts that our board may determine, provided that required dividends, if any, on preferred stock have been paid or provided for. However, to date we have not paid or declared cash distributions or dividends on our common stock and do not currently intend to pay cash dividends on our common stock in the foreseeable future. We intend to retain all earnings, if and when generated, to finance our operations. The declaration of cash dividends in the future will be determined by the board based upon our earnings, financial condition, capital requirements and other relevant factors.

No Preemptive or Similar Rights

Holders of our common stock do not have preemptive rights, and common stock is not convertible or redeemable.

Right to Receive Liquidation Distributions

Upon our dissolution, liquidation or winding-up, the assets legally available for distribution to our stockholders and remaining after payment to holders of preferred stock of the amounts, if any, to which they are entitled, are distributable ratably among the holders of our common stock subject to any senior class of securities.

The Company is authorized to issue 50,000,000 shares of preferred stock, with no par value per share. Pursuant to the Company's Certificate of Incorporation, the Board of Directors has the authority to amend the Company's Certificate of

Incorporation, without further stockholder approval, to designate and determine the preferences, limitations and relative rights of the preferred stock before any issuance of the preferred stock and to create one or more series of preferred stock, fix the number of shares of each such series, and determine the preferences, limitations and relative

rights of each series of preferred stock, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, and liquidation preferences. Our certificate of incorporation provides that only holders of an affected series of preferred stock have the ability to vote on an amendment to the certificate of incorporation that solely relates to the terms of such preferred stock.

Series A Preferred Stock

The Company has authorized 10,000,000 shares of Series A Cumulative Preferred Stock (the “Series A Preferred Stock”). As of November 20, 2017 there were no shares of the Company’s Series A Preferred Stock issued and outstanding.

Series B Convertible Preferred Stock

The following is a summary of the material terms of the Series B Preferred. This summary is not complete. The following summary of the terms and provisions of the Series B Preferred is qualified in its entirety by reference to the Series B Preferred, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part.

General. Our board of directors has authorized the designation of up to 7,000 shares of the 50,000,000 authorized shares of preferred stock as Series B Convertible Preferred Stock and the Company will file the Series B Preferred Certificate of Designation (i) following the effectiveness of the registration statement of which this prospectus forms a part and (ii) prior to the closing of this offering. When issued, the shares of Series B Preferred will be validly issued, fully paid and non-assessable. Each share of Series B Preferred will have a stated value of \$1,000 per share.

Rank. The Series B Preferred will rank on parity to our common stock.

Conversion. Each share of Series B Preferred is convertible into shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences, rights and limitations) at any time at the option of the holder at a conversion price equal to the public offering price of the Class A Units in this offering. Holders of Series B Preferred will be prohibited from converting Series B Preferred into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding.

Liquidation Preference. In the event of our liquidation, dissolution or winding-up, holders of Series B Preferred will be entitled to receive the same amount that a holder of our common stock would receive if the Series B Preferred were fully converted into shares of our common stock at the conversion price (disregarding for such purposes any conversion limitations) which amounts shall be paid *pari passu* with all holders of common stock.

Voting Rights. Shares of Series B Preferred will generally have no voting rights, except as required by law and except that the affirmative vote of the holders of a majority of the then outstanding shares of Series B Preferred is required to, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred, (b) amend our certificate of incorporation or other charter documents in any manner that materially adversely affects any rights of the holders, (c) increase the number of authorized shares of Series B Preferred, or (d) enter into any agreement with respect to any of the foregoing.

Dividends. Shares of Series B Preferred will not be entitled to receive any dividends, unless and until specifically declared by our board of directors. The holders of the Series B Preferred will participate, on an as-if-converted-to-common stock basis, in any dividends to the holders of common stock.

Redemption. We are not obligated to redeem or repurchase any shares of Series B Preferred. Shares of Series B Preferred are not otherwise entitled to any redemption rights or mandatory sinking fund or analogous fund provisions.

Exchange Listing. We do not plan on making an application to list the Series B Preferred on any national securities exchange or other nationally recognized trading system.

Warrants to be Issued in this Offering

The following is a summary of the material terms of the warrants. This summary is not complete. The following summary of the terms and provisions of the warrants is qualified in its entirety by reference to the warrants, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part.

Form. The warrants will be issued in electronic book-entry form to the investors. You should review a copy of the form of warrant, which is filed as an exhibit to the registration statement of which this prospectus forms a part, for a complete description of the terms and conditions applicable to the warrants.

Exercisability. The warrants are exercisable at any time after their original issuance, expected to be _____, 2017, and at any time up to the date that is five years after their original issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Exercise Limitation. A holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Exercise Price. The exercise price per share of common stock purchasable upon exercise of the warrants is \$ _____. The warrants may also be exercised via cashless exercise, whereby the holder will receive upon exercise of the warrant (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrant. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing. We do not plan on making an application to list the warrants on any national securities exchange or other nationally recognized trading system.

Fundamental Transactions. In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

Rights as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Options and Warrants

As of November 20, 2017, we had 1,490,570 shares issuable upon exercise of outstanding warrants at exercise prices ranging from \$1.20 to \$1.96 per share and 255,000 shares issuable upon the exercise of outstanding stock options under the 2013 Stock Incentive Plan at exercise prices ranging from \$1.23 to \$5.50 per share. There are no other outstanding warrants or options at this time.

As of December 1, 2017, there are 7,292 shares of common stock reserved for issuance under the 2013 Equity Incentive Plan.

On October 17, 2017, pursuant to the Akers Biosciences, Inc. 2017 Equity Incentive Plan (the “Plan”), the Board issued (i) John J. Gormally, the Company’s CEO, 150,000 shares of Restricted Stock, (ii) Gary Rauch, the Company’s CFO, 36,277 shares of Restricted Stock, (iii) 58,043 shares of Restricted Stock to a current employee of the Company and (iv) 50,787 shares of Restricted Stock to a former employee of the Company, for a total of 295,107 shares of Restricted stock.

As of December 4, 2017, under the Plan, the Company has issued 295,107 shares of Restricted Stock and has 1,054,893 shares of Common Stock available for issuance.

Anti-Takeover Provisions

The provisions of our certificate of incorporation, bylaws and the New Jersey corporation law summarized in the following paragraphs may be deemed to have anti-takeover effects and may delay, defer, or prevent a tender offer or takeover attempt that a shareholder might consider to be in such shareholder’s best interest, including those attempts that might result in a premium over the market price for the shares held by shareholders, and may make removal of management more difficult.

The authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us.

These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

New Jersey Shareholders Protection Act

A provision of New Jersey law, the New Jersey Shareholders Protection Act (the “SPA”), prohibits certain transactions involving an “interested stockholder” and a corporation. An “interested stockholder” is generally defined as one who is the beneficial owner, directly or indirectly, of 10% or more of the voting power of the outstanding stock of the corporation. The SPA prohibits certain business combinations between an interested stockholder and a New Jersey corporation subject to the SPA for a period of five years after the date the interested stockholder acquired his stock, unless the transaction was approved by the corporation’s board of directors prior to the time the interested stockholder acquired his stock. After the five-year period expires, the prohibition on business combinations with an interested stockholder continues unless certain conditions are met. The conditions include (i) that the business combination is approved by the board of directors of the target corporation; (ii) that the business combination is approved by a vote of two-thirds of the voting stock not owned by the interested stockholder; and (iii) that the stockholders of the corporation receive a price in accordance with the SPA.

Transfer Agent and Registrar

Our transfer agent for our common stock is VStock Transfer LLC, 18 Lafayette Place Woodmere, NY 11598.

SHARES ELIGIBLE FOR FUTURE SALE

Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options and warrants, or the anticipation of these sales, could adversely affect prevailing market prices from time to time and could impair our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of December 12, 2017, after giving pro forma effect to the closing of this offering, we will have there will be 17,612,860 shares of our common stock outstanding. This excludes shares of common stock that may be issued upon exercise of the warrants and conversion of the Series B Preferred to be issued in this offering. Of those shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our “affiliates,” as that term is defined in Rule 144 under the Securities Act, or Rule 144, may only be sold in compliance with the limitations described below.

Rule 144

In general, under Rule 144, any person who is not our affiliate and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, subject to the availability of current public information about us. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares without regard to whether current public information about us is available. A person who is our affiliate or who was our affiliate at any time during the preceding three months, and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately [•] shares immediately after this offering; or
- the average weekly trading volume of our common stock on the Nasdaq Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements, and to the availability of current public information about us.

Our common stock traded on AIM in the United Kingdom

All of the shares of our common stock are admitted for trading on AIM. Our shares that trade on AIM are held in certificated form by individual stockholders or by CREST, which acts as a depositary, pursuant to a trust deed with us or are held in the SIS electronic settlement system. CREST in turn, issues Depositary Interests, or Dis, to each of the brokerage firms that are members of CREST, which hold interests in shares on behalf of their clients who are stockholders. Dis are settled through CREST, operated by Euroclear U.K. & Ireland Limited. Our shares that trade on AIM under the ticker “AKR.L” are unrestricted. Shares of our common stock are restricted under Regulation S of the Securities Act and are considered “restricted securities” under Rule 144. The legends on “AKR” shares require the seller and seller’s broker to provide standard letters in connection with a sale of stock, under which they represent that the sale is in compliance with the offshore resale requirements of Rule 904 of the Securities Act.

The AIM Rules

For so long as any of our common stock is admitted for trading on AIM, we are subject to the AIM Rules. A copy of the AIM Rules may be obtained at the London Stock Exchange’s website at www.londonstockexchange.com. The information on, or that can be accessed through, this website is not part of this prospectus.

The AIM Rules regulate the admission of shares to trading on AIM and impose various continuing obligations on AIM-listed companies. Under the AIM Rules, we are obliged, among other things, to:

- disclose to the public details of certain transactions and various corporate and other information relating to our business and our stockholders;

- seek the approval of our stockholders for certain corporate transactions, such as reverse takeovers, transactions resulting in fundamental changes in our business or a cancellation of our AIM listing;
- publish half-yearly and annual accounts within certain time periods and in accordance with prescribed accounting standards; and
- ensure that our directors and certain employees do not deal in our shares during prescribed periods prior to the publication of our financial results or when we are in possession of material non-public information.

The AIM Rules also require us to retain the services of a nominated advisor, or Nomad, and a broker. The Nomad is a full-time corporate finance advisor approved by the London Stock Exchange to act in this capacity. The Nomad assesses our overall suitability for AIM and assists us in meeting our continuing obligations under the AIM Rules, maximizing the benefits of our AIM quotation and dealing with market issues as they arise. The Nomad also has responsibilities to the London Stock Exchange itself and must comply with the AIM Rules for Nominated Advisers. A broker is a securities house that is a member of the London Stock Exchange and is responsible for facilitating and promoting trading in a company's shares on the market. Often an AIM company will choose the same firm to act as both Nomad and broker. Daniel Stewart & Company Plc is our Nomad.

The AIM Rules also enable the London Stock Exchange to take various steps to fine or censure us or impose other sanctions, including suspending or cancelling the trading of our shares on AIM, should we breach the AIM Rules or in order to preserve the integrity of the market or protect investors.

Disclosure and Transparency Rules

We are required to notify AIM if we are notified that the legal or beneficial interest that a stockholder holds in us (or are deemed to hold through their direct or indirect holding of financial instruments) reaches, exceeds or falls below 3% of our total outstanding shares, or any single percentage point increment above the 3% threshold. Since we are not subject to Chapter 5 of the Disclosure and Transparency Rules of the Financial Services Authority, and under our amended and restated certificate of incorporation and our bylaws there are no provisions requiring disclosure of interests in shares by stockholders, our stockholders are not required to provide us notification upon reaching, exceeding or falling below these thresholds.

Moving Our Shares of Common Stock Between the United States and the United Kingdom

If a holder of our common stock in certificated form, other than shares which are registered in this offering, or as Dis in uncertificated form in the CREST system, wishes to sell its shares on Nasdaq, the holder needs to use an eligible U.S. brokerage firm and, in general, abide by Rule 144. Upon sale of the common stock on Nasdaq through an eligible U.S. brokerage firm, such firm will need to contact our transfer agent, who will either take possession of the share certificate(s) or remove the shares from the CREST system and, in turn, convert such shares to certificated form in the name of Cede & Co, as nominee for DTC. The common stock held by Cede & Co. for DTC will be then be transferred by DTC to the purchaser.

Conversely, if a holder of common stock in the United States wishes to sell its common stock via AIM using the CREST system, the holder will need to contact Capita Registrars and request that the shares be removed from the DTC system and converted to certificated form in the name of Capita Trustees IRG Limited, who will deposit such common stock in the CREST system.

Please note that the arrangements described above may be difficult or unavailable due to:

- temporary delays that may arise because the transfer books for the common stock are closed;

- obligations to pay fees, taxes and similar charges that would arise; or
- restrictions imposed because of laws or regulations applicable to shares of common stock in the United States or the United Kingdom.

UNDERWRITING

Joseph Gunnar & Co., LLC is acting as the sole underwriter of this offering. We have entered into an underwriting agreement, dated [____], 2017, with the underwriter. Subject to the terms and conditions of the underwriting agreement between us and the underwriter, we have agreed to sell to the underwriter, and the underwriter has agreed to purchase from us, at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Underwriters	Number of Class A Units	Number of Class B Units
Joseph Gunnar & Co. LLC		

The underwriter is committed to purchase all the Units offered by us, other than those covered by the over-allotment option described below, if any are purchased. The obligations of the underwriter may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriter's obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriter of officers' certificates and legal opinions.

The underwriter is offering the Units, subject to prior sale, when, as and if issued to and accepted by it, subject to approval of legal matters by its counsel and other conditions specified in the underwriting agreement. The underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-Allotment Option

We have granted the underwriter an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriter to purchase a maximum of 2,307,692 additional shares of common stock (15% of the shares of common stock included in the Class A Units and the shares of common stock underlying the shares of Series B Preferred included as part of the Class B Units sold in this offering) and/or warrants to purchase a maximum of 2,307,692 shares of common stock (15% of the warrants included as part of the Units sold in this offering) solely to cover over-allotments, if any. If the underwriter exercises all or part of this option, it will purchase such common stock covered by the option at the public offering price per Class A Unit, minus one cent, and the warrants covered by the option at a price of one cent per warrant, in each case less the underwriting discounts and commissions. If this option is exercised in full, the total offering price to the public will be approximately \$6.9 million and the total net proceeds, after expenses, to us will be approximately \$6.2 million.

Discounts, Commissions and Expense Reimbursement.

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Class A Unit	Per Class B Unit	Total Without Over-Allotment Option	Total With Over-Allotment Option
Public offering price	\$	\$	\$	\$
Underwriting discount (7%)	\$	\$	\$	\$
Non-accountable expense allowance (1%) ⁽¹⁾	\$	\$	\$	\$
Proceeds, before expense, to us	\$	\$	\$	\$

We have agreed to pay a non-accountable expense allowance to the underwriter equal to 1.0% of the gross (1)proceeds received in this offering; provided, however, the expense allowance of 1.0% is not payable with respect to any securities sold upon exercise of the underwriter's over-allotment option.

The underwriter proposes to offer the Units offered by us to the public at the public offering price per respective Unit set forth on the cover of this prospectus. In addition, the underwriter may offer some of the Units to other securities

dealers at such price less a concession of up to \$ per Class A Unit and \$ per Class B Unit.

If all of the Units offered by us are not sold at the respective public offering prices per Unit, the underwriter may change the offering price per Unit and other selling terms by means of a supplement to this prospectus.

We have paid an expense deposit of \$10,000 to the underwriter, which will be applied against the underwriter's accountable out-of-pocket expenses (in compliance with FINRA Rule 5110(f)(2)(C)) that are payable by us in connection with this offering. We have agreed to reimburse the underwriter for the fees and expenses of its legal counsel in connection with the offering in an amount not to exceed \$75,000, the fees and expenses related to the

use of book building, prospectus tracking and compliance software for the offering in the amount of \$29,500, up to \$15,000 for background checks of our officers and directors, and out-of-pocket fees and expenses of the underwriter for marketing and roadshows for the offering not to exceed \$20,000.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount and non-accountable expense allowance, will be approximately \$138,000.

Underwriter's Warrants

We have agreed to issue to the underwriter warrants to purchase up to an aggregate of 769,231 shares of our common stock (5% of the shares of common stock included in the Class A Units and the shares of common stock underlying the shares of Series B Preferred included in the Class B Units sold in this offering, but excluding any shares of common stock underlying the warrants issued in this offering and any shares of common stock sold (and any shares of common stock underlying any warrants sold) upon exercise of the underwriter's over-allotment option). The warrants will be exercisable at any time, and from time to time, in whole or in part, during the four-year period commencing one year from the date of this prospectus (the effective date of this offering). The warrants are exercisable at a per share price equal to \$_____ per share, or 125% of the public offering price per Class A Unit in the offering. The warrants are deemed underwriter compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The underwriter (or permitted assignees under Rule 5110(g)(1)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the date of this prospectus. In addition, the warrants provide for registration rights upon request, in certain cases. The demand registration right provided will expire five years from the date of this prospectus in compliance with FINRA Rule 5110(f)(2)(G)(iv). The piggyback registration right provided will expire seven years from the date of this prospectus in compliance with FINRA Rule 5110(f)(2)(G)(v). We will bear all fees and expenses attendant to registering the common stock issuable on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be proportionately adjusted in the event of a stock split, stock dividend, recapitalization, reorganization or similar event involving the company in compliance with FINRA Rule 5110(f)(2)(G)(vi).

Discretionary Accounts

The underwriter does not intend to confirm sales of the securities offered hereby to any accounts over which it has discretionary authority.

Lock-Up Agreements

We have agreed with the underwriter not to offer for sale, issue or sell, or register for offer or sale, any of our common stock or securities convertible into our common stock for a period of 180 days after the date of this prospectus, subject to certain exceptions. In addition, pursuant to certain "lock-up" agreements, all of our officers and directors and holders of 5% or more of our outstanding common stock have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic risk of ownership of, directly or indirectly, engage in any short selling of any common stock or securities convertible into or exchangeable or exercisable for any common stock, whether currently owned or subsequently acquired, without the prior written consent of the underwriter, for a period of 180 days from the date of this prospectus, in the case of our officers and directors, and for a period of 90 days from the date of this prospectus, in the case of 5% or more stockholders who are not officers or directors of the company.

Right of First Refusal

For a period of 24 months from the date of this prospectus (the effective date of this offering), the underwriter shall have a right of first refusal to act as sole investment banker, sole book-runner, and/or sole placement agent, at the underwriter's sole discretion, for each and every future public and private equity and debt offerings for the company or any successor to or any subsidiary of the company, including all equity-linked financings, on terms customary to the underwriter. The underwriter shall have the sole right to determine whether or not any other broker-dealer shall have

the right to participate in any such offering and the economic terms of any such participation. The underwriter will not have more than one opportunity to waive or terminate the right of first refusal in consideration of any payment or fee.

Indemnification

We have agreed to indemnify the underwriter against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriter may be required to make for these liabilities.

Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format may be made available on the websites maintained by the underwriter or one or more selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The underwriter may agree to allocate a number of Units to selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriter and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriter's website is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the underwriter in its capacity as underwriter, and should not be relied upon by investors.

Nasdaq Capital Market Listing. Our common stock is listed on The Nasdaq Capital Market under the symbol "AKER."

AIM Listing Our common stock is listed on the AIM under the symbol "AKR.L."

· *Stabilization.* In connection with this offering, the underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

Stabilizing transactions permit bids to purchase securities so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the securities while the offering is in progress.

· Over-allotment transactions involve sales by the underwriter of securities in excess of the number of securities that underwriter is obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriter is not greater than the number of securities that it may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. The underwriter may close out any short position by exercising its over-allotment option and/or purchasing securities in the open market.

· Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriter will consider, among other things, the price of securities available for purchase in the open market as compared with the price at which they may purchase securities through exercise of the over-allotment option. If the underwriter sells more securities than could be covered by exercise of the over-allotment option and, therefore, has a naked short position, the position can be closed out only by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that after pricing there could be downward pressure on the price of the securities in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of our securities. As a result, the price of our securities in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriter makes any representation or prediction as to the effect that the transactions described above may have on the price of our securities. These transactions may be effected on The Nasdaq Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making

In connection with this offering, the underwriter and selling group members may engage in passive market making transactions in our common stock on The Nasdaq Capital Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the securities and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

Other Relationships

The underwriter and certain of its affiliates have provided, and may from time to time in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees; however, except as disclosed in this prospectus, we have no present arrangements with the underwriter or any of its affiliates for any further services.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriter that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

European Economic Area — Belgium, Germany, Luxembourg and Netherlands

The information in this document has been prepared on the basis that all offers of common stock and warrants will be made pursuant to an exemption under the Directive 2003/71/EC (“Prospectus Directive”), as implemented in Member States of the European Economic Area (each, a “Relevant Member State”), from the requirement to produce a prospectus for offers of securities.

An offer to the public of common stock has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State: (a) to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities; (b) to any legal entity that has two or more of (i) an average of

at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements); (c) to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)I of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or (d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of common stock shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

France

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code monétaire et financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers (“AMF”). The common stock has not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the common stock has not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D. 744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d’investisseurs non-qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the common stock cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the “Prospectus Regulations”). The common stock has not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(1) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

Israel

The common stock offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (“ISA”), nor have such common stock been registered for sale in Israel. The common stock may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the common stock being offered. Any resale in Israel, directly or indirectly, to the public of the common stock offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance

with the Israeli securities laws and regulations.

Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Società la Borsa, “CONSOB”) pursuant to the Italian securities legislation and, accordingly, no offering material relating to the common stock may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 (“Decree No. 58”), other than: to Italian qualified investors, as defined in Article 100 of Decree no. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 (“Regulation no. 11971”) as amended

(“Qualified Investors”); and in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the common stock or distribution of any offer document relating to the common stock in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and
- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such common stock being declared null and void and in the liability of the entity transferring the common stock for any damages suffered by the investors.

Japan

The common stock has not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the “FIEL”) pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional

Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the common stock may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires common stock may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of common stock is conditional upon the execution of an agreement to that effect.

Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The common stock has not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the common stock has not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of common stock in Portugal are limited to persons who are “qualified investors” (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the common stock be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are “qualified investors” (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the

information contained in it to any other person.

Switzerland

The common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the common stock has been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common stock will not be supervised by, the Swiss Financial Market Supervisory Authority (“FINMA”).

This document is personal to the recipient only and not for general circulation in Switzerland.

United Arab Emirates

Neither this document nor the common stock has been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor have we received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the common stock within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the common stock, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by us.

No offer or invitation to subscribe for common stock is valid or permitted in the Dubai International Financial Centre.

United Kingdom

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) has been published or is intended to be published in respect of the common stock. This document is issued on a confidential basis to “qualified investors” (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the common stock may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the common stock has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to the Company.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (“FPO”), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together “relevant persons”). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal, that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable

securities laws. Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor. Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriter are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

Lucosky Brookman LLP will render a legal opinion as to the validity of the securities registered hereby. Certain legal matters in connection with this offering will be passed upon for the underwriter by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

EXPERTS

Our financial statements as of and for the years ended December 31, 2016 and 2015 included in this prospectus have been audited by MorisonCogen LLP independent certified public accountants, to the extent and for the periods set forth in their report appearing elsewhere herein, and are included in reliance on such report given upon the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock, warrants to purchase common stock, and Series B Preferred convertible into shares of our common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information in the registration statement and the exhibits of the registration statement. For further information with respect to us and the securities being offered under this prospectus, we refer you to the registration statement, including the exhibits and schedules thereto.

You may read and copy the registration statement of which this prospectus is a part at the SEC's Public Reference Room, which is located at 100 F Street, N.E., Washington, D.C. 20549. You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's Public Reference Room. In addition, the SEC maintains an Internet web site, which is located at www.sec.gov, which contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet web site. We are subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. The internet address of the Company is <http://www.akersbiosciences.com>. Information contained on our website is not a part of, and is not incorporated into, this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

INCORPORATION OF INFORMATION BY REFERENCE

The SEC's rules allow us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus, and subsequent information that we file with the SEC will automatically update and supersede that information. Any statement contained in a previously filed document incorporated by reference will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus modifies or replaces that statement.

We incorporate by reference our documents listed below and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, which we refer to as the "Exchange Act" in this prospectus, between the date of this prospectus and the termination of the offering of the securities described in this prospectus. We are not, however, incorporating by reference any documents or portions thereof, whether specifically listed below or filed in the future, that are not deemed "filed" with the SEC, including any information furnished pursuant to Items 2.02 or 7.01 of Form 8-K or related exhibits furnished pursuant to Item 9.01 of Form 8-K.

This prospectus and any accompanying prospectus supplement incorporate by reference the documents set forth below that have previously been filed with the SEC:

- Our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on April 11, 2017 and Amendment No.1 to the Form 10-K filed with the SEC on April 18, 2017;
- Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed with the SEC on May 15, 2017;
- Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, filed with the SEC on August 14, 2017;
- Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed with the SEC on November 14, 2017;
- Our definitive proxy statement on Schedule 14A, filed with the SEC on July 24, 2017;
- Our Current Reports on Form 8-K filed with the SEC on January 10, 2017 January 13, 2017, April 5, 2017, August 11, 2017, October 13, 2017, October 19, 2017 and December 1, 2017; and
- The description of our common stock contained in our Registration Statement on Form 8-A (Registration No. 001-36268), filed with the SEC on January 17, 2014, under Section 12(b) of the Exchange Act, including any amendment or report filed with the SEC for the purpose of updating the description.

All reports and other documents we subsequently file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering, including all such documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement, but excluding any information furnished to, rather than filed with, the SEC, will also be incorporated by reference into this prospectus and deemed to be part of this prospectus from the date of the filing of such reports and documents.

You may request a free copy of any of the documents incorporated by reference in this prospectus (other than exhibits, unless they are specifically incorporated by reference in the documents) by writing or telephoning us at the following address:

Akers Biosciences, Inc.

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

201 Grove Road

Thorofare, New Jersey 08086

(856) 848-8698

Exhibits to the filings will not be sent, however, unless those exhibits have specifically been incorporated by reference in this prospectus and any accompanying prospectus supplement.

100

INDEX TO FINANCIAL STATEMENTS

September 30, 2017

(unaudited)

	Page
Financial Statements	
Condensed Consolidated Balance Sheets	F-2
Condensed Consolidated Statements of Operations	F-3
Condensed Consolidated Statements of Stockholders' Equity	F-4
Condensed Consolidated Statements of Cash Flows	F-5
Notes to Financial Statements	F-6
December 31, 2016 and December 31, 2015	
(Audited)	

	Page
Financial Statements	
Report of Independent Registered Public Accounting Firm	F-29
Consolidated Balance Sheets	F-30
Consolidated Statements of Operations	F-31
Consolidated Statements of Stockholders' Equity	F-32
Consolidated Statements of Cash Flows	F-33
Notes to Financial Statements	F-34
F-1	

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

September 30, 2017 and December 31, 2016

	2017 (unaudited)	2016 (audited)
ASSETS		
Current Assets		
Cash	\$ 135,133	\$ 72,700
Marketable Securities	10,178	50,001
Trade Receivables, net	1,125,097	601,271
Trade Receivables – Related Parties, net	125,001	31,892
Deposits and other receivables	21,748	23,782
Inventories, net	2,085,867	2,036,521
Prepaid expenses	99,479	168,277
Prepaid expenses – Related Parties	380,789	202,500
Total Current Assets	3,983,292	3,186,944
Non-Current Assets		
Prepaid expenses – Related Party	53,456	270,183
Property, Plant and Equipment, net	242,048	259,392
Intangible Assets, net	1,173,444	1,301,775
Other Assets	76,093	66,813
Total Non-Current Assets	1,545,041	1,898,163
Total Assets	\$ 5,528,333	\$ 5,085,107
LIABILITIES		
Current Liabilities		
Trade and Other Payables	\$ 1,549,047	\$ 1,463,363
Trade and Other Payables – Related Parties	20,245	234,067
Deferred Revenue	12,500	
Total Current Liabilities	1,581,792	1,697,430
Total Liabilities	1,581,792	1,697,430
STOCKHOLDERS' EQUITY		
Convertible Preferred Stock, No par value, 50,000,000 shares authorized, no shares issued and outstanding as of September 30, 2017 and December 31, 2016	—	—
Common Stock, No par value, 500,000,000 shares authorized, 8,901,245 and 5,452,545 issued and outstanding as of September 30, 2017 and December 31, 2016	104,628,437	100,891,786
Deferred Compensation	(8,788)	(24,572)
Accumulated Deficit	(100,673,108)	(97,479,537)
Accumulated Other Comprehensive Income	—	—
Total Stockholders' Equity	3,946,541	3,387,677

Total Liabilities and Stockholders' Equity	\$ 5,528,333	\$ 5,085,107
--	--------------	--------------

See accompanying notes to these condensed consolidated financial statements.

F-2

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Revenues:				
Product Revenue	\$ 638,331	\$ 613,198	\$ 2,378,811	\$ 2,307,328
Product Revenue – Related parties	—	—	124,631	380
License & Service Revenue	37,500	—	37,500	—
Total Revenues	675,831	613,198	2,540,942	2,307,708
Cost of Sales:				
Product Cost of Sales	(323,527)	(236,700)	(846,487)	(713,576)
Gross Income	352,304	376,498	1,694,455	1,594,132
Administrative Expenses	819,565	558,293	2,440,023	2,298,099
Sales and Marketing Expenses	342,763	408,248	1,254,308	1,647,003
Sales and Marketing Expenses – Related Party	34,328	117,949	128,108	117,949
Research and Development Expenses	290,447	247,578	929,730	932,858
Research and Development Expenses – Related Party	—	—	22,994	—
(Reversal of Allowance for) Bad Debt Expenses-Related parties	—	(1,299,609)	—	(1,299,609)
Amortization of Non-Current Assets	42,777	42,777	128,331	128,331
(Loss)/Income from Operations	(1,177,576)	301,262	(3,209,039)	(2,230,499)
Other (Income)/Expenses				
Foreign Currency Transaction (Gain)/Loss	3,195	(3,629)	(6,172)	1,189
Interest and Dividend Income	(3,127)	(5,264)	(9,296)	(23,981)
Other Income	—	—	—	—
Total Other (Income)/Expense	68	(8,893)	(15,468)	(22,792)
(Loss)/Income Before Income Taxes	(1,177,644)	310,155	(3,193,571)	(2,207,707)
Income Tax Benefit	—	—	—	—
Net (Loss)/Income Attributable to Common Stockholders	(1,177,644)	310,155	(3,193,571)	(2,207,707)
Other Comprehensive Income/(Loss)				
Net Unrealized Gain/(Loss) on Marketable Securities	(1,009)	(2,837)	—	3,691
Total Other Comprehensive Income/(Loss)	(1,009)	(2,837)	—	3,691

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

Comprehensive (Loss)/Income	\$ (1,178,653)	\$ 307,318	\$ (3,193,571)	\$ (2,204,016)
Basic income/(loss) per common share	\$ (0.13)	\$ 0.06	\$ (0.39)	\$ (0.41)
Diluted income/(loss) per common share	\$ (0.13)	\$ 0.06	\$ (0.39)	\$ (0.41)
Weighted average basic common shares outstanding	8,892,079	5,434,212	8,268,851	5,428,859
Weighted average diluted common shares outstanding	8,892,079	5,508,545	8,268,851	5,428,859

See accompanying notes to these condensed consolidated financial statements.

F-3

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Condensed Consolidated Statement of Changes in Stockholder's Equity

For the nine months ended September 30, 2017

	Common Shares Issued and Outstanding	Common Stock	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Equity
Balance at December 31, 2016 (audited)	5,452,545	\$ 100,891,786	\$ (24,572)	\$ (97,479,537)	\$ —	\$ 3,387,677
Net loss	—	—	—	(3,193,571)	—	(3,193,571)
Public offering of common stock, net of offering costs of \$494,406	1,789,500	1,652,994	—	—	—	1,652,994
Private offering of common stock, net of offering costs of \$267,443	1,448,400	1,760,317	—	—	—	1,760,317
Exercise of warrants for common stock	200,800	301,200	—	—	—	301,200
Amortization of deferred compensation	—	—	15,784	—	—	15,784
Issuance of non-qualified stock options to key employees	—	14,502	—	—	—	14,502
Issuance of non-qualified stock options for services to non-employees	—	2,183	—	—	—	2,183
Issuance of restricted stock for services for non-employees	10,000	5,455	—	—	—	5,455
Balance at September 30, 2017 (unaudited)	8,901,245	\$ 104,628,437	\$ (8,788)	\$ (100,673,108)	\$ —	\$ 3,946,541

See accompanying notes to these condensed consolidated financial statements.

Edgar Filing: Akers Biosciences, Inc. - Form S-1/A

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
For the nine months ended September 30, 2017 and 2016
(unaudited)

	2017	2016
Cash flows from operating activities		
Net loss	\$ (3,193,571)	\$ (2,207,707)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued income on marketable securities	(148)	13,380
Depreciation and amortization	182,866	221,946
Allowance for/(reversal of) doubtful accounts	46,239	(1,153,413)
Amortization of deferred compensation	15,784	24,834
Share based compensation to employees – options	14,502	22,828
Share based compensation to non-employees – options	2,183	23,676
Share based compensation to non-employees – restricted stock	5,455	—
Changes in assets and liabilities:		
Increase in trade receivables	(570,065)	(275,541)
Increase in trade receivables – related parties	(93,109)	—
Decrease in deposits and other receivables	2,034	65,855
Increase in inventories	(49,346)	(60,862)
Decrease in prepaid expenses	68,797	91,706
Decrease in prepaid expenses – related parties	38,438	58,974
Increase in other assets	(9,280)	—
Increase/(decrease) in trade and other payables	85,685	(418,998)
Increase/(decrease) in trade and other payables – related parties	(213,822)	59,673
Increase in deferred revenue	12,500	—
Net cash used in operating activities	(3,654,858)	(3,533,649)
Cash flows from investing activities		
Purchases of property, plant and equipment	(37,191)	(88,023)
Purchases of marketable securities	(2,709,148)	(37,360)
Proceeds from sale of marketable securities	2,749,119	3,452,833
Net cash provided by investing activities	2,780	3,327,450
Cash flows from financing activities		
Net proceeds from issuance of common stock	3,413,311	—
Net proceeds from exercise of warrants for common stock	301,200	—
Net cash provided by financing activities	3,714,511	—
Net increase/(decrease) in cash	62,433	(206,199)
Cash at beginning of period	72,700	402,059
Cash at end of period	\$ 135,133	\$ 195,860
Supplemental Schedule of Non-Cash Financing and Investing Activities		
Issuance of a restricted common stock grant to an officer	\$ —	\$ 54,725
Net unrealized gains on marketable securities	\$ —	\$ 3,691
Reclassification of note receivable to inventory	\$ —	\$ 750,000
Reclassification of note receivable to prepaid expense	\$ —	\$ 549,609

See accompanying notes to these condensed consolidated financial statements.

F-5

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 1 — Nature of Business

(a) Reporting Entity

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

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

(b) Nature of Business

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

Note 2 — Basis of Presentation and Significant Accounting Policies

(a) Basis of Presentation

The Condensed Consolidated Financial Statements of the Company are prepared in U.S. Dollars and in accordance with accounting principles generally accepted in the United States of America (US GAAP).

Certain information and note disclosures normally included in the financial statements prepared in accordance with US GAAP have been condensed. As such, the information included in these financial statements should be read in conjunction with the audited financial statements as of and for the years ended December 31, 2016 and 2015 included in the Company’s 2016 Form 10-K. In the opinion of the management, these consolidated financial statements include all adjustments, consisting of only normal recurring nature, necessary for a fair statement of the financial position of the Company as of September 30, 2017 and its results of operations and cash flows for the three and nine months ended September 30, 2017 and 2016. The results of operations for the three and nine months ended September 30, 2017 are not necessarily indicative of the results to be expected for the full fiscal year ending December 31, 2017.

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

(b) Use of Estimates and Judgments

The preparation of financial statements in conformity with US GAAP requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. Information about significant areas of estimation, uncertainty and critical judgments in applying accounting policies that have the most significant effect on the amounts recognized

in the financial statements is included in the following notes for revenue recognition, allowances for doubtful accounts, inventory write-downs, impairment of intangible assets and valuation of share based payments.

(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

F-6

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 2 — Basis of Presentation and Significant Accounting Policies (cont.)

Transaction Gains or Losses, resulting from loans and cash balances denominated in Foreign Currencies, are recorded in the consolidated statement of operations and comprehensive loss.

(d) Comprehensive Income (Loss)

The Company follows Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) 220 in reporting comprehensive income (loss). Comprehensive income is a more inclusive financial reporting methodology that includes disclosure of certain financial information that historically has not been recognized in the calculation of net income.

(e) Cash and Cash Equivalents

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

(f) Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, receivables and trade and other payables. The carrying value of cash and cash equivalents, receivables and trade and other payables approximate their fair value because of their short maturities. The fair value of marketable securities is described in Note 4.

(g) Fair Value Measurement — Marketable Securities

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

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

Level 2 Inputs to the valuation methodology include

- quoted prices for similar assets or liabilities in active markets;
- quoted prices for identical or similar assets or liabilities in inactive markets;
- inputs other than quoted prices that are observable for the asset or liability;
- inputs that are derived principally from or corroborated by observable market data by correlation or other means.

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

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

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

F-7

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 2 — Basis of Presentation and Significant Accounting Policies (cont.)

(h) Trade Receivables, Trade Receivables — Related Parties 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 September 30, 2017 and December 31, 2016, allowances for doubtful accounts for trade receivables were \$192,435 and \$1,010,196. Bad debt expenses for trade receivables were \$- and \$47,741 for the three month and nine months ended September 30, 2017 and a credit of \$1,299,609 and a credit of \$1,153,414 for the three and nine months ended September 30, 2016. The credit of \$1,153,414 comprises the reversal of an allowance for bad debts expense — related party of \$1,299,609 and an allowance for bad debts for an external party of \$146,195 included in the administrative expenses for the nine months ended September 30, 2016.

As of September 30, 2017 and December 31, 2016, the aging of trade receivables and trade receivables — related parties was as follows:

Aging Period	September 30			December 31		
	2017	%		2016	%	
Current	\$ 1,008,025	70	%	\$ 464,365	28	%
01-30 Days	41,746	3	%	43,223	3	%
31-60 Days	50,000	3	%	39,203	2	%
61-90 Days	101,093	7	%	6,150	0	%
>90 Days	241,669	17	%	1,090,418	66	%
Subtotal	1,442,533	—		1,643,359	—	
Bad Debts Allowance	(192,435)	—		(1,010,196)	—	
Total	\$ 1,250,098	—		\$ 633,163	—	
Average Days in Receivable	166			194		

The aging above represents the number of days that the account receivable balance exceeds the credit terms. Included in the current category is accounts receivable of \$550,800 and \$- as of September 30, 2017 and December 31, 2016 with payment terms extended to 180 days.

(i) Concentration of Credit Risk

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

All of the Company's cash is maintained with Fulton Bank of New Jersey, Bank of America, NA and PayPal. The funds are insured by the FDIC up to a maximum of \$250,000, but are otherwise unprotected. The Company placed \$130,053 and \$67,865 with Fulton Bank of New Jersey, \$1,040 and \$795 with Bank of America, NA and \$4,040 and

\$4,040 with PayPal as of September 30, 2017 and December 31, 2016. No losses have been incurred in these accounts.

Concentration of credit risk with respect to trade receivables exists as approximately 68% of the Company's product revenue is generated by three customers. These customers accounted for 59% of trade receivables as of September 30, 2017. To limit such risks, the Company performs ongoing credit evaluations of its customers' financial condition.

F-8

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 2 — Basis of Presentation and Significant Accounting Policies (cont.)

(j) Inventories

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

(k) Property, Plant and Equipment

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

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

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

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

	Useful Life (in years)
Plant and equipment	5-12
Furniture and fixtures	5-10
Computer equipment & software	3-5
Leasehold Improvements	Shorter of the remaining lease or estimated useful life

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

(l) Intangible Assets

(i) Patents and Trade Secrets

The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person’s breath, blood, urine and saliva. Propriety protection for the Company’s products, technology and process is important to its competitive position. As of September 30, 2017, the Company has ten patents from the United States Patent Office in effect (9,383,368; 7,896,167; 8,097,171; 8,003,061; 8,425,859; 8,871,521; 8,808,639; D691,056; D691,057 and D691,058). Other patents are in effect in Australia through the Design Registry (348,310; 348,311 and 348,312), European Union Patents 1793906, 2684025, 002216895-0001; 002216895-0002 and 002216895-0003), in Hong Kong (HK11004006) and in Japan (1,515,170; 4,885,134; 4,931,821 5,775,790, and 6023096). Patents are in the national phase of prosecution in many Patent Cooperation Treaty participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the U.S., European and Asian markets.

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

F-9

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 2 — Basis of Presentation and Significant Accounting Policies (cont.)

(ii) Patent Costs

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

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

(iii) Other Intangible Assets

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

(iv) Amortization

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

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

(m) 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.

(n) 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

F-10

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 2 — Basis of Presentation and Significant Accounting Policies (cont.)

- 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 value these investments using the cost method.

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

(o) 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 \$- as of September 30, 2017 and December 31, 2016.

The Company implemented a standard dealer cost model during the year ended December 31, 2016 which includes a provision for rebates to the distributors under limited circumstances. The Company established an accrual of \$27,073 and \$18,858, which is a reduction of revenue as of September 30, 2017 and December 31, 2016. Accounts receivable will be reduced when the rebates are applied by the customer. The Company recognized \$51,791 and \$222,469 during the three and nine months ended September 30, 2017 and \$84,128 and \$299,781 for the three and nine months ended September 30, 2016 for rebates, which is included as a reduction of product revenue in the Condensed 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.

(p) 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.

F-11

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 2 — Basis of Presentation and Significant Accounting Policies (cont.)

(q) Shipping and Handling Fees and Costs

The Company charges actual shipping plus a handling fee to customers, which amounted to \$13,679 and \$12,321 for the three months ended September 30, 2017 and 2016 and to \$47,148 and \$42,754 for the nine months ended September 30, 2017 and 2016. These fees are classified as part of product revenue in the Condensed 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 \$16,148 and \$63,719 for the three and nine months ended September 30, 2017 and to \$19,695 and \$88,427 for the three and nine months ended September 30, 2016.

(r) Research and Development Costs

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

(s) Stock-based Payments

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

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

The Company estimates the fair value of stock-based awards to non-employees on the date of grant using the Black-Scholes model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the period which services are to be received. At the end of each financial reporting period, prior to vesting or prior to completion of services, the fair value of equity based payments will be re-measured and the non-cash expense recognized during the period will be adjusted accordingly. Since the fair value of equity based payments granted to non-employees is subject to change in the future, the amount of the future expense will include fair value re-measurement until the equity based payments are fully vested or the service is completed.

(t) 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.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 2 — Basis of Presentation and Significant Accounting Policies (cont.)

The table below details the classification of the basic and diluted income/(loss per share for the three and nine months ended September 30, 2017 and 2016:

	Three months ended September 30, 2017		Nine months ended September 30, 2017	
	2016		2016	
Numerator				
Net Income/(Loss)	\$ (1,177,644)	\$ 310,155	\$ (3,193,571)	\$ (2,207,707)
Denominator				
Weighted Average Basic Common Shares Outstanding	8,892,079	5,434,212	8,268,851	5,428,859
Add the Dilutive Effect of Stock Options	—	56,000	—	—
Stock Warrants	—	—	—	—
Unvested Restricted Shares	—	18,333	—	—
Weighted Average Basic and Diluted Common Shares Outstanding	8,892,079	5,508,545	8,268,851	5,428,859
Net Income/(Loss) per Share				
Basic	\$ (0.13)	\$ 0.06	\$ (0.39)	\$ (0.41)
Diluted	\$ (0.13)	\$ 0.06	\$ (0.39)	\$ (0.41)
(u) Reclassifications				

Certain prior year amounts have been reclassified to conform to the current year's presentation.

(v) Recently Adopted Accounting Pronouncements

As of September 30, 2017 and for the period then ended, there were no recently adopted accounting pronouncements that had a material effect on the Company's financial statements.

(w) Recently Issued Accounting Pronouncements Not Yet Adopted

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

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

financial statements. The Company expects to use the modified retrospective adoption method.

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

F-13

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 2 — Basis of Presentation and Significant Accounting Policies (cont.)

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

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

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

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

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

In May 2017, the FASB issued ASU 2017-09, Compensation — Stock Compensation (Topic 718), Scope of Modification Accounting. The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for

F-14

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 2 — Basis of Presentation and Significant Accounting Policies (cont.)

(1) public business entities for reporting periods for which financial statements have not yet been issued and (2) all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments in this Update should be applied prospectively to an award modified on or after the adoption date.

Note 3 — Management Plan

Historically, the Company has relied upon public offerings and private placements of common stock to raise operating capital. During the ten months ending October 31, 2017, the Company raised approximately \$1.7 million in a public offering, \$1.8 million from a private placement of common stock and an additional \$982,000 from the execution of warrants (Notes 11 and 20). As of November 10, 2017, the Company had cash and marketable securities of approximately \$432,000 and working capital of approximately \$2.6 million.

The 2017-19 Strategic Business Plan (“Strat Plan”) was presented to and approved by the Board of Directors on December 12, 2016. The plan outlines the Company’s business objectives for the next three years and sets measurable targets for new product releases, sales and marketing programs to increase market penetration for the Company’s products and operational expense management. The Company has prepared the initial Go-To-Market Plan (“GTM Plan”) for 2018 and will present the completed GTM Plan to the Board of Directors on December 19, 2017 for final approval.

Implementation of the Strat Plan began in January 2017 and although management remains committed to the overall strategy, the Company will not meet the Strat Plan’s revenue targets for 2017. The Company had anticipated the market introduction of its over-the-counter Tri-Cholesterol test in the first half and its PIFA Chlamydia Rapid Assay product during the third quarter of 2017, both of which were delayed.

The Company encountered significant delays from raw material vendors for critical components of the Tri-Cholesterol test which resulted in the product’s first commercial production to be postponed into the third quarter. The first shipments of the product began at the end of September 2017 and feedback from the customer has been favorable. Three additional orders totaling \$110,000 have been received.

The PIFA Chlamydia Rapid Assay test’s introduction has been delayed into 2018 due to unanticipated requests for additional clinical data from the United States Food & Drug Administration (“FDA”). The FDA’s approval of the 510(k) application is required to begin production and commercialization of the product.

The Company continues to encounter periods of cash shortages and is proactively working to minimize their impact on operations. The Company expects to achieve a cash-flow positive position during the next twelve months based upon the revised revenue targets as outlined in the Strat Plan and the 2018 GTM Plan. The Company is actively pursuing financing options with various financial institution, investment banks and other sources to enhance The Company’s liquidity while minimizing dilution to the shareholders.

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

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

costs.

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

F-15

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 3 — Management Plan (cont.)

During the nine months ended September 30, 2017, the Company's average weekly operating cash requirement increased to \$93,714 (2016: \$88,341). The increase resulted from payments to vendors and sub-contractors included in the December 31, 2016 accounts payable balance, a significant royalty payment that had been deferred in 2016 as part of a legal settlement, professional service fees and other payments for contractual obligations. Many of these items are one-time events and the Company anticipates the cash requirements to revert to the \$85,000 to \$90,000 per week by the end of 2017.

Substantial doubt exists about the Company's ability to continue as a going concern within one year after the financial statements are issued. The Company has identified three conditions or events that support this determination:

The Company's current working capital position.

The Company is working diligently to raise additional working capital either through various financial institutions, investment banks or other sources while minimizing dilution to the shareholders.

Executive management continues to monitor expenses and directives are in place to restrict non-essential expenses until the working capital situation is resolved.

Negotiations are underway with multiple customers for the Company's products and are anticipated to be completed during the three months ending March 31, 2018. All parties are confident that a solution can be achieved but a significant delay will impact revenue projections.

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

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

Note 4 — Fair Value Measurement — Marketable Securities

Following is a description of the valuation methodologies used for assets measured at fair value as of September 30, 2017 and December 31, 2016.

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

	As of September 30, 2017				
	Cost	Accrued Income	Unrealized Gains	Unrealized Losses	Fair Value
Level 2:					
Money market funds	\$ 10,000	\$ 1	\$ —	\$ —	\$ 10,001
Municipal securities	—	177	—	—	177
Total Level 2:	10,000	178	—	—	10,178
Total:	\$ 10,000	\$ 178	\$ —	\$ —	\$ 10,178

F-16

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 4 — Fair Value Measurement — Marketable Securities (cont.)

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

Marketable securities include U.S. agency securities, corporate securities, and municipal 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 relating to the available for sale investment securities were recorded in the Condensed Consolidated Statement of Changes in Stockholders' Equity as comprehensive income. These amounts were an unrealized loss of \$1,009 and \$- (net of effect of income tax expense of \$-) for the three and nine months ended September 30, 2017 and an unrealized loss of \$2,837 and an unrealized gain of \$3,691 for the three and nine months ended September 30, 2016.

Proceeds from the sale of marketable securities in the three and nine months ended September 30, 2017 were \$1,003,565 and \$2,749,119 and were \$950,514 and \$3,452,833 for the three and nine months ended September 30, 2016. Gross gains, resulting from these sales, amounted to \$1,719 and \$1,269 for the three months ended September 30, 2017 and 2016 and \$3,375 and \$3,421 for the nine months ended September 30, 2017 and 2016.

Note 5 — Trade Receivables — Related Parties

Trade receivables — related parties are made up of amounts due from related parties of Hainan Savy Akers Biosciences Ltd ("Hainan"), a joint venture between Akers, Thomas Knox, Akers' former Board Chairman, and Hainan Savy Investment Management Ltd, located in the People's Republic of China. The Company holds a 19.9% position in the joint venture. The amount due is non-interest bearing, unsecured and generally has a term of 30-90 days (Note 14). Credit terms of 180 days were extended to Hainan for a bulk purchase of BreathScan Breath Alcohol detectors during June 2017 while Hainan expands their market presence in the People's Republic of China.

Note 6 — Inventories

Inventories consists of the following categories:

	September 30, 2017	December 31, 2016
Raw Materials	\$ 473,443	\$ 440,316
Sub-Assemblies	848,078	907,989
Finished Goods	807,973	749,488
Reserve for Obsolescence	(43,627)	(61,272)
	\$ 2,085,867	\$ 2,036,521

Obsolete inventory charged to cost of goods during the three and nine months ended September 30, 2017 totaled \$2,664 and \$3,158 and \$24,965 and \$27,933 was charged for the three and nine months ended September 30, 2016.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 7 — Property, Plant and Equipment

Property, plant and equipment consists of the following:

	September 30, 2017	December 31, 2016
Computer Equipment	\$ 114,771	\$ 114,771
Computer Software	40,681	40,681
Office Equipment	39,959	39,959
Furniture & Fixtures	38,356	29,939
Machinery & Equipment	1,138,134	1,126,134
Molds & Dies	851,254	834,480
Leasehold Improvements	222,593	222,593
	2,445,748	2,408,557
Less		
Accumulated Depreciation	2,203,700	2,149,165
	\$ 242,048	\$ 259,392

Depreciation expenses totaled \$18,709 and \$54,536 for the three and nine months ended September 30, 2017 and \$65,264 and \$93,615 for the three and nine months ended September 30, 2016.

Note 8 — Intangible Assets

Intangible assets as of September 30, 2017 and December 31, 2016 and the movements for the periods then ended are as follows:

	Patents & Trademarks	Distributor & Customer Relationships	Totals
Cost or Deemed Cost			
At December 31, 2016	\$ 2,626,996	\$ 1,270,639	\$ 3,897,635
Additions	—	—	—
Disposals	—	—	—
At September 30, 2017	\$ 2,626,996	\$ 1,270,639	\$ 3,897,635
Accumulated Amortization			
At December 31, 2016	\$ 1,325,221	\$ 1,270,639	\$ 2,595,860
Amortization Charge	128,331	—	128,331
Disposals	—	—	—
At September 30, 2017	\$ 1,453,552	\$ 1,270,639	\$ 2,724,191
Net Book Value			
At December 31, 2016	\$ 1,301,775	\$ —	\$ 1,301,775
At September 30, 2017	\$ 1,173,444	\$ —	\$ 1,173,444

Amortization expense totaled \$42,777 and \$128,331 during the three and nine months ended September 30, 2017 and \$42,777 and \$128,331 for the three and nine months ended September 30, 2016.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 8 — Intangible Assets(cont.)

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

Period	Amount
2017	\$ 171,108
2018	\$ 171,108
2019	\$ 171,108
2020	\$ 171,108
2021	\$ 171,108

Note 9 — Trade and Other Payables

Trade and other payables consists of the following:

	September 30, 2017	December 31, 2016
Trade Payables	\$ 1,044,056	\$ 923,311
Accrued Expenses	445,241	480,302
Deferred Compensation	59,750	59,750
	\$ 1,549,047	\$ 1,463,363

Trade and other payables — related party are as follows:

	September 30, 2017	December 31, 2017
Trade Payables	\$ 20,245	\$ 182,001
Accrued Expenses	—	52,066
	\$ 20,245	\$ 234,067

As of September 30, 2017, the Company owed ChubeWorkx Guernsey Limited, a major shareholder, royalties of \$17,164 (Note 14) which was paid on October 24, 2017.

As of September 30, 2017, the Company owed Hainan \$670. Senior management at Hainan are actively involved in Shenzhen Savy-Akers Biosciences (“Shenzhen”) which is therefore being included as a related party. The Company owed Shenzhen \$2,411 as of September 30, 2017.

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

Note 10 — Share-based Payments

On January 23, 2014, upon effectiveness of the registration statement filed with the SEC, the Company adopted the 2013 Stock Incentive Plan (the “Plan”) which will provide for the issuance of up to 400,000 shares. The purpose of the Plan is to provide additional incentive to those officers, employees, consultants and non-employee directors of the Company and its parents, subsidiaries and affiliates whose contributions are essential to the growth and success of the Company’s business.

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

On September 30, 2016, the Board of Directors increased the number of authorized shares of common stock subject to the Amended Plan to 830,000 shares. As of September 30, 2017, under the 2013 Amended Plan, grants of restricted stock and options to purchase 268,166 shares of common stock have been issued and are unvested or unexercised and 7,292 shares of common stock remain available for grants.

F-19

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 10 — Share-based Payments (cont.)

On August 7, 2017, the Shareholders approved and the Company adopted the 2017 Equity Incentive Plan (the “Plan”) which will provide for the issuance of up to 1,350,000 shares. The purpose of the Plan is to provide additional incentive to those officers, employees, consultants and non-employee directors of the Company and its parents, subsidiaries and affiliates whose contributions are essential to the growth and success of the Company’s business.

The Plan may be administered by the board or a board-appointed committee. Eligible recipients of option awards are employees, officers, consultants or directors (including non-employee directors) of the Company or of any parent, subsidiary or affiliate of the Company. The board has the authority to grant to any eligible recipient any options, restricted stock or other awards valued in whole or in part by reference to, or otherwise based on, the Company’s common stock.

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

The Company did not issue any options or warrants under the above plan during the three and nine months ended September 30, 2017.

The following table summarizes the option activities for the nine months ended September 30, 2017:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2016	259,000	\$ 4.23	3.05	\$ 20,100
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	(4,000)	3.25	3.89	—
Canceled/Expired	—	—	—	—
Balance at September 30, 2017	255,000	\$ 4.25	2.27	\$ —
Exercisable as of September 30, 2017	250,334	\$ 4.27	2.24	\$ —

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$0.81 for our common shares on September 29, 2017.

A summary of the Company’s non-vested shares as of September 30, 2017 and the changes during the period then ended are as follows:

	Shares	Weighted Average Grant Date Fair Value
Non-Vested Shares		
Non-vested at January 1, 2017	19,834	\$ 2.36
Granted	—	—
Vested	(11,168)	2.07
Forfeited	(4,000)	2.36
Non-vested at September 30, 2017	4,666	\$ 2.36

Unrecognized compensation cost related to non-vested employee stock options totaled \$9,702 as of September 30, 2017. The cost is to be recognized over a weighted average period of 0.88 years.

F-20

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 10 — Share-based Payments (cont.)

During the three and nine months ended September 30, 2017, the Company incurred stock option expenses totaling \$4,373 and \$16,685 and totaled \$38,263 and \$46,504 for the three and nine months ended September 30, 2016.

During the nine months ended September 30, 2017, the Company issued 894,750 warrants in conjunction with the January 2017 public offering and an additional 796,620 warrants with the March 2017 private placement. All warrants carry a five-year expiration term. The table below summarizes the warrant activity for the nine months ended September 30, 2017:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)
Balance at December 31, 2016	—	\$ —	—
Granted	1,691,370	1.88	—
Exercised	(200,800)	1.50	—
Forfeited	—	—	—
Canceled/Expired	—	—	—
Balance at September 30, 2017	1,490,570	\$ 1.73	4.40
Exercisable as of September 30, 2017	1,490,570	\$ 1.73	4.40

Note 11 — Equity

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

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

On June 8, 2016, the Company issued 27,500 restricted common shares to an officer in connection with his employment agreement. These shares vest 1/3 immediately on the date of the grant and the remaining 2/3 vests equally on March 1, 2017 and March 1, 2018. The fair value of these shares was \$54,725 and was based on the share price on the date of the grant. \$5,374 and \$15,784 was recorded during the three months and nine ended September 30, 2017 as administrative expense on the Condensed Consolidated Statement of Operations and Comprehensive Loss and the remaining \$8,788 is reported as deferred compensation, a contra equity account, on the Condensed Consolidated Balance Sheet as of September 30, 2017.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 11 — Equity (cont.)

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

	Shares	\$	\$
Common Shares			
Base Offering	1,667,000	2,000,400	
Over-Allotment	122,500	147,000	
Gross Proceeds			2,147,400
Underwriter/Gunnar Expenses			
Discount		150,318	
Legal Fees		60,000	
Roadshow		1,783	
Miscellaneous		34,005	
Total			246,106
Akers Biosciences Expenses			
Legal & Accounting		197,813	
Registration/Regulatory		50,487	
Total			248,300
Net Proceeds			1,652,994

In addition to the common shares issued, the Company also issued 833,500 warrants with an exercise price of \$1.50 per common share in support of the base offering and 61,250 warrants with an exercise price of \$1.20 per common share. All of the warrants issued have a five-year term.

During the three months ended March 31, 2017, warrant holders from the January 13, 2017 public offering executed 163,300 warrants with an exercise price of \$1.50 per common share, raising net proceeds of \$244,950.

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

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

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 11 — Equity (cont.)

On April 11, 2017, the Company issued 10,000 restricted shares to a consultant for services to be rendered during the year ending December 31, 2017. These shares vested on the date of the grant. The fair value of these shares was \$18,000 and was based on the share price on the date of the grant. The Company recorded \$5,455 during the nine months ended September 30, 2017 as sales and marketing expenses on the Condensed Consolidated Statement of Operations and Comprehensive Loss.

During the three months ended June 30, 2017, warrant holders from the January 13, 2017 public offering executed 37,500 warrants with an exercise price of \$1.50 per common share, raising net proceeds of \$56,250.

Note 12 — Earnings/(Loss) per share

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

Potential common shares consist of options, warrants and unvested restricted stock. Diluted net loss per common share was the same as basic net loss per common share for the three months ended September 30, 2017 since the effect of options and warrants would be anti-dilutive due to the net loss attributable to the common shareholders.

Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were as follows: incentive and award stock options — 255,000; unvested restricted shares of common stock — 9,166; warrants — 1,490,570 as of September 30, 2017.

Potential common shares consist of options, warrants and unvested restricted stock. Diluted net income per common share was the same as basic net income per common share for the three months ended September 30, 2016. Dilutive Instruments included were as follows: incentive and award stock options — 56,000; unvested restricted shares of common stock — 18,333; warrants — - as of September 30, 2016. Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were incentive and award stock options — 203,000 as of September 30, 2016.

Potential common shares consist of options, warrants and unvested restricted stock. Diluted net loss per common share was the same as basic net loss per common share for the nine months ended September 30, 2017 and 2016 since the effect of options and warrants would be anti-dilutive due to the net loss attributable to the common shareholders. Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were as follows: incentive and award stock options — 255,000 (2016: 203,000); unvested restricted shares of common stock — 9,166 (2016: 18,333); warrants — 1,490,570 (2016: -) as of September 30, 2017.

Note 13 — Income Tax Expense

There is no income tax benefit for the losses for the three ended September 30, 2017 since management has determined that the realization of the net deferred tax asset is not assured and has created a valuation allowance for the entire amount of such benefits.

There is no income tax expense for the three months ended September 30, 2016 since the income arose from the reversal of an allowance for doubtful collection of a note. This temporary difference has no tax effect for the Company due to the net operating loss carry forwards available.

There is no income tax benefit for the losses for the nine months ended September 30, 2017 and 2016 since management has determined that the realization of the net deferred tax asset is not assured and has created a valuation allowance for the entire amount of such benefits.

The Company's policy is to record interest and penalties associated with unrecognized tax benefits as additional income taxes in the statement of operations. As of January 1, 2017, the Company had no unrecognized tax benefits, or any tax related interest or penalties. There were no changes in the Company's unrecognized tax benefits during the three and nine months ended September 30, 2017 related to unrecognized tax benefits. With few exceptions, the U.S. and state income tax returns filed for the tax years ended on December 31, 2013 and thereafter are subject to examination by the relevant taxing authorities.

F-23

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 14 — Related Party Transactions

On June 19, 2012, the Company entered into a 3-year exclusive License & Supply Agreement with ChubeWorkx Guernsey Limited (as successor to SONO International Limited) (“ChubeWorkx”) for the purchase and distribution of Akers’ proprietary breathalyzers outside North America. ChubeWorkx paid a licensing fee of \$1,000,000 which was recognized over the term of the agreement through September 30, 2015.

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

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

Under the terms of the Settlement Agreement, the Company will recover the full outstanding principal amount in the current fiscal year in the form of \$750,000 of BreathScan® Alcohol Detector inventory — which the Company intends to subsequently sell — and the balance of \$549,609 as prepaid royalty. Akers’ established an allowance for this doubtful note in the Company’s financial statements for the year ended December 31, 2015. As a result of the Settlement Agreement, the Company reversed the allowance for doubtful note in the amount of \$1,299,609 which was included in the Condensed Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2016.

In addition to addressing the promissory note described above, the Settlement Agreement also allows the Company to market and sell all of the Company’s breath technology tests worldwide, unencumbered by any past/future claims by ChubeWorkx under the Licensing Agreement (entered into with ChubeWorkx in 2012 and subsequently amended in 2013). Under the terms of the Settlement Agreement, ChubeWorkx no longer holds any rights pertaining to Akers’ BreathScan® technology, which serves as the basis for a number of commercialized products including BreathScan® Alcohol Detector and BreathScan OxiChek™; and a number of products in development.

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 \$34,328 and \$128,108 for the three and nine months ended September 30, 2017 and \$117,949 for the three and nine months ended September 30, 2016 which are included in sales and marketing expenses — related party on the Condensed Consolidated Statement of Operations and Comprehensive Loss.

Other terms of the Settlement include: 1) the pledge as security of all earned but unpaid royalties by the Company to ChubeWorkx all Company assets, worthy to satisfy its obligations, including all inventory and receivables, with the exception of (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and

(iv) all equipment required to perform said manufacturing processes and other equipment; 2) the pledge as security of the settlement sum which remains unpaid by the Company to ChubeWorkx all Company (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other

F-24

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 14 — Related Party Transactions (cont.)

equipment; and 3) the grant of voting proxy by ChubeWorkx to the Company which allows the Company to vote ChubeWorkx's shares for corporate formalities under certain conditions.

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

Prior to the acquisition of the BreathScan® Alcohol Detector inventory pursuant to the Settlement Agreement from ChubeWorkx, the Company had pre-existing inventory totaling \$467,646 for the detectors purchased. During the three and nine months ended September 30, 2017, the Company sold 1.8% and 6.2% of the cumulative unit inventory and recognized revenue totaling \$39,100 and \$139,900 and \$- for the three and nine months ended September 30, 2016.

The Company began purchasing manufacturing molds, plastic components and the assembled BreathScan Lync™ device through Hainan and its related party during the year ended December 31, 2016 (Note 9). The Company purchased a total of \$- during the three months ended September 30, 2017 and 2016 and \$16,774 and \$2,287 for the nine months ended September 30, 2017 and 2016 from this related party. As of September 30, 2017, the Company had a prepayment credit of \$25,989 with Shenzhen and owed two other related companies of Hainan \$3,081 which is included in trade and other payables — related parties on the Condensed Consolidated Balance Sheet.

Trade receivables — related parties as of September 30, 2017 and December 31, 2016 were \$125,001 and \$31,892. The amounts due are non-interest bearing, unsecured and generally have a term of 30-180 days (Note 5).

Product revenue — related parties for the three months ended September 30, 2017 and 2016 were \$- and total \$124,631 and \$380 for the nine months then ended. The revenue was the result of sales to Hainan and its related parties.

Note 15 — 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 three months ended September 30, 2017 and 2016 totaled \$40,440 and \$40,290, respectively. Rent expenses for the Thorofare Lease, including related CAM charges totaled \$121,220 and \$120,870 for the nine months ended September 30, 2017 and 2016.

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 \$6,506 and \$6,506 for the three and nine months ended September 30, 2017. The Company posted a security deposit of \$4,330 which is included in other assets on the Condensed 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.

F-25

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 15 — Commitments (cont.)

Rent expenses for the Pitman Lease totaled \$6,608 for the three and nine months ended September 30, 2017. A security deposit of \$4,950 is included in other assets on the Condensed Consolidated Balance Sheet.

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

The schedule of lease commitments is as follows:

	Thorofare Lease	Ramsey Lease	Pitman Lease	Equipment Lease	Total
	\$	\$	\$	\$	\$
Next 12 Months	132,000	25,980	39,650	6,156	203,786
Next 13-24 Months	132,000	17,320	39,650	6,156	195,126
Next 25-36 Months	33,000	—	9,913	513	43,426

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

The Company has agreed to provide PIFA Heparin/PF4 devices, valued at approximately \$90,000, at no charge to NovoTek for their use and are to be shipped upon their request. To date, the products purchased by NovoTek have been used for regulatory submissions, clinical studies or trials and as product samples to generate interest in the product in the Peoples Republic of China.

As of September 30, 2017, the Company had not incurred any expense related to the program.

Note 16 — Major Customers

For the three months ended September 30, 2017, two customers generated 10% or more of the Company's revenue. Sales to these customers accounted for 65% of the Company's revenue. As of September 30, 2017, the amount due from these customers was \$345,201. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

For the nine months ended September 30, 2017, three customers generated 10% or more of the Company's revenue. Sales to these customers accounted for 67% of the Company's revenue. As of September 30, 2017, the amount due from these customers was \$854,103 of which \$500,000 has an extended term of 180 days. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

For the three months ended September 30, 2016, two customers each generated more than 10% of the Company's product revenue. In aggregate, sales to these customers accounted for 74% of the Company's product revenue. As of September 30, 2016, the amount due from these two customers was \$669,437.

For the nine months ended September 30, 2016, three customers each generated more than 10% of the Company's product revenue. In aggregate, sales to these customers accounted for 80% of the Company's product revenue. As of September 30, 2016, the amount due from these three customers was \$675,838. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

Note 17 — Major Suppliers

For the three months ended September 30, 2017, two suppliers accounted for 10% or more of the Company's purchases. These suppliers accounted for 31% of the Company's total purchases. As of September 30, 2017, the amount due to these suppliers was \$30,702.

F-26

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 17 — Major Suppliers (cont.)

For the nine months ended September 30, 2017, one supplier accounted for 10% or more of the Company's purchases. This supplier accounted for 11% of the Company's total purchases. As of September 30, 2017, the amount due to this supplier was \$-.

For the three months ended September 30, 2016, one supplier accounted for more than 10% of the Company's purchases. The supplier accounted for 86% of the Company's total purchases. As of September 30, 2016, the amount due to the supplier was \$6,908.

For the nine months ended September 30, 2016, one supplier accounted for more than 10% of the Company's purchases. The supplier accounted for 61% of the Company's total purchases. As of September 30, 2016, the amount due to the supplier was \$6,908.

Note 18 — Contingencies

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

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

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

Pulse subsequently filed an Amended Complaint, in which Pulse seeks not less than \$500,000 in damages and, among other items, an injunction prohibiting the Company from manufacture, use and sale of the OxiChek product. The Company answered the Amended Complaint on May 30, 2017. Discovery has commenced and is scheduled to conclude on January 22, 2018. The Court has set the trial date for July 17, 2018.

The Company intends to establish a rigorous defense of all claims. As the case has not progressed beyond initial motion practice and early discovery, the Company is unable to assess the potential outcome, no accrual for losses was made as of September 30, 2017. All legal fees were expensed as and when incurred.

Note 19 — Segment Information

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements

Note 19 — Segment Information (cont.)

The total revenue by different product lines was as follows:

Product Line	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
MicroParticle Catalyzed Biosensor (“MPC”)	\$ 104,094	\$ 85,337	\$ 381,569	\$ 195,040
Particle ImmunoFiltration Assay (“PIFA”)	490,058	514,840	1,477,726	2,029,095
Rapid Enzymatic Assay (“REA”)	27,500	—	27,500	—
Other	16,679	13,021	616,647	83,573
Product Revenue Total	\$ 638,331	\$ 613,198	\$ 2,503,442	\$ 2,307,708
License Fees	37,500	—	37,500	—
Total Revenue	\$ 675,831	\$ 613,198	\$ 2,540,942	\$ 2,307,708

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

Geographic Region	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
United States	\$ 626,077	\$ 603,006	\$ 1,755,695	\$ 1,721,967
People’s Republic of China	—	383	627,132	506,781
Rest of World	49,754	9,809	158,115	78,960
Total Revenue	\$ 675,831	\$ 613,198	\$ 2,540,942	\$ 2,307,708

The Company had long-lived assets totaling \$55,504 and \$61,081 located in the People’s Republic of China and \$1,359,987 and \$1,500,086 located in the United States as of September 30, 2017 and December 31, 2016, respectively.

Note 20 — Subsequent Events

On October 12, 2017, the Company entered into Warrant Exercise Agreements with the existing holders from the March 2017 private placement to exercise their current warrants at \$1.00 per share and receive a new warrant which would be convertible into the same number of common shares as the original warrant. The new warrants have an exercise price of \$1.26, expire five years from the date of issuance and are not exercisable for six months after issuance. The incremental fair value resulting from the modification of these warrants will be accounted for as a deemed dividend in the statement of operations.

Pursuant to the Warrant Exercise Agreements, as of the date of the filing of this report, 724,200 warrants were exercised for the purchase of 724,200 shares of the Company’s common stock raising net proceeds of \$680,748.

On October 17, 2017, the Board of Directors issued 295,107 restricted shares of common stock to key employees and officers of the Company as part of the 2017 Equity Incentive Plan. The restricted stock vested immediately and were issued at the closing price of \$0.88 per share. Expenses related to the grants totaled \$259,694 and will be reported on the Consolidated Statement of Operations for the year ending December 31, 2017 as follows:

Expense Category	2017	2016
General & Administrative	\$ 163,924	—

Sales & Marketing	95,770	—
	\$ 259,694	\$ —
F-28		

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Akers Biosciences, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Akers Biosciences, Inc. and Subsidiaries (the “Company”) as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, changes in stockholders’ equity, and cash flows for the years then ended. Akers Biosciences, Inc. and Subsidiaries’ management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Akers Biosciences, Inc. and Subsidiaries as of December 31, 2016 and 2015, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ Morison Cogen LLP

Blue Bell, Pennsylvania

April 11, 2017

F-29

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

December 31, 2016 and 2015

	2016	2015
ASSETS		
Current Assets		
Cash	\$ 72,700	\$ 402,059
Marketable Securities	50,001	4,025,104
Trade Receivables, net	601,271	609,195
Trade Receivables – Related Party, net	31,892	31,512
Deposits and other receivables	23,782	95,577
Inventories, net	2,036,521	1,131,654
Prepaid expenses	168,277	185,967
Prepaid expenses – Related Party	202,500	—
Total Current Assets	3,186,944	6,481,068
Non-Current Assets		
Prepaid expenses – Related Party	270,183	—
Property, Plant and Equipment, net	259,392	251,145
Intangible Assets, net	1,301,775	1,472,883
Other Assets	66,813	66,813
Total Non-Current Assets	1,898,163	1,790,841
Total Assets	\$ 5,085,107	\$ 8,271,909
LIABILITIES		
Current Liabilities		
Trade and Other Payables	\$ 1,463,363	\$ 1,668,731
Trade and Other Payables – Related Party	234,067	—
Total Current Liabilities	1,697,430	1,668,731
Total Liabilities	1,697,430	1,668,731
STOCKHOLDERS' EQUITY		
Convertible Preferred Stock, No par value, 50,000,000 shares authorized, no shares issued and outstanding as of December 31, 2016 and 2015	—	—
Common Stock, No par value, 500,000,000 shares authorized, 5,452,545 and 5,425,045 issued and outstanding as of December 31, 2016 and 2015	100,891,786	100,785,408
Deferred Compensation	(24,572)	—
Accumulated Deficit	(97,479,537)	(94,175,999)
Accumulated Other Comprehensive Loss	—	(6,231)
Total Stockholders' Equity	3,387,677	6,603,178
Total Liabilities and Stockholders' Equity	\$ 5,085,107	\$ 8,271,909

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

F-30

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

For the years ended December 31, 2016 and 2015

	2016	2015
Revenues:		
Product Revenue	\$ 2,956,782	\$ 1,757,982
Product Revenue – Related party	380	36,512
License Revenue	3,750	15,000
License Revenue – Related party	—	305,556
Total Revenues	2,960,912	2,115,050
Cost of Sales:		
Product Cost of Sales	(1,083,087)	(950,792)
Gross Income	1,877,825	1,164,258
Administrative Expenses	3,008,811	4,029,516
Sales and Marketing Expenses	1,983,428	2,543,286
Sales and Marketing Expenses – Related Party	153,854	—
Research and Development Expenses	1,188,868	1,406,895
(Reversal of Allowance for) Bad Debt Expenses – Related party	(1,299,609)	2,163,609
Impairment of Non-Current Assets	—	466,476
Amortization of Non-Current Assets	171,108	236,706
Loss from Operations	(3,328,635)	(9,682,230)
Other (Income)/Expenses		
Foreign Currency Transaction (Gain)/Loss	(3,398)	7,535
Interest and Dividend Income	(21,699)	(102,456)
Other Income	—	(6,052)
Total Other Income	(25,097)	(100,973)
Loss Before Income Taxes	(3,303,538)	(9,581,257)
Income Tax Benefit	—	269,344
Net Loss Attributable to Common Stockholders	(3,303,538)	(9,311,913)
Other Comprehensive Income		
Net Unrealized Gains on Marketable Securities	6,231	13,893
Total Other Comprehensive Income	6,231	13,893
Comprehensive Loss	\$ (3,297,307)	\$ (9,298,020)
Basic and diluted loss per common share	\$ (0.61)	\$ (1.81)
Weighted average basic and diluted common shares outstanding	5,430,205	5,140,920

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Consolidated Statement of Changes in Stockholder's Equity

For the years ended December 31, 2016 and 2015

	Common Shares Issued and Outstanding	Common Stock	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Equity
Balance at December 31, 2014	4,954,837	\$ 99,691,096	\$ —	\$ (84,864,086)	\$ (20,124)	\$ 14,806,886
Net loss	—	—	—	(9,311,913)	—	(9,311,913)
Issuance of restricted common stock to directors & officers	417,708	977,381	—	—	—	977,381
Issuance of restricted common stock to key employees	22,500	27,675	—	—	—	27,675
Issuance of restricted common stock for services	30,000	36,900	—	—	—	36,900
Issuance of non-qualified stock options to key employees	—	23,636	—	—	—	23,636
Issuance of non-qualified stock options for services from non-employees	—	28,720	—	—	—	28,720
Net unrealized gain on marketable securities	—	—	—	—	13,893	13,893
Balance at December 31, 2015	5,425,045	\$ 100,785,408	\$ —	\$ (94,175,999)	\$ (6,231)	\$ 6,603,178
Net loss	—	—	—	(3,303,538)	—	(3,303,538)
Issuance of restricted common stock to officers	27,500	54,725	(54,725)	—	—	—
Amortization of deferred compensation	—	—	30,153	—	—	30,153
Issuance of non-qualified stock options to key employees	—	27,977	—	—	—	27,977
Issuance of non-qualified stock options for services from non-employees	—	23,676	—	—	—	23,676

Net unrealized gain on marketable securities	—	—	—	—	6,231	6,231
---	---	---	---	---	-------	-------

Balance at December

31, 2016	5,452,545	\$	100,891,786	\$	(24,572)	\$	(97,479,537)	\$	—	\$	3,387,677
-----------------	-----------	----	-------------	----	----------	----	--------------	----	---	----	-----------

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

F-32

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

For the years ended December 31, 2016 and 2015

	2016	2015
Cash flows from operating activities		
Net loss for the year	\$ (3,303,538)	\$ (9,311,913)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued income on marketable securities	14,244	4,199
Depreciation and amortization	286,162	299,995
Reserve for obsolete inventory	32,333	—
Impairment of non-current assets	—	466,476
Allowance for doubtful accounts	(1,153,413)	2,163,609
Gain from other non-operating activities	—	(6,052)
Fair value of restricted common stock issued for services	30,153	344,656
Share based compensation to employees – options	27,977	23,636
Share based compensation to non-employees – options	23,676	28,720
Changes in assets and liabilities:		
(Increase)/decrease in trade receivables	(138,272)	513,583
Increase in trade receivables – related party	(380)	—
Decrease in notes receivables – related party	—	176,157
(Increase)/decrease in deposits and other receivables	71,795	(54,142)
Increase in inventories	(187,200)	(226,538)
(Increase)/decrease in prepaid expenses	17,689	(76,774)
Decrease in prepaid expenses – related party	76,927	—
Increase/(decrease) in trade and other payables	(205,368)	827,601
Increase in trade and other payables – related party	234,067	—
Decrease in deferred revenue – related party	—	(305,556)
Net cash used in operating activities	(4,173,148)	(5,132,343)
Cash flows from investing activities		
Purchases of property, plant and equipment	(123,301)	(112,951)
Purchases of marketable securities	(35,944)	(60,940)
Investment in Hainan Savy Akers Biosciences, Ltd. joint venture	—	(64,091)
Proceeds from other non-operating activities	—	6,052
Proceeds from sale of marketable securities	4,003,034	5,310,491
Net cash provided by investing activities	3,843,789	5,078,561
Net decrease in cash	(329,359)	(53,782)
Cash at beginning of year	402,059	455,841
Cash at end of year	\$ 72,700	\$ 402,059
Supplemental Schedule of Non-Cash Financing and Investing Activities		
Issuance of restricted common stock grant to an officer	\$ 54,725	\$ —
Net unrealized gains on marketable securities	\$ 6,231	\$ 13,893
Settlement of note receivable in the form of inventory	\$ 750,000	\$ —
Settlement of note receivable in the form of prepaid expense	\$ 549,609	\$ —
Issuance of restricted common share grants to directors and officers accrued in 2014	\$ —	\$ 697,300

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

F-33

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 1 — Nature of Business

(a) Reporting Entity

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

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

(b) Nature of Business

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

Note 2 — Basis of Presentation

(a) Statement of Compliance

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

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

(b) Use of Estimates and Judgments

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

(c) Functional and Presentation Currency

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

consolidated statement of operations and comprehensive loss.

(d) Comprehensive Income

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.

F-34

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 3 — Significant Accounting Policies

(a) Cash and Cash Equivalents

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

(b) Fair Value of Financial Instruments

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

(c) Fair Value Measurement — Marketable Securities

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

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

Level 2 Inputs to the valuation methodology include

- quoted prices for similar assets or liabilities in active markets;
- quoted prices for identical or similar assets or liabilities in inactive markets;
- inputs other than quoted prices that are observable for the asset or liability;
- inputs that are derived principally from or corroborated by observable market data by correlation or other means.

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

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

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

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

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

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

F-35

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 3 — Significant Accounting Policies (cont.)

As of December 31, 2016 and 2015, allowances for doubtful accounts for trade receivables were \$1,010,196 and \$864,000. Bad debt expenses for trade receivables were \$146,196 and \$864,000 for the years ended December 31, 2016 and 2015.

(e) Concentration of Credit Risk

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

All of the Company's cash is maintained with Fulton Bank of New Jersey, Bank of America, NA and PayPal. The funds are insured by the FDIC up to a maximum of \$250,000, but are otherwise unprotected. The Company placed \$67,865 and \$369,525 with Fulton Bank of New Jersey, \$795 and \$28,494 with Bank of America, NA and \$4,040 and \$4,040 with PayPal as of December 31, 2016 and 2015. No losses have been incurred in these accounts.

Concentration of credit risk with respect to trade receivables exists as approximately 75% of the Company's product revenue is generated by three customers. These customers accounted for 30% of trade receivables as of December 31, 2016. In order to limit such risks, the Company performs ongoing credit evaluations of its customers' financial condition.

(f) Inventories

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

(g) Property, Plant and Equipment

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

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

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

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

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

Leasehold Improvements

Shorter of the
remaining lease or
estimated useful life

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

F-36

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 3 — Significant Accounting Policies (cont.)

(h) Intangible Assets

(i) Patents and Trade Secrets

The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person's breath, blood, urine and saliva. Propriety protection for the Company's products, technology and process is important to its competitive position. As of December 31, 2016, the Company has ten patents from the United States Patent Office in effect (9,383,368; 7,896,167; 8,097,171; 8,003,061; 8,425,859; 8,871,521; 8,808,639; D691,056; D691,057 and D691,058). Other patents are in effect in Australia through the Design Registry (348,310; 348,311 and 348,312), European Union Patents 1793906, 2684025, 002216895-0001; 002216895-0002 and 002216895-0003), in Hong Kong (HK11004006) and in Japan (1,515,170; 4,885,134; 4,931,821 5,775,790, and 6023096). Patents are in the national phase of prosecution in many Patent Cooperation Treaty participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the U.S., European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

(ii) Patent Costs

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

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

(iii) Other Intangible Assets

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

(iv) Amortization

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

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

(i) Recoverability of Long Lived Assets

In accordance with FASB ASC 360-10-35 "Impairment or Disposal of Long-lived Assets", long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the carrying amount

of an asset may not be fully recoverable or that the useful lives of those assets are no longer appropriate. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment.

The Company determines the existence of such impairment by measuring the expected future cash flows (undiscounted and without interest charges) and comparing such amount to the carrying amount of the assets. An impairment loss, if one exists, is then measured as the amount by which the carrying amount of the asset

F-37

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 3 — Significant Accounting Policies (cont.)

exceeds the discounted estimated future cash flows. Assets to be disposed of are reported at the lower of the carrying amount or fair value of such assets less costs to sell. Asset impairment charges are recorded to reduce the carrying amount of the long-lived asset that will be sold or disposed of to their estimated fair values. Charges for the asset impairment reduce the carrying amount of the long-lived assets to their estimated salvage value in connection with the decision to dispose of such assets.

(j) Investments

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

- a) Representation on the Board of Directors
- b) Participation in policy-making processes
- c) Material intra-entity transactions
- d) Interchange of management personnel
- e) Technological dependencies
- f) Extent of ownership and the ability to influence decision making based upon the makeup of other owners when the shareholder group is small.

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 value these investments using the cost method.

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

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

(k) 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 \$- as of December 31, 2016 and 2015.

The Company implemented a significant price increase for certain PIFA products effective May 1, 2015 and a standard dealer cost model during the year ended December 31, 2016. In an effort to phase in these changes, the programs include a provision for rebates to the distributors under limited circumstances. The Company has established an accrual of \$41,120 and \$233,542, which is a reduction of revenue, for the years ended

F-38

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 3 — Significant Accounting Policies (cont.)

December 31, 2016 and 2015. Accounts receivable will be reduced when the rebates are applied by the customer. During the years ended December 31, 2016 and 2015, the Company recognized \$471,949 and \$438,360 in 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.

(l) Income Taxes

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

(m) Shipping and Handling Fees and Costs

The Company charges actual shipping plus a handling fee to customers, which amounted to \$54,928 and \$56,537 for the years ended December 31, 2016 and 2015. 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 \$138,662 and \$115,423 for the years ended December 31, 2016 and 2015.

(n) Research and Development Costs

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

(o) Stock-based Payments

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

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

The Company estimates the fair value of stock-based awards to non-employees on the date of grant using the Black-Scholes model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the period which services are to be received. At the end of each financial reporting period, prior to vesting or prior to completion of services, the fair value of equity based payments will be re-measured and the non-cash expense recognized during the period will be adjusted accordingly. Since the fair value of equity based payments granted to non-employees is subject to change in the future, the amount of the future expense will include fair value re-measurement until the equity based payments are fully vested or the service is completed.

F-39

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 3 — Significant Accounting Policies (cont.)

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

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

(q) Reclassifications

Certain prior year amounts have been reclassified to conform to the current year's presentation.

(r) Recently Adopted Accounting Pronouncements

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements — Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The amendments in this Update provide guidance about management's responsibility to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued and to provide related footnote disclosures. Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued. The amendments in this Update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The amendments in this Update were adopted as of December 31, 2016. See Note 4 for management's evaluation and discussion.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330), Simplifying the Measurement of Inventory. The amendments in this Update require an entity to measure inventory at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. The amendments in this Update are effective for fiscal years beginning after December 15, 2016 and interim periods within fiscal years beginning after December 15, 2017. The amendments in this Update should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. As of December 31, 2016, the Company adopted the amendments in this Update which does not have any material effect on the financial statements.

(s) Recently Issued Accounting Pronouncements Not Yet Adopted

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

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In August 2015, FASB issued ASU 2015-14 which deferred the effective date

of Update 2014-09 to annual reporting periods beginning after December 15, 2018 and interim reporting periods within annual reporting periods beginning after December 15, 2019. Early application is permitted as of annual reporting periods beginning after December 15, 2016 including interim reporting periods within that reporting period. The Company is currently evaluating the effect of the amendments but it does not anticipate a material impact of its financial statements. The Company expects to use the modified retrospective adoption method.

F-40

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 3 — Significant Accounting Policies (cont.)

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740), Balance Sheet Classification of Deferred Taxes. The amendments in this Update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in this Update are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 31, 2018. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. The Company does not expect the adoption of the amendments in this Update to have a material impact on its financial statements.

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

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

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

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

Note 4 — Management Plan

Historically, the Company has relied upon public offerings and private placements of common stock to raise operating capital. During the three month period ending March 31, 2017, the Company raised approximately \$1.7 million in a

public offering and an additional \$1.8 million from a private placement of common stock (Note 23). As of April 5, 2017, the Company had cash and marketable securities of approximately \$2.3 million.

F-41

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 4 — Management Plan (cont.)

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

Implementation of the Strat Plan began in January 2017 and management remains confident that the objectives are achievable, however; during the first half of 2017, the Company may encounter limited periods of cash shortages and is proactively working to minimize their impact on operations. We anticipate maintaining a cash-flow positive position during the next twelve months based upon the revenue targets as outlined in the Strat Plan, the results of the private placement offering in March 2017 and the backing by a shareholder if required. In Addition, the Company has initiated discussions with our primary financial institution to establish a line of credit to manage short-term cash fluctuations.

During the year ended December 31, 2016, the Company significantly reduced operating expenses through a systematic review of operations throughout the organization. As a result, the Company achieved a reduction in our weekly operating cash requirements of approximately 19% to \$80,253 (2015: \$98,699). The Strat Plan assumes the weekly cash requirement to remain steady through the year ending December 31, 2017.

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

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

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

Note 5 — Fair Value Measurement — Marketable Securities

Following is a description of the valuation methodologies used for assets measured at fair value as of December 31, 2016 and 2015.

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

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

Total:	\$	49,971	\$	30	\$	—	\$	—	\$	50,001
F-42										

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 5 — Fair Value Measurement — Marketable Securities (cont.)

	As of December 31, 2015				
	Cost	Accrued Income	Unrealized Gains	Unrealized Losses	Fair Value
Level 2:					
Money market funds	\$ 750	\$ —	\$ —	\$ —	\$ 750
Certificates of deposits	2,050,000	8,584	—	(135)	2,058,449
Corporate Securities	1,528,308	4,934	—	(5,918)	1,527,324
Municipal securities	438,003	756	—	(178)	438,581
Total Level 2:	4,017,061	14,274	—	(6,231)	4,025,104
Total:	\$ 4,017,061	\$ 14,274	\$ —	\$ (6,231)	\$ 4,025,104

Marketable securities include U.S. agency securities, corporate securities, and municipal 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 relating to the available for sale investment securities were recorded in the Consolidated Statement of Changes in Stockholders' Equity as comprehensive income. These amounts were \$6,231 and \$13,893 (net of effect of income tax expense of \$-) for the years ended December 31, 2016 and 2015.

Proceeds from the sale of marketable securities in the year ended December 31, 2016 and 2015 were \$4,003,034 and \$5,310,491. Gross gains as a result of the sales amounted to \$3,582 and \$1,594 and gross losses amounted to \$3,667 and \$8,105 for the years ended December 31, 2016 and 2015, respectively.

Note 6 — Trade Receivables — Related Party

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

Note 7 — Note Receivable — Related Parties

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

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

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 8 — Inventories

Inventories at December 31, 2016 and 2015 consists of the following categories:

	2016	2015
Raw Materials	\$ 440,316	\$ 348,216
Sub-Assemblies	907,989	786,656
Finished Goods	749,488	25,721
Reserve for Obsolescence	(61,272)	(28,939)
	\$ 2,036,521	\$ 1,131,654

For the years ended December 31, 2016 and 2015 \$32,333 and \$- was charged to cost of goods sold for obsolete inventory.

Note 9 — Property, Plant and Equipment

Property, plant and equipment as of December 31, 2016 and 2015 are as follows:

	2016	2015
Computer Equipment	\$ 114,771	\$ 100,405
Computer Software	40,681	40,681
Office Equipment	39,959	50,049
Furniture & Fixtures	29,939	29,939
Machinery & Equipment	1,126,134	1,112,060
Molds & Dies	834,480	756,279
Leasehold Improvements	222,593	222,593
	2,408,557	2,312,006
Less		
Accumulated Depreciation	2,149,165	2,060,861
	\$ 259,392	\$ 251,145

During the years ended December 31, 2016 and 2015 depreciation expense was \$115,053 and \$63,289.

Note 10 — Intangible Assets

Intangible assets as of December 31, 2016 and 2015 and the movements for the years then ended are as follows:

	Patents & Trademarks	Distributor & Customer Relationships	Totals
Cost or Deemed Cost			
At December 31, 2014	\$ 3,851,495	\$ 1,270,639	\$ 5,122,134
Additions	—	—	—
Disposals	(1,224,499)	—	(1,224,499)
At December 31, 2015	\$ 2,626,996	\$ 1,270,639	\$ 3,897,635
Accumulated Amortization			
At December 31, 2014	\$ 1,675,430	\$ 1,270,639	\$ 2,946,069
Amortization Charge	236,706	—	236,706

Disposals	(758,023)	—	(758,023)
At December 31, 2015	\$ 1,154,113	\$ 1,270,639	\$ 2,424,752
F-44			

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 10 — Intangible Assets (cont.)

	Patents & Trademarks	Distributor & Customer Relationships	Totals
Net Book Value			
At December 31, 2014	\$ 2,176,065	\$ —	\$ 2,176,065
At December 31, 2015	\$ 1,472,883	\$ —	\$ 1,472,883
Cost or Deemed Cost			
At December 31, 2015	\$ 2,626,996	\$ 1,270,639	\$ 3,897,635
Additions	—	—	—
Disposals	—	—	—
At December 31, 2016	\$ 2,626,996	\$ 1,270,639	\$ 3,897,635
Accumulated Amortization			
At December 31, 2015	\$ 1,154,113	\$ 1,270,639	\$ 2,424,752
Amortization Charge	171,108	—	171,108
Disposals	—	—	—
At December 31, 2016	\$ 1,325,221	\$ 1,270,639	\$ 2,595,860
Net Book Value			
At December 31, 2015	\$ 1,472,883	\$ —	\$ 1,472,883
At December 31, 2016	\$ 1,301,775	\$ —	\$ 1,301,775

On December 31, 2015, the Company reassigned two fully amortized patents to the original holder as part of the settlement of a legal dispute.

During the years ended December 31, 2016 and 2015 amortization expense was \$171,108 and \$236,706.

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

Period	Amount
2017	\$ 171,108
2018	\$ 171,108
2019	\$ 171,108
2020	\$ 171,108
2021	\$ 171,108

Note 11 — Trade and Other Payables

Trade and other payables as of December 31, 2016 and 2015 are as follows:

	2016	2015
Trade Payables	\$ 923,311	\$ 538,449
Accrued Expenses	480,302	1,020,532
Legal Settlements Payable	—	50,000
Deferred Compensation	59,750	59,750
	\$ 1,463,363	\$ 1,668,731

Trade and other payables — related party as of December 31, 2016 and December 31 2015 are as follows:

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 11 — Trade and Other Payables (cont.)

	2016	2015
Trade Payables (Note 17)	\$ 182,001	\$ —
Accrued Expenses (Note 17)	52,066	—
	\$ 234,067	\$ —

The Company recorded royalty expenses of \$153,854 for the year ended December 31, 2016 for ChubeWorkx Guernsey Limited (“ChubeWorkx”), a major shareholder, in relation to the settlement of legal claims (Note 17). The expense is included in sales and marketing expenses — related party on the Consolidated Statement of Operations and Comprehensive Loss. As of December 31, 2016, the Company owed ChubeWorkx \$17,953 for the period of October 1, 2016 through December 31, 2016 which was paid on January 20, 2017 and had an accrual of \$52,066 for the period of January 1, 2016 through August 17, 2016 which was paid on January 16, 2017.

As of December 31, 2016, the Company owed Hainan \$14,664. Senior management at Hainan are actively involved in two other companies, Shenzhen Savy-Akers Biosciences (“Shenzhen”) and Dong Guan Senming E&P (“Senming”) and are therefore being included as related parties. The Company owed these two companies \$149,384 as of December 31, 2016.

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

Note 12 — Deferred Revenue — Related Party

Deferred revenue represented the unearned revenue from the 3-year exclusive License and Supply Agreement with ChubeWorkx Guernsey Limited (“ChubeWorkx”)(Note 17) for the purchase and distribution of the Company’s proprietary breathalyzer that was signed in June 2012.

On May 7, 2015, the Company and ChubeWorkx mutually terminated the exclusive license and supply agreement that granted worldwide distribution rights to ChubeWorkx for the Company’s breathalyzer test. As a result of this action and per the terms of the original agreement, the Company recognized the remaining \$166,667 of deferred revenue in the statement of operations for the year ended December 31, 2015.

Note 13 — Share-based Payments

On January 23, 2014, upon effectiveness of the registration statement filed with the SEC, the Company adopted the 2013 Stock Incentive Plan (the “Plan”) which will provide for the issuance of up to 400,000 shares. The purpose of the Plan is to provide additional incentive to those officers, employees, consultants and non-employee directors of the Company and its parents, subsidiaries and affiliates whose contributions are essential to the growth and success of the Company’s business.

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

On September 30, 2016, the Board of Directors increased the number of authorized shares of common stock subject to the Amended Plan to 830,000 shares. As of December 31, 2016, under the 2013 Amended Plan, grants of restricted stock and options to purchase 277,333 shares of common stock have been issued and are unvested or unexercised and 13,292 shares of common stock remain available for grants.

The Amended Plan may be administered by the board or a board-appointed committee. Eligible recipients of option awards are employees, officers, consultants or directors (including non-employee directors) of the Company or of any parent, subsidiary or affiliate of the Company. The board has the authority to grant to any eligible recipient any options, restricted stock or other awards valued in whole or in part by reference to, or otherwise based on, the Company's common stock.

F-46

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 13 — Share-based Payments (cont.)

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

On December 30, 2015, the Company approved the issuance of 30,000 options to purchase common shares to key employees at an exercise price of \$1.23 per common share and 15,500 options to purchase common shares for services at a weighted average exercise price of \$3.70 per common share. All options are immediately exercisable and carry a five-year expiration.

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

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

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

	2016		2015	
Expected option term	5 yrs		5 yrs	
Expected volatility	95.02	%	82.86	%
Expected dividend yield	0.00	%	0.00	%
Risk free interest rate	1.16	%	1.73	%

The following table summarizes the option activities for the years ended December 31, 2016 and 2015:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2014	175,000	\$ 4.98	4.50	\$ 600
Granted	45,500	2.07	5.00	—
Exercised	—	—	—	—
Forfeited	—	—	—	—
Cancelled/Expired	—	—	—	—
Balance at December 31, 2015	220,500	\$ 4.38	3.81	\$ —
Exercisable as of December 31, 2015	220,500	\$ 4.38	3.81	\$ —
Balance at December 31, 2015	220,500	\$ 4.38	3.81	\$ —
Granted	38,500	3.40	4.43	—
Exercised	—	—	—	—
Forfeited	—	—	—	—
Cancelled/Expired	—	—	—	—
Balance at December 31, 2016	259,000	\$ 4.23	3.05	\$ 20,100
Exercisable as of December 31, 2016	239,167	\$ 4.31	2.92	\$ 20,100

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$1.90 and \$1.21 for our common shares on December 31, 2016 and 2015.

F-47

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 13 — Share-based Payments (cont.)

The weighted-average fair value of stock options granted for the years ended December 31, 2016 and 2015 was \$1.98 and \$0.70, respectively. A summary of the Company's non-vested shares as of December 31 2016 and the changes during the year then ended are as follows:

Non-Vested Shares	Shares	Weighted Average Grant Date Fair Value
Non-vested at January 1, 2016	—	\$ —
Granted	38,500	1.98
Vested	(18,666)	1.90
Forfeited	—	—
Non-vested at December 31, 2016	19,834	\$ 2.36

Unrecognized compensation cost related to non-vested employee stock options totaled \$33,296 and \$- as of December 31, 2016 and 2015. The cost is to be recognized over a weighted average period of 1.63 years.

During the years ended December 31, 2016 and 2015, the Company incurred stock options expenses totaling \$51,653 and \$52,356, respectively.

Note 14 — Equity

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

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's restricted stock awards vest of a period of one to three years. 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 9, 2015, the Company issued 190,000 common shares to directors for services provided to the Company through December 31, 2014. The fair value of these shares was \$697,300, which was reported as administrative expenses on the Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2014, and the corresponding liability is included in trade and other payables on the December 31, 2014 Consolidated Balance Sheet.

On December 29, 2015, the Company issued 227,708 common shares to directors and officers for services rendered to the Company through December 31, 2015. The fair value of these shares was \$280,081, which was reported as administrative expenses on the Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2015.

On December 29, 2015, the Company issued 22,500 common shares to key employees for services rendered to the Company through December 31, 2015. The fair value of these shares was \$27,675, which was reported as research and development expenses on the Consolidated Statement of Operations and Comprehensive Loss for the year ended

December 31, 2015.

On December 29, 2015, the Company issued 30,000 common shares in exchange for legal services rendered. The fair value of these shares was \$36,900, which was reported as administrative expenses on the Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2015.

F-48

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 14 — Equity (cont.)

On June 8, 2016, the Company issued 27,500 restricted common shares to an officer in connection with his employment agreement. These shares vest 1/3 immediately on the date of the grant and the remaining 2/3 vests equally on March 1, 2017 and March 1, 2018. The fair value of these shares was \$54,725 and was based on the share price on the date of the grant. \$30,153 was recorded during the year December 31, 2016 as administrative expense on the Consolidated Statement of Operations and Comprehensive Loss and the remaining \$24,572 was recorded as deferred compensation, a contra equity account, on the Consolidated Balance Sheet as of December 31, 2016.

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

	Authorized Preferred Stock	Common Stock	Issued Preferred Stock	Common Stock
Balance at December 31, 2014	50,000,000	500,000,000	—	4,954,837
Shares Issued:				
January 9, 2015	—	—	—	190,000
December 29, 2015	—	—	—	280,208
Balance at December 31, 2015	50,000,000	500,000,000	—	5,425,045
Shares Issued:				
June 8, 2016	—	—	—	27,500
Balance at December 31, 2016	50,000,000	500,000,000	—	5,452,545

Note 15 — Loss per share

The calculation of basic and diluted loss per share at December 31, 2016 and 2015 was based on the loss attributable to common shareholders of \$3,303,538 and \$9,311,913. The basic and diluted weighted average number of common shares outstanding for 2016 and 2015 was 5,430,205 and 5,140,920.

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

Potential common shares consist of options and warrants. Diluted net loss per common share was the same as basic net loss per common share for the years ended December 31, 2016 and 2015 since the effect of options and warrants would be anti-dilutive due to the net loss attributable to the common shareholders. Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were as follows: incentive and award stock options — 259,000 for 2016 (2015: 220,500).

Note 16 — Income Tax Expense

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

	Years Ended December 31	
	2016	2015
Current	\$ 895,000	\$ 3,228,852
Deferred	(1,646,000)	835,596

Change in Valuation Allowance	751,000	(3,795,104)
Net	\$ —	\$ 269,344
F-49		

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 16 — Income Tax Expense (cont.)

During 2015, the Company was approved by the State of New Jersey to sell a portion of its state tax benefits that existed as of December 31, 2014, pursuant to the Technology Tax Certificate Transfer Program. The Company received net proceeds of \$269,344 for the year ending December 31, 2015 from the sale of the tax benefits, which has been included as an income tax benefit in the Consolidated Statement of Operations and Comprehensive Loss.

As of December 31, 2016 and 2015, the Company had Federal net operating loss carry forwards of approximately \$60,100,000 and \$58,000,000, expiring through the year ending December 31, 2036. As of December 31, 2016 and 2015, the Company had New Jersey state net operating loss carry forwards of approximately \$9,400,000 and \$7,200,000, expiring through the year ending December 31, 2023.

The principle components of the deferred tax assets and related valuation allowances as of December 31, 2016 and 2015 are as follows:

	Years Ended December 31	
	2016	2015
Reserves and other	\$ 865,000	\$ 2,506,000
Net operating loss carry-forwards	21,618,000	20,728,000
Valuation Allowance	(22,483,000)	(23,234,000)
Net	\$ —	\$ —

The reconciliation of income taxes using the statutory U.S. income tax rate and the benefit from income taxes for the years ended December 31, 2016 and 2015 are as follows:

	Years Ended December 31			
	2016		2015	
Statutory U.S. Federal Income Tax Rate	(35.0	)%	(35.0	)%
New Jersey State income taxes, net of U.S. Federal tax effect	(6.0	)%	(6.0	)%
Benefit from Sale of New Jersey NOL	0.0	%	(2.9	)%
Change in Valuation Allowance	41.0	%	41.0	%
Net	—	%	(2.9	)%

The valuation allowance for deferred tax assets as of December 31, 2016 and 2015 was \$22,483,000 and \$23,234,000. The change in the total valuation for the years ended December 31, 2016 and 2015 were a decrease of \$751,000 and an increase of \$3,795,104. 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, 2016, the Company had no unrecognized tax benefits and no charge during 2016, and accordingly, the Company did not recognize any interest or penalties during 2016 related to unrecognized tax benefits. There is no accrual for uncertain tax positions as of December 31, 2016.

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, 2013 and thereafter are subject to examination by the relevant taxing authorities.

F-50

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 17 — Related Party Transactions

On June 19, 2012, the Company entered into a 3-year exclusive License & Supply Agreement with ChubeWorkx Guernsey Limited (as successor to SONO International Limited) (“ChubeWorkx”) for the purchase and distribution of Akers’ proprietary breathalyzers outside North America. ChubeWorkx paid a licensing fee of \$1,000,000 which was recognized over the term of the agreement through September 30, 2015.

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

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

Under the terms of the Settlement Agreement, the Company recovered the full outstanding principal amount in the current fiscal year in the form of \$750,000 of BreathScan® Alcohol Detector products — which the Company intends to subsequently sell — and the balance of \$549,609 as prepaid royalty. The goods were received in August, 2016. Akers’ established an allowance for this doubtful note in the Company’s financial statements for the year ended December 31, 2015. As a result of the Settlement Agreement, the Company reversed the allowance for doubtful note in the amount of \$1,299,609 which is included in the Condensed Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2016.

In addition to addressing the promissory note described above, the Settlement Agreement also allows the Company to market and sell all of the Company’s breath technology tests worldwide, unencumbered by any past/future claims by ChubeWorkx under the Licensing Agreement (entered into with ChubeWorkx in 2012 and subsequently amended in 2013). Under the terms of the Settlement Agreement, ChubeWorkx no longer holds any rights pertaining to Akers’ BreathScan® technology, which serves as the basis for a number of commercialized products including BreathScan® Alcohol Detector and BreathScan OxiChek™; and a number of products in development.

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 \$153,854 for the year ended December 31, 2016 which are included in sales and marketing expenses — related party on the Consolidated Statement of Operations and Comprehensive Loss.

Other terms of the Settlement include: 1) the pledge as security of all earned but unpaid royalties by the Company to ChubeWorkx all Company assets, worthy to satisfy its obligations, including all inventory and receivables, with the exception of (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other equipment; 2) the pledge as security of

the settlement sum which remains unpaid by the Company to ChubeWorkx all Company (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists,

F-51

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 17 — Related Party Transactions (cont.)

(iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other equipment; and 3) the grant of voting proxy by ChubeWorkx to the Company which allows the Company to vote ChubeWorkx's shares for corporate formalities under certain conditions.

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

The Company began purchasing manufacturing molds, plastic components and the assembled BreathScan Lync device through Hainan and its related parties during the year ended December 31, 2016 (Note 11). The Company purchased a total of \$207,135 during the year ended December 31, 2016 from this related party. As of December 31, 2016, the Company owed the three companies \$164,049 which is included in trade and other payables — related party on the Consolidated Balance Sheet.

Trade receivables — related party as of December 31, 2016 and 2015 were \$31,892 and \$31,512. The amounts due are non-interest bearing, unsecured and generally have a term of 30-90 days (Note 5). This receivable is past due and management deemed it fully collectable.

Product revenue — related party for the year ended December 31, 2016 and 2015 were \$380 and \$36,512. The revenue was the result of sales to Hainan.

Note 18 — Commitments

The Company leases its facility in West Deptford, New Jersey under an operating 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. Under the terms of the lease.

Rent expense, including related CAM charges for the years ended December 31, 2016 and 2015 was \$161,160 and \$161,281.

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

The schedule of lease commitments is as follows:

	Building Lease	Equipment Lease	Total
Next 12 Months	\$ 132,000	\$ 6,156	\$ 138,156
Next 13-24 Months	132,000	6,156	138,156
Next 25-36 Months	132,000	5,130	137,130

Note 19 — Major Customers

For the year ended December 31, 2016, three customers generated 10% or more of the Company's revenue. Sales to these customers accounted for 75% of the Company's revenue. As of December 31, 2016, the amount due from these customers was \$490,725. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

For the year ended December 31, 2015, two customers generated 10% or more of the Company's revenue. Sales to these customers accounted for 65% of the Company's revenue. As of December 31, 2015, the amount due from these customers was \$435,261.

F-52

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 20 — Major Suppliers

For the year ended December 31, 2016, one supplier accounted for 10% or more of the Company's purchases. This supplier accounted for 27% of the Company's total purchases. As of December 31, 2016, the amount due to this supplier was \$164,049. This makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

For the year ended December 31, 2015, three suppliers accounted for 10% or more of the Company's purchases. This supplier accounted for 41% of the Company's total purchases. As of December 31, 2015, the amount due to these suppliers was \$16,317.

Note 21 — Contingencies

On October 17, 2016 the Company was served with a notice that Pulse Health LLC ("Pulse") filed a lawsuit against the Company on September 30, 2016 in United States Federal District Court, District of Oregon, alleging a breach of contract under the Settlement Agreement entered into by the Company and Pulse on April 8, 2011 which settled all claims and disputes between the Company and Pulse arising from a previously executed Technology Development Agreement entered into by the Company and Pulse and damages resulting from said alleged breach. Additionally, Pulse alleges false advertising and unlawful trade practices in connection with the Company's sales activities of the Company's OxiChek products. Pulse is seeking not less than \$500,000 in damages for the allegations. The Company disputes such allegations.

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 was heard by the Court on Friday, March 10, 2017. We expect the Court to issue a ruling on these motions at some point on or before April 21, 2017.

The Company intends to establish a rigorous defense of all claims. As the case has not progressed beyond the initial legal motions and the Company is unable to assess the potential outcome, no accrual for losses was made as of December 31, 2016. All legal fees were expensed as and when incurred.

Note 22 — Segment Information

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

The total revenue by different product lines was as follows:

Product Line	For the years ended December 31,	
	2016	2015
MicroParticle Catalyzed Biosensor ("MPC")	\$ 282,516	\$ 296,328
Particle ImmunoFiltrationAssay ("PIFA")	2,577,148	1,391,017
Other	97,498	107,149
Product Revenue Total	\$ 2,957,162	\$ 1,794,494
License Fees	3,750	320,556

Total Revenue
F-53

\$	2,960,912	\$	2,115,050
----	-----------	----	-----------

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 22 — Segment Information (cont.)

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

Geographic Region	For the years ended December 31,	
	2016	2015
United States	\$ 2,330,723	\$ 1,579,091
People's Republic of China	502,998	37,506
Rest of World	127,191	498,453
Total Revenue	\$ 2,960,912	\$ 2,115,050

As of December 31, 2016, the Company had long-lived assets totaling \$61,081 located in the People's Republic of China and \$1,500,086 located in the United States. All of the Company's long-lived assets were located in the United States as of December 31, 2015.

Note 23 — Subsequent Events

On January 13, 2017, the Company completed a public offering of 1,789,500 common shares, raising net proceeds of \$1,692,044. Below is a summary of the gross proceeds to net proceeds calculation.

	Shares	\$	\$
Common Shares			
Base Offering	1,667,000	2,000,400	
Over-Allotment	122,500	147,000	
Gross Proceeds			2,147,400
Underwriter/Gunnar Expenses			
Discount		150,318	
Legal Fees		60,000	
Roadshow		1,783	
Miscellaneous		34,005	
Total			246,106
Akers Biosciences Expenses			
Legal & Accounting		197,813	
Registration/Regulatory		11,437	
Total			208,350
Net Proceeds			1,692,044

In addition to the common shares issued, the Company also issued 833,500 warrants with an exercise price of \$1.50 per common share in support of the base offering and 61,250 warrants with an exercise price of \$1.20 per common share. All of the warrants issued carry have a five-year term.

On March 31, 2017, the Company completed a private offering of 1,448,400 unregistered shares of common stock, raising net proceeds of 1,760,817. The unregistered shares will be admitted to trading once a Registration Statement, which will be filed with the Securities and Exchange Commission within 20 days, has been deemed effective. Below is a summary of the gross proceeds to net proceeds calculation.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 23 — Subsequent Events (cont.)

	Shares	\$	\$
Common Shares			
Base Offering	1,448,400	2,027,760	
Gross Proceeds			2,027,760
Underwriter/Gunnar Expenses			
Discount		141,943	
Legal Fees		50,000	
Total			191,943
Akers Biosciences Expenses			
Legal Fees		75,000	
Total			75,000
Net Proceeds			1,760,817
In addition to the common shares issued, the Company also issued 724,200 warrants with an exercise price of \$1.96 per common share with a five-year term.			

On April 4, 2017, two warrant holders from the January 13, 2017 public offering exercised 160,000 warrants with an exercise price of \$1.50 per common share, raising net proceeds of \$240,000.

On April 5, 2017, two warrant holders from the January 13, 2017 public offering exercised 3,300 warrants with an exercise price of \$1.50 per common share, raising net proceeds of \$4,950.

7,692,308 Class A Units Consisting of Common Stock and Warrants and

3,000 Class B Units Consisting of Series B Convertible Preferred Stock and Warrants

**(and 7,692,308 shares of common stock underlying shares of Series B Convertible Preferred Stock and
7,692,308 shares of common stock underlying Warrants)**

PROSPECTUS

Joseph Gunnar & Co.

_____, 2017

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, to be paid by the Registrant in connection with the issuance and distribution of the common stock and warrants being registered. All amounts other than the SEC registration fees and FINRA fees are estimates.

SEC Registration Fees	\$1,979.55
FINRA Fees	\$1,591.25
Printing and Engraving Expenses	\$20,000
Legal Fees and Expenses	\$59,500
Accounting Fees and Expenses	\$25,000
Transfer Agent Fees	\$10,000
Miscellaneous	\$20,000
Total	\$138,070.80

Item 14. Indemnification of Directors and Officers

Section 14A:2-7(3) of the New Jersey Business Corporation Act permits a corporation to provide in its certificate of incorporation that a director or officer shall not be personally liable, or shall be liable only to the extent therein provided, to the corporation or its shareholders for damages for breach of any duty owed to the corporation or its shareholders, except that such provision shall not relieve a director or officer from liability for any breach of duty based upon an act or omission (a) in breach of such person's duty of loyalty to the corporation or its shareholders, (b) not in good faith or involving a knowing violation of law or (c) resulting in receipt by such person of an improper personal benefit. Akers Biosciences, Inc.'s certificate of incorporation provides for such limitation of liability.

Section 14A:3-5 of the New Jersey Business Corporation Act empowers a corporation to indemnify any current or former director or officer made a party to a proceeding because he or she is or was a director or officer against liability incurred in the proceeding; provided that such director or officer acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal proceeding, such director or officer had no reasonable cause to believe his conduct was unlawful.

Akers Biosciences, Inc.'s certificate of incorporation provides that the corporation must indemnify its directors and officers to the fullest extent authorized by law. Akers Biosciences, Inc. is also expressly required to advance certain expenses to its directors and officers. Akers Biosciences, Inc. believes that these indemnification provisions are useful to attract and retain qualified directors and executive officers.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 15. Recent Sales of Unregistered Securities

The following sets forth information regarding all unregistered securities issued for the last three years and through November 20, 2017.

On October 17, 2017, pursuant to the Plan, the Board issued (i) John J. Gormally, the Company's CEO, 150,000 shares of Restricted Stock, (ii) Gary Rauch, the Company's CFO, 36,277 shares of Restricted Stock, (iii) 58,043 shares of

Restricted Stock to a current employee of the Company and (iv) 50,787 shares of Restricted Stock to a former employee of the Company, for a total of 295,107 shares of Restricted stock. These issuances are compensation for work performed prior to October 17, 2017.

II-1

In connection with the Warrant Exercise Agreements executed on or about October 12, 2017, the Company issued warrants to each Exercising Holder (as defined in the warrant Exercise Agreement) for the number of shares of Common Stock equal to one hundred percent of the number of exercised shares purchased by such Exercising Holder (the “Warrant Shares”), with an exercise price of \$1.26 per share (each, an “Additional Warrant”, and collectively, the “Additional Warrants”). The Additional Warrants are substantially identical to the Original Warrants, except that the exercise price of the Additional Warrant is \$1.26 and such warrant is not exercisable for six months after issuance.

On March 30, 2017, the Company entered into a Placement Agency Agreement (the “Placement Agency Agreement”) with Joseph Gunnar & Co., LLC (“Joseph Gunnar”), pursuant to which Joseph Gunnar was to act as placement agent in connection with the private placement (the “Offering”) of Common Stock and warrants to purchase Common Stock. The term of the Agreement was from March 30, 2017 until the completion of the Offering. As described below, the Offering was completed on March 30, 2017. Pursuant to the Placement Agency Agreement, Joseph Gunnar received compensation of (i) a cash fee equal to 7% of the gross proceeds of the Offering received by the Company; (ii) 72,420 warrants to purchase Common Stock (the “Placement Agent Warrants”); and (iii) reimbursement for actual expenses of \$50,000. The Placement Agent Warrants have a strike price of \$1.96, and are exercisable from September 30, 2017 through January 9, 2022.

In connection with the Offering, on March 30, 2017, the Company entered into a Securities Purchase Agreement (the “Securities Purchase Agreement”) and a Registration Rights Agreement (the “Registration Rights Agreement”) with four purchasers (the “Purchasers”). Pursuant to the Securities Purchase Agreement, the Purchasers purchased an aggregate of \$2,027,760 of Common Stock and Purchaser Warrants (the “SPA Securities”) at a price of \$1.40 per share of Common Stock and Purchaser Warrants to purchase up to fifty percent of the Common Stock sold in the Offering. The Purchaser Warrants have a strike price of \$1.96, and are exercisable from September 30, 2017 through March 30, 2022. The Securities Purchase Agreement contains customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. Additionally, the Purchasers may participate in a subsequent offering of the Company’s securities in an aggregate amount of up to 35% of the subsequent offering.

During the twelve-month period ended December 31, 2016, the Company issued 27,500 restricted shares to one employee. This issuance was made pursuant to the Akers Biosciences, Inc. 2013 Equity Incentive Plan.

During the twelve-month period ended December 31, 2015, The Company issued 470,208 restricted shares to eight directors, officers and employees. The issuances were made pursuant to the Akers Biosciences, Inc. 2013 Equity Incentive Plan.

The issuance of the securities whose information is set forth in this Item 15 were not registered under the Securities Act but qualified for exemption under Section 4(a)(2) of the Securities Act on its own or because the issuance of such securities by the Company complied with Regulation D (Rule 506(b)).

ITEM 16. Exhibits and Financial Statement Schedules.

(a)

Exhibit Number	Description of Exhibit
1.1*	<u>Form of Underwriting Agreement</u>
3.1	<u>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).</u>

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).

II-2

Exhibit Number	Description of Exhibit
3.5	<u>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).</u>
3.6	<u>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).</u>
3.7*	<u>Form of Amendment to Certificate of Incorporation, Certificate of Series B Preferred Stock Designation.</u>
4.1*	<u>Form of Underwriter's Warrant</u>
4.2	<u>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).</u>
4.3	<u>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).</u>
4.4	<u>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).</u>
4.5	<u>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).</u>
4.6**	<u>Form of Stock Certificate of Series B Preferred Stock</u>
4.7**	<u>Form of Common Stock Purchase Warrant</u>
5.1*	<u>Opinion of Lucosky Brookman LLP</u>
10.1	<u>Employment Agreement, dated January 12, 2011 between Raymond F. Akers, Jr. Phd and Akers Biosciences, Inc. and letter of amendment dated August 3, 2013. (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).</u>
10.2	<u>Consulting Agreement between Akers Biosciences, Inc. and Nicolette Consulting Group, dated January 12, 2011(incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).</u>
10.3	<u>Consulting Agreement between Akers Biosciences, Inc. and DataSys Solutions, LLC, dated January 1, 2012. (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).</u>
10.4	<u>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).</u>

- 10.5 Share Purchase Agreement by and between Akers Biosciences, Inc. and Chubeworkx, dated June 12, 2013.
(incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1
filed with the Securities and Exchange Commission on August 7, 2013).
- 10.6 Voting Agreement by and between Akers Biosciences, Inc., Chubeworkx and Thomas J. Knox, dated June
12, 2013(incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form
S-1 filed with the Securities and Exchange Commission on August 7, 2013).
- 10.7 Subscription Agreement by and between Akers Biosciences, Inc. and Chubeworkx, dated June 12,
2013(incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form
S-1 filed with the Securities and Exchange Commission on August 7, 2013).
- II-3

Exhibit Number	Description of Exhibit
10.8	<u>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).</u>
10.9	<u>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).</u>
10.10	<u>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).</u>
10.11	<u>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).</u>
10.12	<u>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).</u>
10.13	<u>Promissory Note entered into by Thomas J. Knox issued in favor of Akers Biosciences, Inc. dated November 15, 2013 (incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 18, 2013).</u>
10.14	<u>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).</u>
10.15	<u>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).</u>
10.16	<u>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).</u>
10.17	<u>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).</u>
10.18	<u>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).</u>
10.19	<u>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</u>

S-1/A filed with the Securities and Exchange Commission on December 6, 2013).

- 10.20 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).
- 10.21 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).

II-4

Exhibit Number	Description of Exhibit
10.22	<u>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).</u>
10.23	<u>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).</u>
10.24	<u>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).</u>
10.25	<u>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).</u>
10.26	<u>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).</u>
10.27	<u>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).</u>
10.28	<u>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).</u>
10.29	<u>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).</u>
23.1*	<u>Consent of Morison Cogen LLP, dated December 14, 2017.</u>
23.2*	<u>Consent of Lucosky Brookman LLP (Reference is made to Exhibit 5.1).</u>
24.1**	<u>Power of Attorney (set forth on the signature page of the Registration Statement)</u>

* Filed herewith

** Previously filed

ITEM 17. Undertakings.

The undersigned registrant hereby undertakes that:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;
- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

II-5

- (2) That for the purpose of determining any liability under the Securities Act of 1933 each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (6) The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.
- (7) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the provisions described in Item 14 above, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

II-6

(8) The undersigned Registrant hereby undertakes:

(i) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(ii) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(iii) For purposes of determining any liability under the Securities Act, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (§ 230.430A of this chapter), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Thorofare, State of New Jersey, on December 14, 2017.

Akers Biosciences, Inc.

By: */s/ John J. Gormally*
John J. Gormally
Chief Executive Officer
(Principal Executive Officer)

By: */s/ Gary M. Rauch*
Gary M. Rauch
Vice President, Finance and Treasurer (Principal Financial Officer and
Principal Accounting Officer)

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates stated.

Signature	Title	Date
<i>/s/ John J. Gormally</i> John J. Gormally	Chief Executive Officer and Director (Principal Executive Officer)	December 14, 2017
<i>/s/ Raymond F. Akers Jr., Phd</i> Raymond F. Akers Jr. Phd	Executive Chairman and Chief Scientific Director	December 14, 2017
* Gary M. Rauch	Vice President, Finance & Treasurer (Principal Financial Officer and Principal Accounting Officer)	December 14, 2017
* Christopher C. Schreiber	Director	December 14, 2017
* Richard C. Tarbox III	Director	December 14, 2017
* Bill J. White	Director	December 14, 2017

* Pursuant to Power of Attorney

By: */s/ John J. Gormally*
John J. Gormally
Attorney-in-Fact