Akers Biosciences Inc
Form S-3/A
November 15, 2016

As filed with the Securities and Exchange Commission on November 15 , 2016

Registration No. 333- 214214

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1

to

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

AKERS BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

New Jersey	**22-2983783**
(State or other jurisdiction of	**(I.R.S. Employer**

incorporation or organization) Identification Number)

201 Grove Road

Thorofare, New Jersey 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 08086

(Address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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101 Wood Avenue South 5th Floor

Iselin, NJ 08830

(732) 395-4400

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: From time to time after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. [ ]

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, other than securities offered only in connection with dividend or interest reinvestment plans, 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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective on filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. [ ]

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	[ ]	**Accelerated filer**	[ ]
Non-accelerated filer	[ ] **(Do not check if a smaller reporting company)**	**Smaller reporting company**	[X]

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Amount to be registered/proposed maximum offering price per unit/proposed maximum aggregate offering price**	**Amount of registration fee**
Common Stock	(1)(2)	
Preferred Stock	(1)(2)	
Warrants	(1)(2)	
Rights	(1)(2)	
Units	(1)(2)	
Total	$ 7,000,000	$ 811.30(3)

(1) This registration statement covers an indeterminate number of shares of common stock, shares of preferred stock, warrants, rights, and units that may be sold by the registrant from time to time, for a maximum aggregate offering price of all securities not to exceed $7,000,000. Any securities registered hereunder may be sold separately or as units with other securities registered hereunder. The securities registered also include an indeterminate amount and number of shares of common stock as may be issued upon exercise of warrants, conversion of preferred stock, or pursuant to the anti-dilution provisions of any such securities. The securities registered also include an indeterminate amount and number of shares of preferred stock as may be issued upon exercise of warrants or pursuant to the anti-dilution provisions of any such securities.

(2) The proposed maximum aggregate offering price per class of security will be determined from time to time by the registrant in connection with the issuance by the registrant of the securities registered hereunder and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3 under the Securities Act of 1933, as amended (the “Securities Act”).

(3) The registration fee has been calculated in accordance with Rule 457(o) under the Securities Act.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the 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. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated November 15 , 2016.

PROSPECTUS

AKERS BIOSCIENCES, INC.

$7,000,000

Common Stock

Preferred Stock

Warrants

Units

We may offer and sell up to $7 million in the aggregate of the securities identified above from time to time in one or more offerings. This prospectus provides you with a general description of the securities.

Each time we offer and sell securities, we will provide a supplement to this prospectus that contains specific information about the offering and the amounts, prices and terms of the securities. The supplement may also add, update or change information contained in this prospectus with respect to that offering. You should carefully read this prospectus and the applicable prospectus supplement before you invest in any of our securities.

We may offer and sell the securities described in this prospectus and any prospectus supplement to or through one or more underwriters, dealers and agents, or directly to purchasers, or through a combination of these methods. If any underwriters, dealers or agents are involved in the sale of any of the securities, their names and any applicable purchase price, fee, commission or discount arrangement between or among them will be set forth, or will be calculable from the information set forth, in the applicable prospectus supplement. See the sections of this prospectus entitled "About this Prospectus" and "Plan of Distribution" for more information. No securities may be sold without delivery of this prospectus and the applicable prospectus supplement describing the method and terms of the offering of such securities.

INVESTING IN OUR SECURITIES INVOLVES RISKS. SEE THE "RISK FACTORS" ON PAGE 22 OF THIS PROSPECTUS AND ANY SIMILAR SECTION CONTAINED IN THE APPLICABLE PROSPECTUS SUPPLEMENT CONCERNING FACTORS YOU SHOULD CONSIDER BEFORE INVESTING IN OUR SECURITIES.

Our common stock is listed on the Nasdaq Capital Market under the symbol "AKER." On November 11, 2016, the last reported sale price of our common stock on the Nasdaq Capital Market was $3.25 per share.

The aggregate market value of our outstanding common stock held by non-affiliates is $15,080,848 based on 5,452,545 shares of outstanding common stock, of which 4,640,261 are held by non-affiliates, and a per share price of $3.25 based on the closing sale price of our common stock on November 11, 2016. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell our common stock in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below $75,000,000. We have not offered any securities pursuant to General Instruction I.B.6. of Form S-3 during the prior 12 calendar month period that ends on and includes the date of this prospectus.

We are an emerging growth company, as defined in Section 2(a) of the Securities Act of 1933.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2016.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the U.S. Securities and Exchange Commission, or the SEC, using a "shelf" registration process. By using a shelf registration statement, we may sell securities from time to time and in one or more offerings up to a total dollar amount of $7 million as described in this prospectus. Each time that we offer and sell securities, we will provide a prospectus supplement to this prospectus that contains specific information about the securities being offered and sold and the specific terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus with respect to that offering. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement, you should rely on the prospectus supplement. Before purchasing any securities, you should carefully read both this prospectus and the applicable prospectus supplement, together with the additional information described under the heading "Where You Can Find More Information; Incorporation by Reference."

We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We will not make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus and the applicable prospectus supplement to this prospectus is accurate as of the date on its respective cover, and that any information incorporated by reference is accurate only as of the date of the document incorporated by reference, unless we indicate otherwise. Our business, financial condition, results of operations and prospects may have changed since those dates.

When we refer to "Akers," "ABI", "we," "our," "us" and the "Company" in this prospectus, we mean Akers Biosciences, Inc., unless otherwise specified. When we refer to "you," we mean the holders of the applicable series of securities.

WHERE YOU CAN FIND MORE INFORMATION; INCORPORATION BY REFERENCE

Available Information

We file reports, proxy statements and other information with the SEC. Information filed with the SEC by us can be inspected and copied at the Public Reference Room maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of this information by mail from the Public Reference Room of the SEC at prescribed rates. Further information on the operation of the SEC's Public Reference Room in Washington, D.C. can be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site that contains reports, proxy and information statements and other information about issuers, such as us, who file electronically with the SEC. The address of that website is *http://www.sec.gov*.

Our web site address is *http://www.akersbio.com*. The information on our web site, however, is not, and should not be deemed to be, a part of this prospectus.

This prospectus and any prospectus supplement are part of a registration statement that we filed with the SEC and do not contain all of the information in the registration statement. The full registration statement may be obtained from the SEC or us, as provided below. Forms of the documents establishing the terms of the offered securities are or may be filed as exhibits to the registration statement. Statements in this prospectus or any prospectus supplement about these documents are summaries and each statement is qualified in all respects by reference to the document to which it refers. You should refer to the actual documents for a more complete description of the relevant matters. You may inspect a copy of the registration statement at the SEC's Public Reference Room in Washington, D.C. or through the SEC's website, as provided above.

Incorporation 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, 2015, filed with the SEC on March 30, 2016.

Our Annual Report on Form 10-K/A for the year ended December 31, 2015, filed with the SEC on March 30, 2016.

Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the SEC on May 12, 2016.

Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August, 11, 2016.

Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed with the SEC on November 14, 2016.

Our Current Reports on Form 8-K filed with the SEC on April 25, 2016, May 18, 2016, August 19, 2016, and October 12, 2016.

The description of our Common Stock contained in our Registration Statement on Form S-1, filed with the SEC on August 7, 2013, and 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.

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.

THE COMPANY

Overview

Akers Biosciences, Inc. (“Akers,” “ABI”, “we” or the “Company”) develops, manufactures, and supplies rapid, point-of-care screening and testing products designed to bring health-related information directly to the patient or clinician in a time- and cost-efficient manner. 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 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 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, including:

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

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 MarketsandMarkets report, *In-Vitro Diagnostic (IVD) Market (Applications, End-users & Types) Trends & Global Forecasts (Major & Emerging Markets — G7, Japan & BRIC) (2011 – 2016)*, published in January 2012 (the "IVD Market Report"), the use of such tests continues to grow as a result of increased patient awareness, patient self-testing, and the aging baby boomer population across the globe. Other major drivers for the growth of the *in vitro* diagnostic ("IVD") industry are a rise in the number of diseases like respiratory and hospital-acquired infections and a rise in chronic diseases such as diabetes, hypertension, cardiovascular diseases, and cancer, which allows for both an increased understanding of the molecular processes underlying many disease states and the opportunity for clinicians to quickly incorporate that targeted information into treatment decisions (e.g. companion testing). According to an article published on in vitro diagnostics by Medical Device and Diagnostic Industry ("MDDI") online in March 2013, in the past, the *in vitro* diagnostics industry has focused on developing tests that require significant time, skill, and often costly, specialized equipment. Patient specimens often had to be collected remotely and processed in a central laboratory with test results sent to a physician at a later date. This general protocol is not particularly well-adapted to the practice of medicine in a cost-effective, timely manner. The pressures on public health budgets and falling profits among third party payors such as insurers, necessitates an alternative approach to disease management. Moreover, the implementation of "Obamacare" in the United States mandates that tens of millions of additional people receive cost-effective healthcare. This reality has changed the American healthcare landscape as evidenced by the steady growth of the retail health clinic and urgent care 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 to or at the point-of-care and do not require the use of expensive equipment or a highly trained or specialized staff. As a result, an individual's current health status can immediately be incorporated into diagnostic and treatment decisions, improving the overall efficiency of the healthcare experience in the eyes of the patient, and ultimately the payor. In addition, in the developing world, the portability and ease-of-use of such point-of-care tests can serve to drastically improve the level of disease screening and subsequent patient care. We believe the benefits of our technology platforms are therefore well-suited to the diagnostic demands of third world countries that seek to deliver modern medical diagnosis in the midst of primitive infrastructures. In addition, some of our products have received FDA clearance for over-the-counter use and others that do not fall within the oversight of regulatory authorities have the added benefit of being self-tests that deliver personal health information on-demand. 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 into the home.

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 region and Eastern Europe are projected to be the fastest growing by Frost & Sullivan. The Company's main presence is in the United States, but the Company's recently executed joint venture, distribution and licensing agreements have initiated the Company's strategic move to the China and European Union marketplaces.

Strategy

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

Military/Government.

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

Technology Overview

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. These products contain microparticles that change color when a subject has a positive test result. The microparticles are coated with recently discovered agents that both decrease the time to result and provide a more defined color change when appropriate. MPC Biosensor-based products are packaged in small, disposable cartridges through which test subjects can easily blow for several seconds. In the United States, the MPC Biosensor Technology is protected by three United States patents pending, covering all MPC Biosensor products such as BreathScan and the Breath PulmoHealth "Check" suite of products. Breath Ketone "Check" has one US and one international patent 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. Akers' PIFA® Technology is currently protected by United States patent (5,827,749) covering all PIFA tests

such as Heparin, Malaria and Chlamydia. Specific to the PIFA Heparin tests, the Company has one international Patent (JP 4,931,821) granted in force, and three patent applications pending (one US and two international).

SMC Technology

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

Rapid Enzymatic Assay

Rapid Enzymatic Assay ("REA") technology enables the rapid detection of metabolites in blood and urine in assay formats that are easy-to-use and deliver quantitative or semi-quantitative results. Products that employ REA technology are primarily intended for pharmaceutical, nutritional and over-the-counter ("OTC") markets. Akers has three United States patents (8,808,639; 8,003,061; 8,425,859) for this technology covering our Tri-Cholesterol "Check" test, along with one US patent application pending.

minDNA ™ Technology

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

Sample Preparation Technology

Rapid Blood Cell Separation Technology

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 United States patents (7,896,167; 8,097,171) and one international patent (JP 4,885,134), with two additional international patent applications pending.

Product Portfolio

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 in the eyes of the patient, and ultimately the payer. In addition, in the developing world, the portability and ease-of-use of such point-of-care tests can serve to drastically improve the level of disease screening and subsequent patient care. We believe the benefits of our technology platforms are therefore well-suited to the diagnostic demands of countries in the developing world that seek to deliver modern medical diagnosis in the midst of primitive infrastructures. In addition, some of our products have received FDA 510(k) clearance for over-the-counter ("OTC") use. Other self-tests deliver personal health information of a non-medical nature, on-demand, and are not FDA regulated; these products are still manufactured in compliance with its ISO 13485 quality management system ("QMS-Compliant"). Akers believes that all its technology platforms and products address the needs of the evolving healthcare delivery system that is moving patient care closer to or in the home.

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

Our marketed and emerging products include:

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

Product	**Platform**	**Market/Pipeline**	**Not FDA-regulated; QMS-Compliant**	**FDA Clearance Required *Prescription Use/OTC***	**FDA Clearance Status Obtained/Needed**	**Description**

		Only			
PIFA® Heparin/PF4 & PIFA PLUSS® PF4	PIFA	Marketed	Prescription Use	Obtained	Rapid tests for Heparin/PF4 antibodies to detect an allergy to the widely used blood thinner, Heparin
PIFA PLUSS® Chlamydia	PIFA	Pipeline	Prescription Use	Needed	Rapid tests for a 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
PIFA PLUSS TroponinI	PIFA	Pipeline	Prescription Use	Needed	Rapid test for the diagnosis of a myocardial infarction

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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 US consumers; CE certification is not required to market the product in the EU given that BreathScan® results are not used to diagnose any medical conditions. However, the Company has received certification under the French Standard, NF X 20-702 which defines the specifications that chemical breath alcohol detectors must meet in order to be sold to consumers in France. In addition, 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 .02%, .04%, .05% and .08% blood alcohol concentrations ("BACs") and provide users with a test result in two minutes. If the crystals in the interior of the device change from yellow to aqua, the user has tested positive for the specific alcohol level. Should the crystals remain yellow, the result is negative.

The Company's proprietary breath alcohol detection technology is paired with the quantitative precision of an electronic analyzer in the BreathScan® PRO alcohol detection system. As with all BreathScan® products, the test subject exhales into a specially calibrated, BreathScan® PRO detector. The testing coordinator then inserts the used detector into the BreathScan® PRO Digital Analyzer. After two minutes, the Analyzer's sophisticated optics calculate the subject's BAC; the detectable range spans from 0.00% to 1.50% BAC. Unlike other electronic breathalyzers, BreathScan® PRO never requires recalibration so it is in "ready" mode at all times. In 2011, the Company received FDA over-the-counter clearance for the system, providing a commercialization path in the 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. Unlike the aforementioned BreathScan® disposable detectors, BreathScan® PRO is required to have a CE-Mark as the system includes an electronic component, namely the digital analyzer.

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

Other Emerging MPC Platform Products

The Company's MPC Biosensor technology is being applied to the development of products that serve the nutraceutical and weight loss marketplaces. As a category, these disposable screening tests are exempt from FDA 510(k) premarket clearances. Biomarkers related to various metabolic processes can be measured in breath condensate. As a result, Akers has used its proprietary, easy-to-use platform to design disposable breath tubes 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 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 Breath Ketone “Check” disposable breath tube for the diagnosis of ketoacidosis in diabetics. Breath Ketone “Check” is being designed to provide real-time information that allows diabetics to determine if they have a more severe level of ketone (acid) build up in their body that can cause a life-threatening medical emergency called ketoacidosis. The estimated 28.5 million Type I (insulin-dependent) diabetics worldwide are at particular risk for ketoacidosis and require routine monitoring of their ketone levels. To date, the medical industry relies on blood and urine-based ketone testing methods, which are invasive and/or inconvenient. Since breath and blood ketone levels are closely correlated, the Breath Ketone “Check” is designed to offer healthcare professionals and their patients a convenient, accurate method, which can be completed anytime, anywhere, to quickly determine if an individual’s ketone level is approaching a dangerous threshold requiring medical attention. Since this product requires FDA 510(k) clearance, the Company continues to develop its technical file and complete required clinical studies to complete the regulatory submission.

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 Ketone “Check” and the Breath PulmoHealth “Check” suite of products will require the development of individual clinical trial programs to facilitate eventual FDA 510(k) submissions. The Company has self-certified Breath Ketone “Check” 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, PIFA PLUSS® PF4, and a variety of rapid Infectious Disease screening tests which target markets in the developing world.

PIFA® Heparin/PF4 Rapid Assay and PIFA PLUSS® PF4 remain the only FDA-cleared rapid manual assays that quickly 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. According to "*Current Concepts Review: Heparin-Induced Thrombocytopenia"*, published by Foot and Ankle International in 2008 (the "HIT Report"), patients with HIT are at risk of developing limb- and life-threatening complications, so the timely test result provided by 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 approximately four hours of technician time to complete the 20+ assay test procedure in-house, Clinicians were subjected to a 24-to-72 hour turnaround time if the HIT-antibody determination was outsourced to a reference laboratory. Especially in the latter scenario, the patient information obtained is retrospective in nature as the HIT-antibody result cannot be factored into time-sensitive diagnostic and treatment decisions. The Company has also introduced PIFA PLUSS PF4 to U.S. hospitals to further improve the rate at which healthcare professionals can obtain a HIT-antibody result.

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

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

Other PIFA® Platform Assays in development

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

Akers' PIFA® technology provides a testing format that meets the aforementioned criteria. The Company can quickly apply the PIFA PLUSS® methodology to its infectious disease testing products to further consolidate the test result turn-around time and eliminate the need for any specialized sample preparation personnel or equipment which are usually not at the disposal of healthcare professionals in remote locations. To date, the Company's custom reagent work has focused on a variety of infectious diseases, markers of cardiovascular disease, and blood typing tests including the following:

Chlamydia

Malaria

Dengue Fever

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 for professional use. At present, the Company's Tri-Cholesterol "Check" business strategy is to focus on distribution activities in countries within the developing world. Once Akers completes an assessment of opportunities within the region, it intends to determine if additional clinical data outside of the robust technical file assembled to support FDA-clearance and CE-certification will be required for product marketing.

The REA Technology is currently protected by 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 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. US medical device manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products are known as current good manufacturing practices ("cGMP's"). cGMP requirements for devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. To date, we have not experienced any significant difficulty locating and obtaining the materials necessary to fulfill our production requirements.

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 Industries, Inc. ("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, 2015 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, the Company's Non-Executive Co-Chairman, 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 Ketone “Check” ®
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
ligand assay method	US	5,827,749	Manufacture		PIFA® Heparin/PF4 Rapid Assay; PIFA PLUSS® PF4; PIFA PLUSS® Infectious Diseases Rapid Assays
methods and kits for detecting heparin/platelet factor 4 antibodies	Japan	4,931,821	Manufacture	10/4/2025	PIFA® Heparin/PF4 Rapid Assay; PIFA PLUSS® PF4
test strip card	US	8,003,061	Manufacture	5/6/2024	Tri-Cholesterol “Check”®
test strip card	US	8,425,859	Manufacture	5/6/2024	Tri-Cholesterol “Check”®
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 Ketone "Check" 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 for of its commercialized products/product components: PIFA Heparin/PF4 Rapid Assay; Heparin/PF4 Serum Panels; Tri-Cholesterol "Check" and BreathScan PRO Detectors,

Analyzer Field Kit, Starter Kit and Blow Bags.

Third-Party Reimbursement

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

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

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

Other U.S. Regulation

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

Employees

We currently employ 32 full-time equivalent employees, contractors or consultants, which include 12 in research and development, 4 in general and administrative, 5 in sales and marketing and 11 in direct and indirect manufacturing. We also engage a number of temporary employees and consultants. None of our employees are represented by a labor union or are a party to a collective bargaining agreement. We believe that we have good relations with our employees.

Corporate Information

We were incorporated in the State of New Jersey in 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 mailing address of our headquarters is 201 Grove Road, Thorofare, New Jersey 08086, and our telephone number at that location is (856) 848-8698.

RISK FACTORS

Investment in any securities offered pursuant to this prospectus and the applicable prospectus supplement involves risks. You should carefully consider the risk factors incorporated by reference to our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or Current Reports on Form 8-K we file after the date of this prospectus, and all other information contained or incorporated by reference into this prospectus, as updated by our subsequent filings under the Exchange Act, and the risk factors and other information contained in the applicable prospectus supplement before acquiring any of such securities. The occurrence of any of these risks might cause you to lose all or part of your investment in the offered securities.

SPECIAL NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties, principally in the sections entitled “Risk Factors.” All statements other than statements of historical fact contained in this prospectus, including statements regarding future events, our future financial performance, business strategy and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “
“plans,” “potential,” “predicts,” “should,” or “will” or the negative of these terms or other comparable terminology. Although w
do not make forward looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under “Risk Factors” or elsewhere in this prospectus, which may cause our or our industry’s actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements.

Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by which, that performance or those results will be achieved. Forward-looking statements are based on information available at the time they are made and/or management’s good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from what is expressed in or suggested by the forward-looking statements.

Forward-looking statements speak only as of the date they are made. You should not put undue reliance on any forward-looking statements. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information, except to the extent required by applicable securities laws. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

USE OF PROCEEDS

We intend to use the net proceeds from the sale of the securities as set forth in the applicable prospectus supplement.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to, our articles of incorporation and bylaws, which have been publicly filed with the SEC. See “Where You Can Find More Information; Incorporation by Reference.”

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.

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.

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 11, 2016 there were no shares of the Company's Series A Preferred Stock issued and outstanding.

Holders of Series A Preferred Stock shall be entitled to receive preferential dividends at a rate of $0.00135 per share of Series A Preferred Stock per annum. Such dividends shall compound annually and be fully cumulative, and shall accumulate from the date of original issuance of the Series A Preferred Stock.

The holders of Series A Preferred Stock are entitled to the number of votes into which their shares of Series A Preferred Stock are convertible and votes together with the Company's common stock as a class. The Series A Preferred Stock is convertible at any time into common stock, at the rate of 0.0320512 shares of common stock for each 1 share of Series A Preferred Stock, for an additional payment of $0.05 per each 1 share of converted Series A Preferred Stock, subject to adjustment (the "Conversion Price").

If the Company issues any additional shares of its common stock, options or convertible securities, excluding any securities issued as compensation or options issued in connection with an employee incentive plan approved by the board of directors (the "Additional Shares"), for consideration less than $0.0145, then the Conversion Price shall be reduced, concurrently with such issue, to the consideration per share received by the Company for such issuance of Additional Shares; provided that if such issuance or deemed issuance was without consideration, the Company shall be deemed to have received an aggregate of $0.001 of consideration for all such Additional Shares.

In the event of (i) any liquidation, dissolution or winding up of the affairs of the Company, whether voluntary or involuntary (each a “Liquidation”), (ii) merger, consolidation or transfer of voting control in which the stockholders immediately prior to such transaction do not own securities representing a majority of the voting power of the surviving entity or its parents immediately following such transaction, but excluding (x) any transaction effected exclusively to change the domicile of the Company, or (y) any transaction effected principally for bona fide equity financing purposes in which cash is received by the Corporation or indebtedness is cancelled or converted or a combination thereof (an “Acquisition”), (iii) a sale, lease, or other disposition of all or substantially all of the assets of the Company (an “Asset Transfer”)(items (i), (ii) and (iii), each a “Liquidation Event”), the holder of Series A Preferred Stock shall be entitled to receive, prior and in preference to holders of common stock, assets of the Company available for distribution to the holders of capital stock of the Company up to and including any amounts of any dividends due and owing.

For so long as the Series A Preferred Stock is outstanding, the holders of the Series A Preferred, provided that the holders own more than 15% of the Company’s common stock or all of the Series A Preferred Stock, voting as a separate class, shall be entitled to elect one (1) member of the board at each election of directors.

For so long as the Series A Preferred Stock is outstanding, the approval of a majority of holders of the Series A Preferred Stock, voting as a separate class, shall be required to take certain actions, including but not limited to, (i) any amendment alteration or repeal to certificate of Incorporation or Bylaws so as to adversely affect the rights of the Series A Preferred Stock, (ii) any authorization or designation of securities ranking on a parity with or senior to the Series a Preferred Stock and (iii) any increase or decrease to the number of members of the board.

Options and Warrants

As of November 11, 2016, we had 259,000 shares issuable upon exercise of outstanding options and no shares issuable upon the exercise of warrants. There are no other outstanding warrants or options at this time.

Anti-Takeover Provisions

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.

The NASDAQ Capital Market Listing

Our common stock is listed on the NASDAQ Capital Market under the symbol “AKER.”

Transfer Agent and Registrar

The U.S. transfer agent and registrar for our common stock is Vstock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598.

DESCRIPTION OF WARRANTS

General

We may issue warrants to purchase shares of our common stock and preferred stock in one or more series together with other securities or separately, as described in the applicable prospectus supplement. Below is a description of certain general terms and provisions of the warrants that we may offer. Particular terms of the warrants will be described in the warrant agreements to be entered into by the Company, a warrant agent to be named by the Company, and the holders from time to time of the warrants and the prospectus supplement relating to the warrants. Copies of the form agreement for each warrant and the warrant certificate, if any, reflecting the provisions to be included in such agreements that will be entered into with respect to a particular offering of each type of warrant, will be filed with the SEC and incorporated by reference as exhibits to the registration statement of which this prospectus forms a part. You should read the applicable warrant agreement for additional information before you purchase any of our warrants.

The prospectus supplement relating to any warrants we offer will describe the specific terms relating to the offering. These terms may include some or all of the following:

- the specific designation and aggregate number of, and the price at which we will issue, the warrants;
- the currency or currency units in which the offering price, if any, and the exercise price are payable;
- the designation, amount and terms of the securities purchasable upon exercise of the warrants;
- if applicable, the exercise price for shares of our common stock and the number of shares of common stock to be received upon exercise of the warrants;
- if applicable, the exercise price for shares of our preferred stock, the number of shares of preferred stock to be received upon exercise, and a description of that series of our preferred stock;
- the date on which the right to exercise the warrants will begin and the date on which that right will expire or, if you may not continuously exercise the warrants throughout that period, the specific date or dates on which you may exercise the warrants;
- whether the warrants will be issued in fully registered form or bearer form, in definitive or global form or in any combination of these forms, although, in any case, the form of a warrant included in a unit will correspond to the form of the unit and of any security included in that unit;
- any applicable material U.S. federal income tax consequences;

the identity of the warrant agent for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars or other agents;

the proposed listing, if any, of the warrants or any securities purchasable upon exercise of the warrants on any securities exchange;

if applicable, the date from and after which the warrants and the common stock and preferred stock will be separately transferable;

if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;

the procedures and conditions relating to the exercise of the warrants;

information with respect to book-entry procedures, if any;

the triggering event and the terms upon which the exercise price and the number of underlying securities that the warrants are exercisable into may be adjusted;

the anti-dilution provisions of the warrants, if any;

any redemption or call provisions;

whether the warrants may be sold separately or with other securities as parts of units; and

any additional terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

Until the warrants are exercised, holders of the warrants will not have any rights of holders of the underlying securities.

Outstanding Warrants

As of November 11, 2016, we had no outstanding warrants to purchase shares of common stock.

DESCRIPTION OF RIGHTS

We may issue rights to our stockholders to purchase shares of our common stock or preferred stock described in this prospectus. We may offer rights separately or together with one or more additional rights, preferred stock, common stock, warrants or any combination of those securities in the form of units, as described in the applicable prospectus supplement. Each series of rights will be issued under a separate rights agreement to be entered into between us and a bank or trust company, as rights agent. The rights agent for any rights we offer will be set forth in the applicable prospectus supplement. The rights agent will act solely as our agent in connection with the certificates relating to the rights of the series of certificates and will not assume any obligation or relationship of agency or trust for or with any holders of rights certificates or beneficial owners of rights. The following description sets forth certain general terms and provisions of the rights to which any prospectus supplement may relate. The particular terms of the rights to which any prospectus supplement may relate and the extent, if any, to which the general provisions may apply to the rights so offered will be described in the applicable prospectus supplement. To the extent that any particular terms of the rights, rights agreement or rights certificates described in a prospectus supplement differ from any of the terms described below, then the terms described below will be deemed to have been superseded by that prospectus supplement. We encourage you to read the applicable rights agreement and rights certificate for additional information before you decide whether to purchase any of our rights.

The prospectus supplement relating to any rights that we offer will include specific terms relating to the offering, including, among other matters:

- the date of determining the stockholders entitled to the rights distribution;
- the aggregate number of shares of common stock, preferred stock or other securities purchasable upon exercise of the rights;
- the exercise price;
- the aggregate number of rights issued;
- whether the rights are transferrable and the date, if any, on and after which the rights may be separately transferred;
- the date on which the right to exercise the rights will commence, and the date on which the right to exercise the rights will expire;
- the method by which holders of rights will be entitled to exercise;
- the conditions to the completion of the offering;
- the withdrawal, termination and cancellation rights;
- whether there are any backstop or standby purchaser or purchasers and the terms of their commitment;

whether stockholders are entitled to oversubscription right;

any U.S. federal income tax considerations; and

any other terms of the rights, including terms, procedures and limitations relating to the distribution, exchange and exercise of the rights.

If less than all of the rights issued in any rights offering are exercised, we may offer any unsubscribed securities directly to persons other than stockholders, to or through agents, underwriters or dealers or through a combination of such methods, including pursuant to standby arrangements, as described in the applicable prospectus supplement. In connection with any rights offering, we may enter into a standby underwriting or other arrangement with one or more underwriters or other persons pursuant to which such underwriters or other persons would purchase any offered securities remaining unsubscribed for after such rights offering.

DESCRIPTION OF UNITS

We may issue units consisting of any combination of the other types of securities offered under this prospectus in one or more series. We may evidence each series of units by unit certificates that we will issue under a separate agreement. We may enter into unit agreements with a unit agent. We will indicate the name and address of the unit agent in the applicable prospectus supplement relating to a particular series of units.

The following description, together with the additional information included in any applicable prospectus supplement, summarizes the general features of the units that we may offer under this prospectus. You should read any prospectus supplement and any free writing prospectus that we may authorize to be provided to you related to the series of units being offered, as well as the complete unit agreements that contain the terms of the units. Specific unit agreements will contain additional important terms and provisions and we will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from another report that we file with the SEC, the form of each unit agreement relating to units offered under this prospectus.

If we offer any units, certain terms of that series of units will be described in the applicable prospectus supplement, including, without limitation, the following, as applicable:

- the title of the series of units;
- identification and description of the separate constituent securities comprising the units;
- the price or prices at which the units will be issued;
- the date, if any, on and after which the constituent securities comprising the units will be separately transferable;
- a discussion of certain United States federal income tax considerations applicable to the units; and
- any other terms of the units and their constituent securities.

PLAN OF DISTRIBUTION

We may sell the securities from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods or through underwriters or dealers, through agents and/or directly to one or more purchasers. The securities may be distributed from time to time in one or more transactions:

at a fixed price or prices, which may be changed;

at market prices prevailing at the time of sale;

at prices related to such prevailing market prices; or

at negotiated prices.

Each time that we sell securities covered by this prospectus, we will provide a prospectus supplement or supplements that will describe the method of distribution and set forth the terms and conditions of the offering of such securities, including the offering price of the securities and the proceeds to us, if applicable.

Offers to purchase the securities being offered by this prospectus may be solicited directly. Agents may also be designated to solicit offers to purchase the securities from time to time. Any agent involved in the offer or sale of our securities will be identified in a prospectus supplement.

If a dealer is utilized in the sale of the securities being offered by this prospectus, the securities will be sold to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale.

If an underwriter is utilized in the sale of the securities being offered by this prospectus, an underwriting agreement will be executed with the underwriter at the time of sale and the name of any underwriter will be provided in the prospectus supplement that the underwriter will use to make resales of the securities to the public. In connection with the sale of the securities, we or the purchasers of securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for which they may act as agent. Unless otherwise indicated in a prospectus supplement, an agent will be acting on a best efforts basis and a dealer will purchase securities as a principal, and may then resell the securities at varying prices to be determined by the dealer.

Any compensation paid to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers will be provided in the applicable prospectus supplement. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act, or to contribute to payments they may be required to make in respect thereof and to reimburse those persons for certain expenses.

Any common stock will be listed on the Nasdaq Capital Market, but any other securities may or may not be listed on a national securities exchange. To facilitate the offering of securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involve the sale by persons participating in the offering of more securities than were sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option, if any. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

We may engage in at the market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act.

In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The

third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

We do not make any representation or prediction as to the direction or magnitude of any effect that the transactions described above might have on the price of the securities. In addition, we do not make any representation that underwriters will engage in such transactions or that such transactions, once commenced, will not be discontinued without notice.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

To comply with applicable state securities laws, the securities offered by this prospectus will be sold, if necessary, in such jurisdictions only through registered or licensed brokers or dealers. In addition, securities may not be sold in some states unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business for which they receive compensation.

LEGAL MATTERS

Lucosky Brookman LLP will pass upon certain legal matters relating to the issuance and sale of the securities offered hereby on behalf of Akers Biosciences, Inc. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

EXPERTS

Morison Cogen LLP, independent registered public accounting firm, has audited the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, as set forth in their report which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Morison Cogen LLP’s report, given on their authority as experts in accounting and auditing.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. ***Other Expenses of Issuance and Distribution***

The following is an estimate of the expenses (all of which are to be paid by the registrant) that we may incur in connection with the securities being registered hereby.

SEC registration fee	$811.30
FINRA filing fee	*
Printing expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue Sky, qualification fees and expenses	*
Transfer agent fees and expenses	*
Trustee fees and expenses	*
Warrant agent fees and expenses	*
Miscellaneous	*
Total	$*

* These fees are calculated based on the securities offered and the number of issuances and accordingly cannot be estimated at this time.

Item 15. ***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 16. ***Exhibits***

(a) *Exhibits*

A list of exhibits filed with this registration statement on Form S-3 is set forth on the Exhibit Index and is incorporated herein by reference.

Item 17. ***Undertakings***

(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 the 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 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(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;

Provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(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:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *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 effective date, 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 effective date.

(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.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement 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.

(h) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission 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.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Thorofare, New Jersey, on the 15th day of November , 2016.

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)

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John J. Gormally and Gary M. Rauch, or either of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to file and sign any and all amendments, including post-effective amendments and any registration statement for the same offering that is to be effective under Rule 462(b) of the Securities Act, to this registration statement, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Thomas Knox **Thomas Knox**	Chairman of the Board	November 15, 2016
/s/ Raymond Akers, Jr. **Raymond Akers, Jr.**	Director	November 15, 2016
/s/ Brandon Knox **Brandon Knox**	Director	November 15, 2016
/s/ Robert E. Andrews **Robert E. Andrews**	Director	November 15, 2016
/s/ Dr. Raza Bokhari **Dr. Raza Bokhari**	Director	November 15, 2016

EXHIBIT INDEX

Exhibit Number	Description
1.1*	Form of Underwriting Agreement.
3.1	Amended & Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.2	Amendment to Certificate of Incorporation dated June 2, 2008 (incorporated herein by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.3	Amendment to Certificate of Incorporation, Certificate of Designation of Series A Preferred Stock, dated September 21, 2012. (incorporated herein by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.4	Amendment to Certificate of Incorporation dated January 22, 2013 (incorporated herein by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.5	Amended and Restated By-laws dated August 5, 2013 (incorporated herein by reference to Exhibit 3.5 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
4.1*	Form of Certificate of Designation.
4.2*	Form of Preferred Stock Certificate.
4.3*	Form of Warrant Agreement.
4.4*	Form of Warrant Certificate.
4.5*	Form of Rights Agreement.
4.6*	Form of Units Agreement.
4.7*	Form of Note.
5.1	Opinion of Lucosky Brookman LLP.
23.1	Consent of Morison Cogen LLP.
23.2	Consent of Lucosky Brookman LLP (Included in Exhibit 5.1).

24.1 Powers of Attorney (incorporated by reference to the signature page hereto).

* To be filed by reference in connection with the offering of the securities.