

Akers Biosciences Inc  
Form 424B5  
January 06, 2017

**Filed Pursuant to Rule 424(b)(5)**  
**Registration No. 333-214214**

**The information in this preliminary prospectus supplement is not complete and may be changed. A registration statement relating to these securities became effective under the Securities Act of 1933, as amended. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and we are not soliciting an offer to buy these securities, in any jurisdiction where the offer or sale is not permitted.**

PRELIMINARY PROSPECTUS SUPPLEMENT SUBJECT TO COMPLETION DATED JANUARY 6, 2017  
(To the Prospectus dated November 16, 2016)

**Shares of Common Stock**  
**Warrants to Purchase up to**  
Shares of Common Stock

**Akers Biosciences, Inc.**

Akers Biosciences, Inc. is offering \_\_\_\_\_ shares of common stock and warrants to purchase up to \_\_\_\_\_ shares of common stock pursuant to this prospectus supplement and the accompanying prospectus.

Our common stock is listed on the AIM under the symbol “AKR.L” and on the NASDAQ Capital Market under the symbol “AKER.” On January 5, 2017, the last reported sale price of our common stock on the NASDAQ Capital Market was \$1.75 per share. There is no established public trading market for the warrants and we do not expect a market to develop.

Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities in a public primary offering with a value of more than one-third of the aggregate market value of our common stock held by non-affiliates in any twelve-month period, so long as the aggregate market value of our common stock held by non-affiliates remains

below \$75,000,000. The aggregate market value of our outstanding common stock held by non-affiliates pursuant to General Instruction I.B.6 of Form S-3 was approximately \$15,312,861, which was calculated based on 5,452,545 shares of common stock outstanding, as of January 5, 2017, of which 4,640,261 shares were held by non-affiliates, and a price per share of \$3.30, which was the closing sale price of our common stock on the NASDAQ Capital Market on November 14, 2016. Other than the shares of common stock and warrants offered pursuant to this prospectus supplement, 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 hereof.

**Our business and an investment in our securities involve a high degree of risk. See “Risk Factors” beginning on page S-3 of this prospectus supplement.**

**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 or any accompanying prospectus supplement. Any representation to the contrary is a criminal offense.**

	<b>Combined Per Share and Half-Warrant</b>	<b>Total</b>
Public offering price	\$	\$
Underwriting discount <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to us	\$	\$

<sup>(1)</sup> The underwriters will receive compensation in addition to the underwriting discount. See “Underwriting” beginning on page S-26 of this prospectus supplement for a description of the compensation payable to the underwriters.

We have granted a 45-day option to the representative of the underwriters to purchase up to \_\_\_\_\_ additional shares of common stock and/or additional warrants to purchase up to \_\_\_\_\_ shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver our shares and warrants to purchasers in the offering on or about \_\_\_\_\_, 2017.

**Joseph Gunnar & Co.**

, 2017





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## **ABOUT THIS PROSPECTUS SUPPLEMENT**

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus concerning Akers Biosciences, Inc. The second part is the accompanying prospectus, dated November 16, 2016, including the documents incorporated by reference therein, which provides more general information, some of which may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined together with all documents incorporated by reference. If the description of the offering varies between this prospectus supplement, on the one hand, and the accompanying prospectus, or in any document incorporated by reference that was filed with the Securities and Exchange Commission, or SEC, before the date of this prospectus supplement, on the other hand, you should rely on the information contained in this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document incorporated by reference into this prospectus supplement or the accompanying prospectus — the statement in the document having the later date modifies or supersedes the earlier statement. You should rely only on the information contained in or incorporated by reference into this prospectus supplement or contained in or incorporated by reference into the accompanying prospectus to which we have referred you. We have not authorized anyone to provide you with information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. We may authorize one or more “free writing prospectuses” (i.e. written communications concerning the offering that are not part of this prospectus supplement) that may contain certain material information relating to this offering. The information contained in, or incorporated by reference into, this prospectus supplement and contained in, or incorporated by reference into, the accompanying prospectus is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of securities. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you under the captions “Where You Can Find More Information” and “Incorporation of Documents by Reference” in this prospectus supplement and in the accompanying prospectus.

We are offering to sell, and are seeking offers to buy, securities only in jurisdictions where such offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of securities in certain jurisdictions or to certain persons within such jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about and observe any restrictions relating to the offering of securities and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and any accompanying prospectus, including the documents that we incorporate by reference, contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

In some cases, you can identify forward-looking statements by terminology, such as “expects,” “anticipates,” “intends,” “estimates,” “plans,” “believes,” “seeks,” “may,” “should,” “could” or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in such statements. Any forward-looking statements are only estimates or predictions of future events based on information currently available to our management and management’s current beliefs about the potential outcome of future events.

You should read this prospectus supplement, the accompanying prospectus and the documents that we reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus supplement forms a part, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this prospectus supplement and any accompanying prospectus is accurate as of the date on the front cover of this prospectus supplement. Because the risk factors referred to above, as well as the risk factors referred to on page S-iii of this prospectus supplement and incorporated herein by reference, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and except as may be required under applicable securities laws, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this prospectus supplement and the accompanying prospectus, and particularly our forward-looking statements, by these cautionary statements.



## PROSPECTUS SUPPLEMENT SUMMARY

*This summary highlights information contained elsewhere or incorporated by reference into this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our securities. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the “Risk Factors” section contained in this prospectus supplement and our consolidated financial statements and the related notes and the other documents incorporated by reference into this prospectus supplement and the accompanying prospectus. Unless we have indicated otherwise or the context otherwise requires, references in this prospectus supplement, the accompanying prospectus or the documents incorporated by reference herein and therein to the “Company,” “Akers,” “we,” “us” and “our” refer to Akers Biosciences, Inc. and its subsidiaries.*

### Overview

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

### **Recent Developments**

On December 1, 2016, the Company signed a distribution agreement with First Check Diagnostics, LLC, a major global diagnostic device and service provider, to serve as the exclusive distributor of the Company's rapid cholesterol self-test in the United States under the "First Check" brand. The test is the only combined rapid test that provides an estimate of a person's total cholesterol and their High Density Lipoprotein ('HDL' or 'good cholesterol') levels, which in turn allows for an estimate of a person's Low Density Lipoprotein ('LDL' or 'bad cholesterol') levels.

As described in the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016, the Company recognized no revenue for PIFA Heparin/PF4 products from Novotek during the three months ended September 30, 2016. The remaining products were manufactured during the three months ended December 31, 2016 and the remaining \$2,000,000 of revenue under the order will be recognized when the criteria for the recognition of revenue is met.

## Corporate Information

The Company was incorporated under the laws of the State of New Jersey on March 9, 1989 under the name A.R.C. Enterprises, Inc. The Company changed its name to Akers Research Corporation on September 28, 1990. On February 24, 1996 the Company changed its name from Akers Research Corporation to Akers Laboratories, Inc. On March 26, 2002 the Company changed its name to Akers Biosciences, Inc. Our principal executive office is located at 201 Grove Road Thorofare, New Jersey USA 08086. Our phone number is (856) 848-8698 and our website is [www.akersbio.com](http://www.akersbio.com). Information contained in our website does not form part of the prospectus and is intended for informational purposes only.

## The Offering

Common stock offered by us	shares of common stock (or purchase additional shares in full).	shares if the representative exercises its option to
Warrants Offered	Warrants to purchase up to shares of common stock. Each warrant will have an exercise price of \$ per share, will be exercisable upon issuance and will expire on the date that is five years from the date of issuance. This prospectus also includes the offering of the shares of common stock issuable upon exercise of the warrants.	
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to additional shares and/or additional warrants at the public offering price less underwriting discounts and commissions.	
Common stock to be outstanding after this offering	shares.	
Use of Proceeds	We currently intend to use the net proceeds from this offering for growth and working capital. See "Use of Proceeds" on page S-23 for further information.	
Risk Factors	See "Risk Factors" beginning on page S-3 of this prospectus supplement and other information included or incorporated by reference into this prospectus supplement and the accompanying prospectus for a discussion of factors you should carefully consider before investing in our securities.	
NASDAQ Capital Market trading symbol	AKER	
AIM symbol	AKR.L	

Unless we indicate otherwise, all information in this prospectus supplement is based on 5,452,545 shares of common stock outstanding as of January 5, 2017 and;

assumes no exercise by the underwriters of their option to purchase up to an additional        shares of common stock and/or additional warrants to purchase up to        shares of common stock to cover overallotment, if any;

excludes the shares issuable upon the exercise of warrants sold in this offering;

excludes 259,000 shares of our common stock issuable upon exercise of outstanding stock options under our equity incentive plan at a weighted average exercise price of \$4.23 per share, with 73,292 shares remaining available for future grant under such plans;

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## RISK FACTORS

*You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks we are not presently aware of or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the risk factors and other information contained or incorporated by reference into this prospectus supplement and the accompanying prospectus, specifically including the risk factors contained in our Quarterly Report on Form 10-Q for the period ended September 30, 2016 filed with the SEC on November 14, 2016, Quarterly Report on Form 10-Q for the period ended June 30, 2016 filed with the SEC on August 11, 2016, Quarterly Report on Form 10-Q for the period ended March 31, 2016 filed with the SEC on May 12, 2016, our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on March 30, 2016, Annual Report on Form 10-K/A for the year ended December 31, 2015 filed with the SEC on March 30, 2016 and the financial statements and related notes filed therewith.*

### Risks Relating to this Offering

***Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.***

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that you do not agree with or that do not improve our results of operations or enhance the value of our common stock (see “Use of Proceeds”). Our failure to apply these funds effectively could have a material adverse effect on our business and cause the price of our common stock to decline.

***You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.***

Since the price per share of our common stock being offered is higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the public offering price of \$ per share, and after deducting the underwriting discount and estimated offering expenses payable by us, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of \$ per share in the net tangible book value of the common stock. See the section entitled “Dilution” in this prospectus supplement for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

***Future sales of substantial amounts of our common stock could adversely affect the market price of our common stock.***

Future sales of substantial amounts of our common stock, or securities convertible or exchangeable into shares of our common stock, into the public market, including shares of our common stock issued upon exercise of options, or perceptions that those sales could occur, could adversely affect the prevailing market price of our common stock and our ability to raise capital in the future.

***There is no public market for the warrants to purchase shares of our common stock being offered in this offering.***

There is no established public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any national securities exchange or other nationally recognized trading system, including the NASDAQ Capital Market. Without an active market, the liquidity of the warrants will be limited.

***Due to the speculative nature of warrants, there is no guarantee that it will ever be profitable for investors in the offering to exercise their warrants.***

The warrants offered hereby do not confer any rights of share ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire our common stock at a fixed price for a limited period of time. Investors in this offering may exercise their right to acquire the shares of common stock underlying their warrants at any time after the date of issuance by paying an exercise price of \$ per share prior to their expiration on the date that is five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. See “Description of the Securities We are Offering.” There can be no assurance that the market price of our common stock will ever equal or exceed the exercise price of the warrants, and, consequently, whether it will ever be profitable for investors to exercise their warrants.

## **Risks Related to the Company and Our Business**

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

We have recorded a net loss attributable to common stockholders in most reporting periods since our inception. Our net loss for the nine months ended September 30, 2016 and 2015 were \$2,207,707 and \$5,734,921, respectively. Our

accumulated deficit at September 30, 2016 was \$96,383,706. Losses are expected to continue for the foreseeable future. The Company expects to continue to have development costs as it develops its next generation of products. We may never achieve profitable operations or positive cash flow.

***Our operating expenses will increase as we make further expenditures to enhance and expand our operations in order to support additional growth in our business.***

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

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

As of December 31, 2015, we had two principal customers; Cardinal Health, Inc. (“Cardinal Health”) and Fisher Healthcare (“Fisher”) each of which has the non-exclusive right to distribute PIFA Heparin/PF4 Rapid Assays within the U.S.

For the nine months ended September 30, 2016, Cardinal Health and Fisher accounted for approximately 59% of the Company’s product revenue.

Because of our dependence on a limited number of key customers, the loss of a major customer (or loss of a key program with a major customer), or any significant reduction in orders by a major customer or termination of the any of their distribution agreements would materially affect our business, our results of operations and our financial condition. We expect that sales to relatively few customers will continue to account for a significant percentage of our net sales for the foreseeable future, however there can be no assurance that any of these customers or any of our other customers will continue to utilize our products or our services at current levels.

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

As of September 30, 2016, three customers accounted for 38% of our trade receivables. In the case of insolvency by one of our significant customers, a trade receivable with respect to that customer might not be collectible, might not be fully collectible, or might be collectible over longer than normal terms, each of which could adversely affect our financial position.

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

We use a diverse and broad range of raw materials in the manufacturing of our products. We purchase all of our raw materials and select items, such as packaging, from external suppliers. In addition, we purchase some supplies from single sources for reasons of proprietary know-how, quality assurance, sole source availability, or due to regulatory qualification requirements and disruption of these sources could have, at a minimum, a temporary adverse effect on shipments and the financial results of the Company. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. To date, we have not experienced any significant difficulty locating and obtaining the materials necessary to fulfill our production requirements. One supplier accounted for 61% of the Company’s total purchases during the nine months ended September 30, 2016. Any prolonged inability to obtain



certain materials or components could have an adverse effect on the Company's financial condition or results of operations and could result in damage to its relationships with its customers and, accordingly, adversely affect the Company's business.

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

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

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

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

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

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

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

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

We can manufacture and sell our products only if we comply with certain regulations of government agencies. As a U.S. manufacturer, we must operate our production facility in accordance with the requirements established by the FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act). As such, we have implemented a quality system that is intended to comply with applicable regulations. Our manufacturing plant is subject to periodic inspections by the FDA, and at last inspection, the facility was found to be in substantial compliance with current good manufacturing practice (cGMP) requirements. Although the Company is dedicated to remaining in compliance with

such practices, the cGMP requirements could change and negatively impact our ability to manufacture our products without modifications to our operating procedures or changes to our equipment or human resource allocations which may materially affect our business.

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

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

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the efficacy and potential advantages over alternative treatments;

the ability to offer our products for sale at competitive prices;

the willingness of the target population to accept and adopt our products;

the strength of marketing and distribution support and the timing of market introduction of competitive products;

and

publicity concerning our products or competing products and treatments.

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

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

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

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

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

In accordance with the specifications of the foreign purchaser;

Not in conflict with the laws of the country to which they are intended for export;

Labeled on the outside of the shipping package that they are intended for export; and

Not sold or distributed in the U.S.

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

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

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

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

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

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

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

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

Conducting clinical trials is a lengthy, time-consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through clinical trials the safety and effectiveness of our products. We have incurred, and we will continue to incur, substantial expense for, and devote a significant amount of time to, product development, pilot trial testing, clinical trials and regulated, compliant manufacturing processes. During the year ended December 31, 2015 research and development expense totaled \$1,406,895. The estimated research and development expense for the year ending December 31, 2016 is \$1,200,000.

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

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

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

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



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

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

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

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

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

finances, injunctions and civil penalties;

recall, detention or seizure of our products;

the issuance of public notices or warnings;

operating restrictions, partial suspension or total shutdown of production;

refusing our requests for 510(k) clearance of new products;

withdrawing 510(k) clearance already granted; and

criminal prosecution.

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

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

Achieving market acceptance for our existing products such as our direct-to-consumer offerings (disposable breathalyzers) and clinical laboratory testing solutions (Particle Immuno Filtration Assay (“PIFA”) based heparin-induced thrombocytopenia and infectious disease rapid tests) and introducing new products (breath condensate detectors for the health & wellness categories) require substantial marketing efforts and will require our sales account executives, contract partners, outside sales agents and distributors to make significant expenditures of time and money. In some instances we will be significantly or totally reliant on the marketing efforts and expenditures of our contract partners, outside sales agents and distributors. The Company has aligned its sales resources with the regional sales segmentation of our clinical products distributors. Although this has positively impacted sales, the large account executive territories may prove to be inefficient as we commercialize products and may hinder our revenue growth.

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

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

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

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

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

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

expend considerable funds and other resources on the development of next-generation products without any guarantee that these products will be successful.

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

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

The Company does not control the efforts of its distributors and its distributors are not prohibited from selling competing products. Our ability to sell our products depends largely on the Company's relationships with such distributors. Accordingly, we are subject to the risk that they may not commit the financial and other resources to market and sell our products to our level of expectation, they may experience financial hardship or they may otherwise terminate our relationship on short notice. In the U.S. clinical laboratory marketplace, many of our existing and potential customers purchase our products through our two national distributors, Cardinal Health and Fisher Health. Our sales account executives work in tandem with the distributor's sales representatives to gain access to decision makers within the majority of U.S. medical facilities. In addition, the Company relies on its distribution network to negotiate pricing arrangements and contracts with Group Purchasing Organizations and their affiliated hospitals and other members. For the years ended December 31, 2015 and 2014, 90% and 48%, respectively of total revenue from the sale of the Company's Heparin/PF4 Assay products was generated through our U.S. distributors' purchases, with Cardinal Health accounting for 57% and 36% of such sales for each year ended December 31, 2015 and 2014. In the future, if we are unable to maintain existing relationships and/or grow to be recognized as a prominent medical device supplier within these organizations, and/or develop new relationships with additional U.S. and international distributors, our competitive position would likely suffer and our business would be harmed.

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

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

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

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

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

operations.

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

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

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

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

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

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

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



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

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

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

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***Our business is vulnerable to inflation.***

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

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

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

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

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

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

adequate.

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

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

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

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

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

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

***We may fail to recruit and retain qualified personnel.***

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

***We may face risks in connection with potential acquisitions.***

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

operations or cash flows could be adversely affected.

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

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

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

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

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

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

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

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

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

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

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

***We may be subject to general commercial litigation which, given the Company's extensive licensing and other strategic arrangement, may impact the Company's rights to and use of its intellectual property.***



In the course of conducting our business, we work with and enter into contracts with various partners, such as distributors. From time to time contractual and other general commercial disputes and litigations may arise between us and our partners. Because certain of the contracts we have with partners include licensing and other strategic arrangements pertaining to our intellectual property, commercial disputes and litigations could impact our rights to, use of, and overall ability to derive revenue from the intellectual property underlying the dispute.

Currently, we are engaged in a commercial litigation with Pulse Health LLC (“Pulse”). On September 30, 2016 Pulse filed a lawsuit against us in United States Federal District Court, District of Oregon. Pulse alleges a breach of contract under the Settlement Agreement entered into by us and Pulse on April 8, 2011 (the “Settlement Agreement”). The Settlement Agreement settled all claims and disputes between us and Pulse pertaining to a Technology Development Agreement. Additionally, Pulse alleges false advertising and unlawful trade practices in connection with our sales activities regarding our OxiChek products. We dispute the allegations. The lawsuit is in an early stage and we intend to establish a rigorous defense of all claims. In the event we fail to defend against the litigation, we may be subject to injunctive or equitable relief and disgorgement of profits with respect to our OxiChek products, which could materially impact our financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

identify in a timely manner or at all as a result of the deferred implementation of this additional level of review.

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

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

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

### **Risks Relating to our Common Stock and Warrants**

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

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

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

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

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

variations in our revenue and operating expenses;

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

market conditions in our industry and the economy as a whole;

developments in the financial markets and worldwide or regional economies;

announcements of innovations or new products or services by us or our competitors;

announcements by the government relating to regulations that govern our industry;

sales of our common stock or other securities by us or in the open market; and

changes in the market valuations of other comparable companies.

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

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

Our common stock is already admitted to trading on AIM and the NASDAQ Capital Market. Price levels for our ordinary shares could fluctuate significantly on either market, independent of our share price on the other market.

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

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

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



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

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

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

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

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

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

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

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

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

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

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

As a publicly traded company, we generally incur legal, accounting and other expenses estimated to range from \$250,000 to \$350,000 per year, including costs associated with the periodic reporting requirements applicable to a company whose securities are registered under the Exchange, as well as additional corporate governance requirements, including applicable requirements under the Sarbanes-Oxley Act and other rules implemented by the SEC. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect compliance with these public reporting requirements and associated rules and regulations to increase our legal and financial costs, particularly after we are no longer an emerging growth company, and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of

directors, our board committees or as our executive officers. Further, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and, potentially, civil litigation.

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

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## **USE OF PROCEEDS**

We estimate that our net proceeds from the sale of the common stock and warrants offered pursuant to this prospectus supplement, will be approximately \$       million, or approximately \$       million if the underwriters exercise in full their option to purchase additional shares and/or warrants, based upon the combined public offering price of \$       per share and half-warrant and after deducting the underwriting discount and the estimated offering expenses that are payable by us and excluding the proceeds, if any, from the warrants issued pursuant to this offering.

We currently intend to use the net proceeds from this offering for growth and working capital, including introducing new products to the market, fulfilling future purchase orders, expanding research and development initiatives, and for other general corporate purposes.

We have not yet determined the amount of net proceeds to be used specifically for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from this offering. Pending any use, as described above, we intend to invest the net proceeds in high-quality, short-term, interest-bearing securities.

## **DIVIDEND POLICY**

We have never declared or paid cash dividends on our capital stock. We currently intend to retain our future earnings, if any, for use in our business and therefore do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion.

**DILUTION**

If you purchase our securities in this offering, your interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the net tangible book value per share of our common stock after this offering. We calculate net tangible book value per share by dividing our net tangible assets (tangible assets less total liabilities) by the number of shares of our common stock issued and outstanding as of September 30, 2016.

Our net tangible book value at September 30, 2016 was \$3,125,948, or \$0.5733 per share, based on shares of our common stock outstanding. After giving effect to the issuance and sale of all the shares and warrants in this offering at the combined public offering price of \$            per share and half-warrant, less the estimated offering expenses, our pro forma and as adjusted pro forma net tangible book value at September 30, 2016 would be \$            or \$            per share. This represents an immediate increase in pro forma net tangible book value of \$            per share to existing stockholders and an immediate dilution of \$            per share to investors in this offering. The following table illustrates this per share dilution:

Public offering price per share of common stock and half-warrant	\$
Net tangible book value per share as of September 30, 2016	\$
Increase per share attributable to this offering	\$
As adjusted net tangible book value per share as of September 30, 2016 after this offering	\$
Dilution per share to new investors participating in this offering	\$

If the underwriters exercise in full their option to purchase additional shares of common stock at the public offering price of \$            per share, the as adjusted net tangible book value deficit after this offering would be \$            per share, representing an increase in net tangible book value of \$            per share to existing stockholders and immediate dilution in net tangible book value of \$            per share to purchasers in this offering at the public offering price.

To the extent that outstanding options are exercised, or we issue new options under our equity incentive plan, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that the additional capital is raised through the sale of common stock or securities convertible or exchangeable into common stock, such issuance could result in further dilution to our stockholders.

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## DESCRIPTION OF THE SECURITIES WE ARE OFFERING

In this offering, we are offering \_\_\_\_\_ shares of our common stock together with warrants to purchase up to an aggregate of \_\_\_\_\_ shares of our common stock at the combined public offering price of \$ \_\_\_\_\_ per share and half-warrant. Each warrant is exercisable upon issuance at an exercise price of \$ \_\_\_\_\_ per share, and will expire five years after its original issuance. This prospectus also includes the offering of the shares of common stock issuable upon exercise of the offered warrants.

### Common Stock

The material terms and provisions of our common stock are described under the captions “Description of Capital Stock” on page 22 of the accompanying prospectus and “Common Stock” beginning on page 3 of the accompanying prospectus.

### Warrants

The following is a brief summary of certain terms and conditions of the warrants and is subject in all respects to the provisions contained in the warrants.

The warrants will be issued as individual warrant agreements to the investors in this offering. You should review the form of warrant, to be filed as an exhibit to the Current Report on Form 8-K filed with the SEC in connection with this offering, for a complete description of the terms and conditions applicable to the warrants. The following brief summary of the material terms and provisions of the common stock and the warrants offered pursuant to this prospectus is subject to, and qualified in its entirety by, the form of warrant.

The warrants are exercisable at any time after their original issuance, expected to be January \_\_\_\_\_, 2017, and at anytime, and from time to time, up to the date that is five years after their original issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is effective and available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not effective or available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of



shares of common stock determined according to the formula set forth in the warrant. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will round up to the next whole share or pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

The exercise price per whole share of common stock purchasable upon exercise of the warrants is \$            per share of common stock. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

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

We do not plan on applying to list the warrants on the NASDAQ Capital Market, any other national securities exchange or any other nationally recognized trading system.

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

## UNDERWRITING

Joseph Gunnar & Co., LLC is acting as the representative of the underwriters in this offering. We have entered into an underwriting agreement dated January , 2017 with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally agreed to purchase from us, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock and warrants listed next to its name in the following table:

Underwriter	Number of Shares	Number of Warrants
Joseph Gunnar & Co., LLC		

The underwriters are committed to purchase all the shares of common stock and warrants offered by us other than those covered by the option to purchase additional shares and/or warrants described below, if they purchase any shares. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act of 1933, as amended, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the common stock and warrants, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The underwriters propose to offer the commons stock and warrants offered by us to the public at the public offering price per share set forth on the cover of this prospectus supplement. In addition, the underwriters may offer some of the common stock and warrants to other securities dealers at such price less a concession of \$ per share. If all of the shares offered by us are not sold at the public offering price per share, the underwriters may change the offering price per share and other selling terms by means of a supplement to this prospectus.

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase a maximum of \_\_\_\_\_ additional shares of common stock and/or additional warrants to purchase up to \_\_\_\_\_ shares of common stock from us to cover over-allotments. If the underwriters exercise all or part of this option, they will purchase shares covered by the option at the public offering price that appears on the cover page of this prospectus supplement, less the underwriting discounts and commissions. If this option is exercised in full, the total offering price to the public will be \$ \_\_\_\_\_ and the total net proceeds, before expenses, to us will be \$ \_\_\_\_\_.

*Discounts and Commissions.* The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	<b>Per Combined Share and Half- Warrant</b>	<b>Total  Without Over-Allotment</b>	<b>With Over-Allotment</b>
Public offering price	\$	\$	\$
Underwriting discount (7%)	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

We have paid a deposit of \$20,000 to the representative, which will be applied against the accountable expenses that will be paid by us to the underwriters in connection with this offering. The underwriting agreement, however, provides that the \$20,000 expense deposit paid to the representative will be returned to the extent the offering expenses are not actually incurred.

We have also agreed to pay the underwriters' expenses relating to the offering, including (a) all fees, expenses and disbursements relating to background checks of the Company's officers and directors in an amount not to exceed \$10,000 in the aggregate; (b) the fees and expenses of the underwriters' legal counsel not to exceed \$50,000; (c) the \$29,500 cost associated with the use of Ipreo's book building, prospectus tracking and compliance software; and (d) up to \$20,000 of the representative's actual accountable "road show" expenses for this offering.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discounts and commissions, will be approximately \$ .

*Lock-Up Agreements.* We and our directors and officers expect to enter into lock up agreements with the representative prior to the commencement of this offering pursuant to which each of these persons or entities, for a period of (i) 180 days (in the case of our directors and officers) and (ii) 90 days (in the case of the Company and any successor to the Company) from the date of the underwriting agreement without the prior written consent of the representative, agree not to (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our securities or any securities convertible into or exercisable or exchangeable for shares of our common stock; (2) file or caused to be filed any registration statement relating to the offering of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock; or (3) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our capital stock, whether any such transaction described in clause (1), (2) or (3) above is to be settled by delivery of shares of our capital stock or such other securities, in cash or otherwise, except for certain exceptions and limitations.

*Electronic Offer, Sale and Distribution of Securities.* A prospectus supplement in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectus supplements electronically. The representative may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus supplement in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus supplement or the registration statement of which this prospectus supplement forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

*Other Relationships.* Certain of the underwriters and their affiliates have provided and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees; however, except as disclosed in this prospectus supplement, we have no present arrangements with any of the underwriters for any further services.

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

*AIM Listing.* Our common stock is listed on the AIM under the symbol “AKR.L.”

*Stabilization.* In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while the offering is in progress.

Over-allotment transactions involve sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position that may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the over-allotment option. If the underwriters sell more shares than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our shares or common stock or preventing or retarding a decline in the market price of our shares or common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The NASDAQ Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

*Passive market making.* In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on The NASDAQ Capital Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

#### **Offer Restrictions Outside the United States**

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

## **Australia**

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

## **China**

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

## **European Economic Area—Belgium, Germany, Luxembourg and Netherlands**

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- (a) to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);
- (c) to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or
- (d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

## **France**



This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code monétaire et financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers (“AMF”). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D. 744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d’investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

## **Ireland**

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the “Prospectus Regulations”). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

## **Israel**

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the ISA), or ISA, nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

## **Italy**

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Società e la Borsa, “CONSOB” pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 (“Decree No. 58”), other than:

to Italian qualified investors, as defined in Article 100 of Decree no.58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 15 May 1999 (“Regulation no. 11971”) as amended (“Qualified Investors”);

in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and

in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

## **Japan**

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the “FIEL”) pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

## **Portugal**

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are “qualified investors” (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

## **Sweden**

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are “qualified investors” (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

## **Switzerland**

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

### **United Arab Emirates**

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has the Company received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by the Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

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## **United Kingdom**

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to “qualified investors” (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to us.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (“FPO”), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together “relevant persons”). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

## **Canada**

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal, that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws. Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult

with a legal advisor. Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

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## **LEGAL MATTERS**

The validity of the issuance of the securities offered hereby will be passed upon for us by Lucosky Brookman LLP. Certain legal matters in connection with this offering will be passed upon for the underwriters by Greenberg Traurig, LLP, New York, New York.

## **EXPERTS**

The consolidated balance sheets of Akers Biosciences, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended have been audited by Morison Cogen LLP, independent registered public accounting firm, as stated in their report which is incorporated herein by reference. Such financial statements have been incorporated herein (by reference) in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

## **WHERE YOU CAN FIND MORE INFORMATION**

This prospectus supplement and the accompanying prospectus are part of the registration statement on Form S-3 we filed with the Securities and Exchange Commission, under the Securities Act, and do not contain all the information set forth in the registration statement. Whenever a reference is made in this prospectus supplement or the accompanying prospectus to any of our contracts, agreements or other documents, the reference may not be complete, and you should refer to the exhibits that are a part of the registration statement or the exhibits to the reports or other documents incorporated by reference into this prospectus supplement and the accompanying prospectus for a copy of such contract, agreement or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the SEC's public reference room mentioned below, or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

Because we are subject to the information and reporting requirements of the Exchange Act, we file annual, quarterly and special reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room.

We also maintain a web site at [www.akersbio.com](http://www.akersbio.com), through which you can access our SEC filings. The information set forth on our web site is not part of this prospectus supplement.



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## INCORPORATION OF DOCUMENTS BY REFERENCE

We incorporate by reference the filed documents listed below, except as superseded, supplemented or modified by this prospectus, and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (unless otherwise noted, the SEC file number for each of the documents listed below is 001-36268):

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, October 12, 2016, and December 22, 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.

You may request and obtain a copy of these filings, at no cost, by writing or telephoning us at the following address or phone number:

Akers Biosciences, Inc.

201 Grove Road

Thorofare, New Jersey 08086

(856) 848-8698

## **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 November 16, 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.

## Edgar Filing: Akers Biosciences Inc - Form 424B5

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 minDNA analyzer, 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 <i>Prescription Use/OTC</i>	FDA Clearance Status Obtained/Needed	Description
BreathScan™	MPC	Marketed		OTC	Obtained	Disposable breath alcohol detector
BreathScan® PRO	MPC	Marketed		OTC	Obtained	Quantitative breath alcohol detection system
Breath 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 <i>Prescription Use/OTC</i>	FDA Clearance Status Obtained/Needed	Description
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**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
<i>PIFA PLUSS</i> <i>TroponinI</i>	PIFA	Pipeline	Prescription Use	Needed	Rapid test for the diagnosis of a myocardial infarction

### 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 PLUS® PF4, and a variety of rapid Infectious Disease screening tests which target markets in the developing world.

PIFA® Heparin/PF4 Rapid Assay and PIFA PLUS® 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 PLUS PF4 to U.S. hospitals to further improve the rate at which healthcare professionals can obtain a HIT-antibody result.

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

Since the appropriate regulatory clearances have been obtained in the United States for these products, the Company does not anticipate needing to fund additional clinical trials to facilitate product marketing domestically. In addition, the current technical file that has been assembled for seraSTAT® and PIFA PLUS PF4® will also be used to support Akers’ CE-marking self-certification process to initiate product sales in the EU; the PIFA Heparin/PF4 Rapid Assay is already CE-marked. The Company’s strategy in 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 PLUS® 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 PLUS 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, 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®.



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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:

<b>Description</b>	<b>Jurisdiction</b>	<b>Utility Patent No.</b>	<b>Type of Protection</b>	<b>Expiration Date</b>	<b>Product(s) To Which They Relate</b>
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 PLUS® PF4; PIFA PLUS® 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 PLUS® PF4 and PIFA PLUS® 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 PLUS® PF4 and PIFA PLUS® Infectious Diseases Rapid Assays
ligand assay method	US	5,827,749	Manufacture		PIFA® Heparin/PF4 Rapid Assay; PIFA PLUS® PF4; PIFA PLUS® 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 PLUS® PF4
test strip card	US	8,003,061	Manufacture	5/6/2024	Tri-Cholesterol “Check”®
test strip card	US	8,425,859	Manufacture	5/6/2024	Tri-Cholesterol “Check”®
test strip card	US	8,808,639	Manufacture	5/6/2024	Tri-Cholesterol “Check”®

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

Akers' Tri-Cholesterol "Check", PIFA Heparin/PF4 Rapid Assay, BreathScan PRO alcohol detection system, and the Breath 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 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 we 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.



**Shares of Common Stock**

**Warrants to Purchase up to      Shares of Common Stock**

**PROSPECTUS SUPPLEMENT**

**Joseph Gunnar & Co.**

January    , 2017



