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

#### AMENDMENT NO.1 to FORM S-1 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

#### AKERS BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in its Charter)

New Jersey

(State or other jurisdiction of incorporation or organization)

2835

(Primary Standard Industrial Classification Code Number) 22-2983783

(I.R.S. Employer Identification No.)

201 Grove Road Thorofare, New Jersey USA 08086 (856) 848-8698

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

Thomas A. Nicolette Akers Biosciences, Inc. 201 Grove Road Thorofare, New Jersey USA 08086 (856) 848-2116

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

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Approximate date of commencement of proposed sale to the public: Upon after the effective date of this Registration Statement.

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

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

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

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

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

Large Accelerated Filer ☐ Accelerated Filer ☐ Smaller Reporting Company ☒

#### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	posed Maximum gregate Offering Price(1)	Amou	nt of Registration Fee
Common Stock, no par value per share (2)(3)	\$ 17,250,000	\$	2,352.90
Underwriters' Warrants to Purchase Common Stock (4)	0		0
Common Stock Underlying Underwriters' Warrants (5)	\$ 937,500		127.88
Total	\$ 18,187,500	\$	2,480.78

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").
- (2) Includes shares of common stock that may be issued upon exercise of a 45-day option granted to the underwriter to cover over-allotments, if any.
- (3) Pursuant to Rule 416 under the Securities Act, the shares of common stock registered hereby also include an indeterminate number of additional shares of common stock as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions.

- (4) In accordance with Rule 457(g) under the Securities Act, because the shares of the Registrant's common stock underlying the Underwriters' warrants are registered hereby, no separate registration fee is required with respect to the warrants registered hereby.
- (5) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. The warrants are exercisable at a per share exercise price equal to 125% of the public offering price. As estimated solely for the purpose of recalculating the registration fee pursuant to Rule 457 (g) under the Securities Act, the proposed maximum aggregate offering price of the underwriters' warrants is \$937,500, which is equal to 125% of \$750,000 (5% of \$15,000,000).

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

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

#### PRELIMINARY PROSPECTUS

#### SUBJECT TO COMPLETION

**DATED OCTOBER 7, 2013** 

## Shares of Common Stock



Akers Biosciences, Inc. is offering shares of its common stock in an initial public offering. Currently, our common stock is traded on the AIM market of the London Stock Exchange, or AIM, under the symbol AKR.L. Shares traded under the AKR.L symbol are deemed to be unrestricted by the AIM market. The closing price of our shares on AIM on August 5, 2013 was .0118 £ based on an exchange rate of \$1.530 per 1.00 £ or \$0.0181 per share. At present, there is a very limited market for our common stock in the AIM market. We intend to continue trading on AIM upon completion of this offering and will apply to list our common stock on The NASDAQ Capital Market under the symbol "AKER".

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

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 7 of this prospectus for a discussion that should be considered in connection with an investment in our common stock.

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

	Per Share	e Total
Public offering price	\$	\$
Underwriting discounts and commissions (1)	\$	\$
Offering proceeds to us, before expenses	\$	\$

(1) The underwriters will receive compensation in addition to the discounts and commissions. See "Underwriting" for a full description of compensation payable to the underwriters.

We have granted a 45-day option to the underwriters to purchase up to additional shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver the shares to purchasers in the offering on or about  $\,$  , 2013.

### **Aegis Capital Corp**

The date of this prospectus is , 2013

# Akers Biosciences, Inc.



CHUBE® disposable breathalyzers are the only US-manufactured alcohol detectors to have FDA-clearance and French (NF) & Australian (AS) certifications.

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You should rely only on the information contained in this prospectus. Neither we nor the underwriters have authorized anyone to provide you with information that is different. We are not making an offer to sell these securities in any jurisdiction where an offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate as of the date on the front cover of this prospectus only. Our business, prospects, financial condition and results of operations may have changed since that date.

Until and including \_\_\_\_\_\_\_\_, 25 days after the date of this prospectus, all dealers that buy, sell or trade our ordinary shares, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

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

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#### SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should read the entire prospectus carefully before making an investment decision, especially the "Risk Factors" and the financial statements and the related notes. Unless the context provides otherwise, all references herein to "ABI", the "Company", "we", "our" and "us" refer to Akers Biosciences, Inc. "£" refers to the Britsh Pound.

#### Overview

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

Our platform technologies include:

Testing Platform Technology	Description
MPC Biosensor (MPC <sup>TM</sup> )	Permits the rapid determination of medical conditions through biomarkers in breath condensate
Particle ImmunoFiltration Assay (PIFA®)	Selective filtration of microparticles in response to antibody/antigen binding
Rapid Enzymatic Assay (REA <sup>TM</sup> )	Detection of blood or urine metabolites through enzymatic chemistries in quantitative or semi-quantitative formats
minDNA™	Facilitates the analysis of DNA by a handheld photometric reader from a mixture consisting of a patient's whole blood specimen and a disposable reagent
Synthetic Macrocycle Complex (SMC <sup>TM</sup> )	Novel organic macrocyclic compounds and electronic readers determine quantitative levels of therapeutic drugs
Our sample preparation technology includes:	
Sample Preparation Technology	<b>Description</b>
seraSTAT® Rapid Blood Cell Separation ("Separator")	Rapid extraction of serum (liquid fraction) from whole blood through the use of membrane technology

All of ABI's 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, neuropsychiatry, oncology and infectious diseases / bioagent detection, as well as for on- and off-the-job alcohol safety initiatives.

ABI 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 Adminstration ("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, ABI's 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 payor. In addition, in the developing world, the portability and ease-of-use of such point-of-care tests can serve to drastically improve the level of disease screening and subsequent patient care. We believe the benefits of our technology platforms are therefore well-suited to the diagnostic demands of countries in the developing world that seek to deliver modern medical diagnosis 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 a quality management system ("QMS-Compliant"). ABI 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 set forth our marketed and current pipeline products indentifies the appropriate "prescription use" or "OTC" designation and whether the required clearance has been obtain

Our marketed and emerging products include:

Product	Platform	Market/Pipeline	Not FDA- regulated; QMS- Compliant Only	FDA Clearance Required Prescription Use/OTC	FDA Clearance Status Obtained/Needed	Description
BreathScan <sup>®</sup> /CHUBE <sup>TM</sup>	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
$METRON^{TM}$	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
VIVO	MPC	Marketed	X			Non-invasive, quantitative measurement of biological markers for oxidative stress that relates to cellular damage
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® Infectious Diseases	PIFA	Pipeline	Prescription Use	Obtained	Rapid tests for a variety of infectious diseases, especially those that are prevalent outside of the United States
seraSTAT®	seraStat	Marketed	Prescription Use	Obtained	Rapid blood cell separator, marketed under the brand name seraSTAT $^{\text{(S)}}$ , 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	ОТС	Obtained	Rapid test for Total and high density lipoprotein cholesterol and estimates low density lipo protein

ABI 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 ABI's FDA-cleared rapid diagnostic tests help facilitate targeted diagnoses and real-time treatment. We also believe that ABI's rapid diagnostic tests surpass most other current diagnostic products with their flexibility, speed, ease-of-use, readability, low cost and accuracy. In minutes, detection of disease states and medical conditions can be performed on single-patient specimens, without sacrificing accuracy.

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

- · cost pressures/efficiency of healthcare delivery;
- · need for tools for pharmaceutical companies to monitor side effects of medicines/new agents in development;
- 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.

#### **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 increasing baby booming population across the globe. Other major drivers for the growth of the in vitro diagnostic ("IVD") industry is a rise in the number of diseases like respiratory and hospital-acquired infections and a rise in the chronic diseases such as diabetes, hypertension, cardiovascular diseases, and cancer. 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 centers market.

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

In a June 6, 2013 article "Global In Vitro Diagnostics Markets Outpace Pharma Industry Growth" by Frost & Sullivan's estimated that 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's. The Company's main presence is in the United States, but recently executed distribution and licensing agreements have initiated ABI's strategic move to the China and European Union marketplaces.

#### Strategy

ABI's 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. ABI utilizes its existing platform technologies to internally develop its new products as the Company's proprietary methods.

ABI 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.

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

- · clinical laboratories;
- · physicians' office/retail and urgent care clinics;
- · 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.

#### **Recent Developments**

On June 19, 2013, the Company entered into an amended License and Supply Agreement (the "Amended License and Supply Agreement") with Chubeworkx Guernsey Limited ("Chubeworkx"), (EN)10 (Guernsey) Limited (formerly BreathScan International (Guernsey) Limited) and (EN)10 Limited (formerly BreathScan International Limited). The Amended License and Supply Agreement expanded the marketing and distribution of Chubeworkx "BE CHUBE" program worldwide using the ABI breathalyzer.

On June 19, 2013, simultaneous with entering into the Amended License and Supply Agreement, the Company and Chubeworkx entered into a purchase agreement (the "Chubeworkx Purchase Agreement") pursuant to which Chubeworkx purchased 80,000,000 shares of the Company's common shares for an aggregate purchase price of \$1,600,000. Pursuant to the Chubeworkx Purchase Agreement, Chubeworkx was granted the right to appoint one director to the Company's board. Chubeworkx nominated Gavin Moran as its representative on the board of directors of the Company and he was so appointed, effective July 1, 2013.

#### Risks That We Face

An investment in our common stock involves a high degree of risk. You should carefully consider the risks summarized below. The risks are discussed more fully in the "Risk Factor" section of this prospectus immediately following this prospectus summary. These risks include, but are not limited to:

- we have a history of losses and we may never achieve sustained profitability. Our net losses for the year ended December 31, 2012 and the six months ended June 30, 2013 were \$2,557,820 and \$200,962, respectively;
- · we depend 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;
- 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. There can be no assurances that such capital will be available to the Company on favorable terms or at all;
- · we have very limited marketing resources and limited sales capabilities, which may make commercializing our products difficult;

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

our insiders and affiliated parties beneficially own a significant portion of our stock and have significant influence over our affairs and all matters subject to shareholder vote

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.

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

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

#### **Company Information**

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

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

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. We will 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 exceed \$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. Pursuant to Section 102 of the JOBS Act, we have elected executive compensation disclosure and have omitted a compensation discussion and analysis from this prospectus. Pursuant to Section 107 of the JOBS Act, we have elected to 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.

#### THE OFFERING

Common stock offered by us: Shares

Over-allotment option: We have granted the underwriters a 45-day option to purchase up to additional shares of our common stock

from us at the initial public offering price, less underwriting discounts and commissions. The option may be

exercised only to cover any over-allotments.

Common stock outstanding after this offering: Shares

Use of Proceeds: We estimate that the net proceeds from our sale of shares of our common stock in this offering will be

approximately \$ million, or approximately \$ million if the underwriters exercise their over-allotment option in full, based upon an assumed initial public offering price of \$ per share, which is the midpoint of the range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions

and estimated offering expenses payable by us.

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

sales channels and other capital expenditures.

**Risk Factors:** See the section entitled "Risk Factors" beginning on page [●] for a discussion of factors to consider carefully

before deciding whether to purchase shares of our common stock.

Proposed NASDAQ Symbol: AKER

AIM Symbol AKR.L

NASDAQ listing requirements include a stock price threshold and NASDAQ is likely to use both our trading price on AIM and our offering price in determining whether or not we meet that threshold. As a result, prior to effectiveness, the Company may need to take necessary steps to meet NASDAQ listing requirements, including but not limited to a reverse split of our common stock.

The number of shares of common stock to be issued and outstanding after this offering is based on 329,515,666 shares of common stock issued and outstanding as of August 5, 2013 and (i) includes 50,000,000 shares to be issued upon conversion of the outstanding Series A Preferred Stock prior to the consummation of this offering and (ii) excludes:

· shares reserved for future issuances under our 2013 Stock Incentive Plan (the "2013 Plan"). All future grants will be made pursuant to the 2013 Plan. The amount of shares reserved for future issuances under our 2013 Plan will be equal to % of the amount of shares outstanding;

· 310, 344 shares issuable upon exercise of outstanding warrants; and

· shares issuable upon exercise of the Underwriters' warrants.

#### SUMMARY FINANCIAL DATA

The following tables set forth a summary of our historical financial data as of, and for the period ended on, the dates indicated. We have derived the statement of operations data for the years ended December 31, 2012 and 2011 from our audited financial statements included elsewhere in this prospectus. The statement of operations data for the six months ended June 30, 2013 and 2012 and the balance sheet data as of June 30, 2013 have been derived from our unaudited financial statements appearing elsewhere in this prospectus. This unaudited interim financial information has been prepared on the same basis as our audited financial statements and, in our opinion, reflects all adjustments, consisting only of normal and recurring adjustments, that we consider necessary for a fair presentation of our financial position as of June 30, 2013 and operating results for the periods ended June 30, 2013 and 2012. You should read this data together with our financial statements and related notes appearing elsewhere in this prospectus and the sections in this prospectus entitled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The historical results are not necessarily indicative of the results to be expected for any future periods and the results from the six months ended June 30, 2013 should not be considered indicative of results expected for the fiscal year 2013.

#### Summary of Statement of Operations Data

	Six Months Ended June 30,			Fiscal Yea Decemb				
	2013 2012				2012	2011		
Total revenue	\$ 2,639,085	\$	787,194	\$	1,522,363	\$	1,785,068	
Cost of sales	\$ 1,409,384	\$	469,335	\$	1,007,951	\$	956,620	
Gross profit	\$ 1,229,701	\$	317,589	\$	514,412	\$	828,448	
Net loss	\$ (200,962)	\$	(1,338,259)	\$	(2,557,820)	\$	(3,626,944)	
Basic and diluted net loss per share	\$ (0.00)	\$	(0.01)	\$	(0.01)	\$	(0.02)	
Weighted average basic and diluted shares outstanding	206,587,489		169,415,666		178,316,486		163,519,502	

#### Summary of Balance Sheet Information

#### As of June 30, 2013

	 Actual	As Adjusted
Current assets	\$ 3,682,838	
Total assets	\$ 6,514,898	
Long-term liabilities	\$ -	
Total liabilities	\$ 1,811,837	
Total stockholders' equity	\$ 4,703,061	

#### RISK FACTORS

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

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

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

We have recorded a net loss in most reporting periods since our inception. Our net loss for the year ended December 31, 2012 and the six months ended June 30, 2013 were \$2,557,820 and \$200,962, respectively. Our accumulated deficit at June 30, 2013 was \$80,395,315. Losses are continuing through the date of this prospectus and are expected to continue for the foreseeable future. The Company expects to continue to have development costs as it develops its next generation of products. We may never achieve profitable operations or positive cash flow.

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

Historically, we limited our investment in infrastructure; however, following this offering we expect our infrastructure investments to increase substantially to support our anticipated growth and as a result of our becoming a public reporting company in the United States. We intend to make additional investments in automated manufacturing systems and personnel in order to expand our operations to support anticipated growth in our business. In addition, to be competitive and take advantage of market opportunities, we may need to make changes to our sales model in the future. These changes may result in higher selling, general and administrative expenses as a percentage of our revenue. We also expect to incur additional operating costs as a public reporting company following the completion of this offering. 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, 2012, our principal customers included two clinical laboratory distributors, Cardinal Health and Fisher healthcare, that distribute our PIFA Heparin/PF4 Rapid Assays in the United States. Effective May 1, 2007 we entered into a distribution agreement (as subsequently amended, the "Cardinal Health Agreement") with Cardinal Health 200, Inc. ("Cardinal Health"). The Cardinal Health Agreement grants Cardinal Health the non-exclusive right to distribute PIFA Herapin / PF4 Rapid Assays. Pricing terms for each product are included in the Cardinal Agreement and vary depending on product and volume of the order. The Cardinal Health Agreement automatically renews for successive twelve month unless either party (a) upon 30 days written notice if either party commits or suffers any act of bankruptcy or insolvency, or fails to cure any material breach of the provisions of the agreement within 30 days after written notice of such breach, or (b) upon 90 days written notice with or without cause. On June 15, 2010 we entered into a distribution agreement with Fisher Healthcare, a Division of Fisher Scientific Company L.L.C. (as subsequently amended, the "Fisher Agreement"). The Fisher Agreement grants non-exclusive rights for Fisher Healthcare to distribute PIFA Heparin/PF4 Rapid Assays, Heparin/PF4 serum panels, and BreathScan disposable breath alcohol detectors in the United States. Under the Fisher Agreement we are required to fill all orders placed by Fisher Healthcare and do not have the right to decline such orders. The initial term of the agreement was June 15, 2010 through May 31, 2012 and included initial pricing terms for each product that varied depending on the product; however, ABI is able to submit pricing increases on an annual basis. The Fisher Agreement automatically renews for successive twelve month periods at Fisher Healthcare's option in its sole discretion. There are no minimum purchase requirements under either of the agreements.

For the year ended December 31, 2012, these two entities accounted for approximately 57% of the Company's revenue. Chubeworkx, which distributes ABI'S breathalyzers for its "Be CHUBE" selling initiative that is being rolled out worldwide, became a significant purchaser of ABI's products in 2013. For six months ended June 30, 2013, Cardinal Health, Fisher Healthcare and Chubeworkx accounted for approximately 16%, 4% and 67% of our revenue, respectively. 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 Cardinal Health Agreement or Fisher Agreement would materially reduce our net sales and gross profit and adversely affect our business, our results of operations and our financial condition. We expect that sales to relatively few customers will continue to account for a significant percentage of our net sales for the foreseeable future, however there can be no assurance that any of these customers or any of our other customers will continue to utilize our products or our services at current levels.

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

As of December 31, 2012, Chubeworkx, Cardinal Health and Fisher Healthcare accounted for 67% of our accounts receivable. More Significantly, As of June 30, 2013, Chubeworkx, Cardinal Health and Fisher Healthcare accounted for 96% of our accounts receivable. In the case of insolvency by one of our significant customers, an account 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. 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 (the 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. During the year ended December 31, 2012 and the six months ended June 30, 2013, three suppliers accounted for 43% and 56%, respectively, of the Company's total purchases. 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 before we expect cash flows from operations will be adequate to cover our anticipated expenses. We believe that the proceeds of this offering and revenue from operations will be sufficient to satisfy our needs for at least the next 18 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, potentially at a price lower than our initial public offering price or the market price of our common stock at the time of such issuance. If we cannot secure sufficient additional funding we may be forced to forego strategic opportunities or delay, scale back and 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 operations procedures or changes to our equipment or human resource allocations which may materially affect our business.

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

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

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

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

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

We plan to market some of our products in foreign jurisdictions, initially in China, 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 sale of some medical devices within the European Union. Some of our current products that require CE Markings have them and it is anticipated that additional and future products may require them as well. We may be required to conduct additional testing or to provide additional information, resulting in additional expenses, to obtain necessary approvals. If we fail to obtain approval in such foreign jurisdictions, we would not be able to sell our products in such jurisdictions, thereby reducing the potential revenue from the sale of our products.

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

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

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

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

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

In the European Union, a product that meets the definition of an In Vitro Diagnostic Medical Device ("IVD") in accordance with the European Directive (98/79/EC) must receive 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/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. Given the expense and length of the ISO certification process, ABI currently has not pursued ISO certification for its manufacturing facility which may limit the Company's ability to launch selling initiatives, of certain products, within international markets such as India and Canada. ABI may not be able to obtain foreign regulatory approval on a timely basis, if at all and to do so may cause ABI to incur additional costs or prevent ABI 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. Our principal competitors often have considerably greater financial, technical and marketing resources than we do. 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, 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, the ability to offer rebates or higher discounts and incentives; and greater resources for product development, sales and intellectual property protection. 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. The estimated research and development expense for the year ending December 31, 2014 is \$1,400,000.

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, including 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 and of the control, if any, 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 a 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 submitter.

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 device 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 for any modification, we also may be required to cease marketing and/or recall the modified device until we obtain a new 510(k) clearance or PMA approval.

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

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

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

· criminal prosecution.

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

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

Achieving market acceptance for our existing products such as our direct-to-consumer offerings (disposable breathalyzers) and clinical laboratory testing solutions (Particle ImmunoFiltration 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. In early 2013, the Company reduced its account executive staff by 40% to streamline operations and align ABI's sales resources with the regional sales segmentation of our clinical products distributors. Although this headcount reduction has positively impacted our budgets without negatively effecting sales in comparison to the first six months of the prior fiscal year, the large account executive territories may prove to be inefficient as we commercialize products and may hinder our revenue growth.

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

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

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

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

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

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

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

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

The Company does not control the efforts of its distributors and its distributors are not prohibited from selling competing products. Our ability to sell our products depends largely on the Company's relationships with such distributors. Accordingly, we are subject to the risk that they may not commit the financial and other resources to market and sell our products to our level of expectation, they may experience financial hardship or they may otherwise terminate our relationship on short notice. In the U.S. clinical laboratory marketplace, many of our existing and potential customers purchase our products through our two national distributors, Cardinal Health, Inc. and Fisher HealthCare. ABI's sales account executives work in tandem with distributor 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 2011 and 2012 and the six months ended June 30, 2013, 65%, 77% and 83%, 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 59%, 68% and 66%, respectively of total sales for the years ended December 31 2011 and 2012 and the six months ended June 30, 2013. In the future, if we are unable to maintain existing relationships and/or grow to be recognized as a prominent medical device supplier within these organizations, and/or develop new relationships with additional U.S. and international distributors, our competitive position would likely suffer and our business would be harmed.

We have just begun to develop formal business relationships with foreign distributors for all of our in-line products. We will therefore be dependent upon the financial health of these organizations to further grow our business. 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 an exclusive distributor in mainland China to register ABI's PIFA Heparin/PF4 Rapid Assay for eventual sale. Since additional clinical studies must be performed by our distributor 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 product and permit sales activity. Failure to gain product registration in China will hinder the Company's ability to increase its revenue.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### Our business is vulnerable to inflation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are highly dependent on our Executive Chairman, Raymond F. Akers, Jr. PhD, because of his expertise and experience in biotechnology and diagnostics, as well as Thomas A. Nicolette, our Chief Executive Officer. We have three year employment agreements with our executive officers containing customary non-disclosure, non-compete, confidentiality and assignment of inventions provisions. We do not have "key person" life insurance policies for any of our officers. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

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

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

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

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

We cannot be assured that any of our pending patent applications will result in the issuance of a patent to us. The U.S. Patent and Trademark Office, or 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 issue as 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. On January 9, 2012, the Company was notified of an action to recover unpaid royalties for the exclusive use of a patent used in the production of our MPC Biosensor products (MicroParticle Catalyzed Biosensor). The dispute related to the method used to calculate royalty payments and the scope of the products involved for the period dated March 17, 2007 through March 19, 2012. On April 23, 2012, the Company agreed to an arbitration settlement of \$137,791. On January 11, 2012, the Company was notified of a demand for arbitration from Trinity Biotech Manufacturing Limited related to the distributor agreement between the parties dated June 19, 2008.On October 15, 2012, the Company agreed to an arbi

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

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. To date, neither the Company, its founders, directors nor officers have been involved in any material litigation relating to Company matters. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our 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 we 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 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, allowance 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 in this prospectus 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, which may be up to five years following this offering, 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.

#### Risks Related to the Market

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

Recent global economic conditions, including a disruption of financial markets, could adversely affect us, primarily through limiting our access to capital. In addition, the continuation or worsening of general market conditions in economies important to our businesses may adversely affect our clients' level of spending and ability to obtain financing, leading to us being unable to generate the levels of sales that we require. Current and continued disruption of financial markets could have a material adverse effect on the Company's business, financial condition, results of operations and future prospects.

#### Risks Relating to This Offering and an Investment in Our Common Stock

Our insiders and affiliated parties beneficially own a significant portion of our stock and have significant influence over our affairs and all matters subject to shareholder vote.

Following this offering, our executive officers, directors and affiliated parties beneficially own approximately % of our outstanding common stock. As a result, our executive officers, directors and affiliated parties have significant influence to:

- · elect or defeat the election of our directors;
- · amend or prevent amendment of our articles of incorporation or bylaws; and
- effect or prevent a merger, sale of assets or other corporate transaction.

In addition, sales of significant amounts of shares held by our directors and executive officers, or the prospect of these sales, could adversely affect the valuation of our Company.

There can be no assurances that our shares will be listed on the NASDAQ Capital Market and, if they are, our shares will be subject to potential delisting if we do not meet or continue to maintain the listing requirements of the NASDAQ Capital Market.

We have applied to list the shares of our common stock on the NASDAQ Capital Market, or NASDAQ. An approval of our listing application by NASDAQ will be subject to, among other things, our fulfilling all of the listing requirements of NASDAQ. We do not currently qualify for listing on NASDAQ and will need to take all necessary measures to do so, including but not limited to effecting a reverse split of our common stock. In addition, NASDAQ has rules for continued listing, including, without limitation, minimum market capitalization and other requirements. Failure to maintain our listing, or de-listing from NASDAQ, would make it more difficult for shareholders to dispose of our common stock and more difficult to obtain accurate price quotations on our common stock. This could have an adverse effect on the price of our common stock. Our ability to issue additional securities for financing or other purposes, or otherwise to arrange for any financing we may need in the future, may also be materially and adversely affected if our common stock is not traded on a national securities exchange.

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

There has been no public market for our common stock in the U.S. prior to this offering. Since 2002, our shares of common stock have been listed for trading on the AIM market. However, historically there has been limited volume of trading in our common stock on the AIM market, which has limited the liquidity of our common stock on that market. We cannot predict whether or how investor interest in our common stock on the AIM market might translate to the market price of our common stock or the development of an active trading market in the U.S. or how liquid that market might become.

The public offering price for our common stock was determined through negotiations with the underwriters based on a number of factors, including the historic trading prices of our common stock on the AIM market, which might not be indicative of prices that will prevail in the trading market for our common stock after the offering. An active trading market for our shares in the U.S. may never develop or be sustained following this offering. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders. The absence of an active trading market increases price volatility and reduces the liquidity of our common stock. As long as this condition continues, the sale of a significant number of shares of common stock at any particular time could be difficult to achieve at the market prices prevailing immediately before such shares are offered and, if an active market for our common stock does not develop, it may be difficult to sell shares you purchase in this offering without depressing the market price for the shares, or at all. In addition, in the event that an active trading market does not develop, the price of our common stock may not be a reliable indicator of the Company's fair value.

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;
- · actual or expected changes in our growth rates or our competitors' growth rates;
- 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.

Beneficial holders of ordinary shares through the Depository Trust Company will not be legal shareholders of the Company and therefore will have no direct rights as shareholders and must act through their participating broker to exercise those rights.

The underwriters have designated that Cede & Co., as nominee for the Depository Trust Company, or DTC, will hold the ordinary shares in this offering on behalf of, and as nominee for, investors who purchase ordinary shares. We have no contractual relationship with DTC. Investors who purchase the common shares (although recorded as owners within the DTC system) are legally considered holders of beneficial interests in those shares only and will have no direct rights against the Company. Investors who purchase common stock in this offering must look solely to their participating brokerage in the DTC system for payment of dividends, the exercise of voting rights attaching to the common stock and for all other rights arising with respect to the common stock.

Under our Bylaws, the required minimum notice period to convene a general meeting is not less than 10 and no more than 60 calendar days. When a general meeting is convened, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw your common stock from the DTC system to allow you to directly cast your vote with respect to any specific matter. In addition, a participating DTC brokerage firm may not be able to send voting instructions to you or carry out your voting instructions in a timely manner. We cannot assure you that you will receive voting materials in time to ensure that you can instruct your participating DTC brokerage, or its designee, to vote your shares. As a result, you may not be able to exercise your right to vote and you may lack recourse if your common shares are not voted as you requested. In addition, if you hold your shares indirectly through the DTC system, you will not be able to call a shareholder meeting.

Upon the completion of this offering, our common stock will be 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 we are applying for our shares additionally to be listed and traded on 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.

In the event that our common stock is listed on the NASDAQ our stock price could fall and we could be delisted 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 broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section of this prospectus entitled "Use of Proceeds." The failure by our management to apply these funds effectively could harm our business.

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

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

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

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

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

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

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

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

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

#### We will incur significant costs as a result of being a publicly traded company and such costs may increase when we cease to be an emerging growth company.

As a publicly traded company, we will incur legal, accounting and other expenses estimated to range from \$150,000 to \$250,000 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 as of the date of this offering. However, when we cease to be an emerging growth company, we will be unable to take advantage of the reduced regulatory requirements and any associated cost savings.

## Efforts to comply with the applicable provisions of Section 404 of the Sarbanes-Oxley Act will involve significant expenditures, and non-compliance with Section 404 of the Sarbanes-Oxley Act may adversely affect us and the market price of our common stock.

Under current SEC rules, beginning with our fiscal year ending December 31, 2014, we will be required to report on our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act, and related rules and regulations of the SEC; although, as an emerging growth company, we are exempt from the requirement to provide an auditor attestation to management's assessment of its internal controls as required by Section 404(b) of the Sarbanes-Oxley Act. We will be required to review on an annual basis our internal control over financial reporting, and on a quarterly and annual basis to evaluate and disclose changes in our internal control over financial reporting. As a result, we expect to incur additional expenses in the near term that may negatively impact our financial performance and our ability to make distributions. This process also will result in a diversion of management's time and attention. We cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations, and we may not be able to ensure that the process is effective or that our internal control over financial reporting is or will be effective in a timely manner. In the event that we are unable to maintain or achieve compliance with the applicable provisions of Section 404 of the Sarbanes-Oxley Act and related rules, we and the market price of our common stock may be adversely affected.

#### A sale of a substantial number of shares of the common stock may cause the price of our common stock to decline

Following the closing of this offering, we will have shares of common stock issued and outstanding, assuming no exercise of the underwriters' over-allotment option. Substantially all of these shares will be available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. Additionally, we will reserve for issuance shares of our common stock issuable upon exercise of the warrants offered pursuant to this prospectus, assuming no exercise of the underwriters' over-allotment option. Upon exercise of these warrants, the underlying shares of our common stock may be resold into the public market. If the exercise price of these warrants is below the market price of our common stock from time to time, holders of warrants may exercise their warrants, in which case investors in our common stock would experience dilution. We cannot predict if future issuances or sales of our common stock, or the availability of our common stock for issuance or sale, will harm the market price of our common stock or our ability to raise capital.

Sales of a substantial number of shares of our common stock and the exercises of outstanding options and warrants may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. We may become involved in securities class action litigation that could divert management's attention and harm our business.

#### You will experience immediate dilution in the book value per share of common stock as a result of this offering,

If you invest in shares in our common stock, your interest will be diluted to the extent of the difference between the offering price per share of the shares in our common stock as adjusted net tangible book value per share of our common stock immediately after completion of this offering. The historical net tangible book value of our common stock as of June 30, 2013 was approximately \$2.14 million, or \$0.008 per share. Historical net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities, divided by the total number of shares of common stock outstanding. After giving effect to conversion of the 50,000,000 shares of Series A Preferred Stock, the proforma net tangible book value per share as of June 30, 2013 would have been approximately \$ per share. After giving effect to the receipt of the net proceeds from our sale in this offering of shares of common stock at an assumed initial public offering price of \$ per share, the mid-point of the price range set forth on the cover page of this prospectus, applying proceeds as set forth in Use of Proceeds and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, the adjusted proforma net tangible book value would have been \$ or \$ per share. This represents an increase in net tangible book value of approximately \$ per share to our existing stockholders, and an immediate dilution of \$ per share to investors purchasing securities in this offering.

Dilution in net tangible book value per share represents the difference between the amount per share paid by purchase of our common stock in this offering and the as adjusted proforma net tangible book value per share of our common stock immediately following this offering.

If the underwriter's over-allotment option is exercised in full, the as adjusted net tangible book value per share of our common stock after giving effect to this offering would be \$\ \text{per share}, which amount represents an immediate increase in net tangible book value of \$\ \text{per share} of our common stock to existing shareholders and an immediate dilution in net tangible book value of \$\ \text{per share} of our common stock to new investors purchasing shares in this offering. See the section entitled "Dilution" below.

#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled "Risk Factors", "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business", contains forward-looking statements that include information relating to future events, future financial performance, strategies, expectations, competitive environment, regulation and availability of resources. These forward-looking statements include, without limitation, statements regarding: proposed new products or services; our statements concerning litigation or other matters; statements concerning projections, expectations, estimates or forecasts for our business, financial and operating results and future economic performance; statements of management's goals and objectives; trends affecting our financial condition, results of operations or future prospects; our financing plans or growth strategies; and other similar expressions concerning matters that are not historical facts. Words such as "may", "will", "should", "could", "would", "predicts", "potential", "continue", "expects", "anticipates", "future", "intends", "plans", "believes" and "estimates," and similar expressions, as well as statements in future tense, identify 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

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

#### DIVIDEND POLICY

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

#### DETERMINATION OF OFFERING PRICE

The offering price of the common stock has been arbitrarily determined and bears no relationship to any objective criterion of value. The price does not bear any relationship to our assets, book value, historical earnings or net worth. No valuation or appraisal has been prepared for our business.

Prior to this offering, there has been no public market in the United States for our shares. The public offering price will be determined through negotiations between us and Aegis Capital Corp., as representative of the underwriters. The factors to be considered in determining the public offering price may include our future prospects and those of our industry in general, sales, earnings and certain of our other financial operating information in recent periods, and the market prices of securities and certain financial and operating information of companies engaged in activities similar to those we engage in. The price of our shares on AIM during recent periods will also be considered in determining the public offering price. It should be noted, however, that historically there has been a limited volume of trading in our shares on AIM. Therefore, the price of our shares on AIM will only be one factor in determining the public offering price. The estimated public offering price range set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors.

We cannot assure you that the public offering price will correspond to the price at which the shares will trade in the public market subsequent to the offering or that an active trading market for the shares will develop in the United States and continue after the offering.

#### MARKET PRICE INFORMATION FOR OUR SHARES

We are making an application for our shares to be listed on The NASDAQ Capital Market upon consummation of this offering. They have not previously been listed on The NASDAQ Capital Market or any other U.S. market. However, our shares are currently listed on AIM under the symbol "AKR.L". Our shares began trading on AIM in May 2002.

As of August 5, 2013, there were 279,515,666 shares outstanding and approximately 615 holders of record of our shares. On a fully diluted basis, there would be 329,826,010 shares outstanding.

On August 5, 2013, the closing price of our shares listed on AIM was 0.01180 £ or \$0.0181 using an exchange rate of \$1.530.

The following table shows the high and low market prices for our shares for each fiscal quarter for the two most recent fiscal years. Market prices for our shares have fluctuated significantly since they were listed on AIM and trading volume on AIM have been very small in relation to the number of our total outstanding shares. As a result, the market prices shown in the following table may not be indicative of the market prices at which our shares will trade after this offering.

	High			Low				Exchange		
Period		GBP	USD			GBP		USD		Rate *
Third Quarter 2013										
(through Aug 2, 2013)	£	0.0123	\$	0.0187	£	0.0105	\$	0.0159	\$	1.5175
Second Quarter 2013		0.0173		0.0266		0.0105		0.0161	\$	1.5290
First Quarter 2013		0.0148		0.0238		0.0110		0.0172		1.5618
Fourth Quarter 2012		0.0142		0.0229		0.0080		0.0129		1.6102
Third Quarter 2012		0.0100		0.0162		0.0062		0.0096		1.5536
Second Quarter 2012		0.0100		0.0160		0.0068		0.0106		1.5605
First Quarter 2012		0.0250		0.0388		0.0082		0.0131		1.5965
Fourth Quarter 2011		0.0325		0.0506		0.0188		0.0295		1.5667
Third Quarter 2011		0.0400		0.0642		0.0225		0.0351		1.5599
Second Quarter 2011		0.0438		0.0718		0.0288		0.0463		1.6085
First Quarter 2011		0.0675		0.1049		0.0300		0.0483		1.6104

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

#### DILUTION

The historical net tangible book value of our common stock as of June 30, 2013 was approximately \$2.14 million, or \$0.008 per share. Historical net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities, divided by the total number of shares of common stock outstanding. After giving effect to conversion of the 50,000,000 shares of Series A Preferred Stock, the proforma net tangible book value per share as of June 30, 2013 would have been approximately \$ per share. After giving effect to the receipt of the net proceeds from our sale in this offering of shares of common stock at an assumed initial public offering price of \$ per share, the mid-point of the price range set forth on the cover page of this prospectus, applying proceeds as set forth in Use of Proceeds and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, the adjusted proforma net tangible book value would have been \$ or \$ per share. This represents an increase in net tangible book value of approximately \$ per share to our existing stockholders, and an immediate dilution of \$ per share to investors purchasing securities in this offering.

Dilution in net tangible book value per share represents the difference between the amount per share paid by purchase of our common stock in this offering and the as adjusted pro forma net tangible book value per share of our common stock immediately following this offering.

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

Assumed public offering price per share of common stock	\$
Proforma net tangible book value per share as June 30, 2013	\$
Increase in proforma net tangible book value per share attributable to this offering	\$
As adjusted proforma net tangible book value per share after this offering	\$
Dilution to new investors	\$

If the underwriter's over-allotment option is exercised in full, the as adjusted net tangible book value per share of our common stock after giving effect to this offering would be \$\ \text{per share}, which amount represents an immediate increase in net tangible book value of \$\ \text{per share} of our common stock to existing shareholders and an immediate dilution in net tangible book value of \$\ \text{per share} of our common stock to new investors purchasing shares in this offering.}

#### CAPITALIZATION

The following table presents a summary of our cash, cash equivalents, short-term investments and capitalization as of June 30, 2013:

- · on an actual basis; and
- on an as adjusted basis to (i) reflect our receipt of estimated net proceeds of approximately \$\) million from the sale of shares of common stock in this offering at an assumed public offering price of \$\) per share, the closing price of the Company's common stock on \$\), 2013, after deducting the estimated underwriting discounts and commissions and estimated offering expenses and (ii) the conversion of outstanding shares of Series A Preferred Stock into 50,000,000 shares of common stock immediately prior to the consummation of this offering.

You should read the following table in conjunction with "Use of Proceeds," "Selected Financial Information," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the historical financial statements and the related notes thereto included in this prospectus.

			e 30, 20 A	13 as Adjusted
Cash, cash equivalents and short-term investments	\$	1,553,884	\$	
Long-term debt	\$	_	\$	
Stockholders' equity				
Convertible preferred stock ((i) Actual: 50,000,000 shares authorized, no par value; 10,000,000 shares issued and outstanding				
and (ii) As Adjusted: shares authorized, no par value; shares issued and outstanding)	\$	225,000	\$	
Common stock ((i) Actual: 500,000,000 shares authorized, no par value; 279,515,666 shares issued and outstanding and (ii) As				
Adjusted: shares authorized, no par value; shares issued and outstanding)	\$	84,873,376	\$	
Accumulated deficit	\$	(80,395,315)	\$	
Total Stockholders equity (deficit)	\$	4,703,061	\$	
Total Capitalization	\$	4,703,061	\$	,
21				

The table excludes the following as of June 30, 2013:

· shares of common stock issuable upon exercise of the underwriter's over-allotment option.

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

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

#### **Results of Operations**

#### Management's Plans and Basis of Presentation

To date, the Company has in large part relied on equity financing to fund its operations, raising \$3,200,000 in 2011 in a secondary public offering, \$675,000 in private placements in 2012 and \$1,600,000 in private placements in 2013. The Company has experienced recurring losses and negative cash flows from operations, however, at June 30, 2013, the Company's performance for the first half of the year had improved. Management's strategic plans include the following:

- · continuing to advance the development and commercialization of the Company's products, especially those that utilize MPC Biosensor, PIFA and seraSTAT technologies;
- continuing to strengthen and forge domestic and international relationships with well-established sales organizations with strong distribution channels in specific target markets for both our currently marketed and emerging products;
- · establishing clinical protocols that support regulatory submissions and publication of data within peer-reviewed journals; and
- · continuing to monitor and implement cost control initiatives to conserve cash.

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

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

At June 30, 2013, ABI had cash and cash equivalents of \$1,553,884, working capital of \$1,871,001, stockholders' equity of \$4,703,061 and an accumulated deficit of \$80,395,315. The Company believes that its current working capital position will be sufficient to meet its estimated cash needs for at least 12 months following the consummation of this offering. If the Company does not obtain additional capital as needed, the Company would potentially be required to reduce the scope of its research and development activities. The Company is closely monitoring its cash balances, cash needs and expense levels.

#### Revenue

Six months ended June 30, 2013 and 2012

The Company's total revenue as of June 30, 2013 was \$2,639,085, a 235% increase over the same period in 2012. Product revenue for the six months ended June 30, 2013 was \$2,272,418 as compared to \$787,194 during the same period in 2012. Licensing revenue during the period was \$366,667, compared to \$0 during the same period in 2012.

The significant increase of product revenue was largely attributed to the revenue generated through the manufacturing and shipping of CHUBE-branded disposable breath alcohol detectors under the Company's Supply and Licensing Agreement with Chubeworkx Guernsey Ltd ("Chubeworkx"). The private labeled CHUBE tubes are certified under two international quality standards:

- · AS 3547:1997, the Australian Standardsmark license, referred to as the "5 ticks mark" for Breath alcohol testing devices for personal use; and
- NF X 20-702, the French Standard for disposable breathalyzers.

These certifications cleared that way for the CHUBE breathalyzers to be marketed by ABI's UK based partner, (en) <sup>10</sup> Guernsey Limited" ("(en)10"), in Australia, New Zealand, South Africa, and in and around France. In December 2012, ABI received a purchase order from Chubeworkx to manufacture 3.5 million units of their custom breath alcohol detectors which would be deliverable in 2013. In April 2013, the Company announced that it received a second order from Chubeworkx for an additional 1.4 million CHUBE-branded, disposable breath alcohol detectors. All of the 4.9 million units ordered CHUBE tubes have been delivered as of June 30, 2013 contributing \$1.47 million to ABI's six months ended June 30, 2013 revenue totals. Under the licensing portion of the agreement which originated in September 2012, the Company granted Chubeworkx an exclusive license to market their private-labeled CHUBE breath alcohol detectors outside of North America in exchange for an upfront license fee of \$1,000,000 which has been received in full. In 2012, the Company recognized \$27,778 of the license fee as revenue and in the six months ended June 30, 2013, booked an additional \$166,667. The remaining \$805,555 will be recognized as revenue over the next 29 months. On June 13, 2013, ABI announced that the Company had extended the reach of Chubeworkx'exclusive territory to include North America. In addition, Chubeworkx agreed to purchase 80,000,000 shares of common stock (the "Subscription").

ABI also experienced growth in sales of its PIFA Heparin/PF4 rapid tests, up 2% over the same period last year which was achieved despite a 40% reduction in headcount in the Company's account executive sales force.

Cost of sales for the period ended June 30, 2013 increased compared to the 2012 period to \$1,409,384 from \$468,335. This was largely due to an increase in the cost of inventories and temporary staff to support CHUBE product sales.

As a percentage of sales, gross profit margin for six months ended June 30, 2013 was 47% as compared to 40% for the same period in 2012. The improvement was due primarily to the increase in licensing revenue and improved bulk pricing for raw materials from vendors for the materials utilized in the production of the Chubeworkx products.

Year 2012 compared to Year 2011

ABI's total revenue for the year ended December 31, 2012, totaled \$1,522,363, a 15% decrease over the same period in 2011. The decrease in sales was primarily attributed to the Company's relatively flat PIFA Heparin/PF4 Rapid Assay sales growth and increasing competition from lower-priced, lower-quality products within the Human Resources sector of the United States breathalyzer market. Growth in PIFA revenue was realized in the fourth quarter of 2012 as the Company began to benefit from the change in strategy of its dedicated technical sales account executives moving away from a direct selling model to one that works in tandem with over 300 sales representatives of ABI's US distribution partners, Cardinal Health ("Cardinal") and Fisher HealthCare ("Fisher"). In addition, the Company began shipping its PIFA PLUSS PF4 product line extension in late November 2012. The aforementioned domestic distributors, Cardinal and Fisher, accounted for close to \$850,000 of the total 2012 sales and individually represented 89% and 12%, and of such sales. The remaining \$270,000 in sales was generated from ABI's direct customers.

Cost of sales for the year ended December 31, 2012 increased by 5% compared to the same period in 2011 to \$1,007,951 from \$956,620 in 2011. ABI's gross profit margin was 34% for the year ended 2012 as compared to 46% in 2011. The differential between 2011 and 2012's cost of sales and gross profit margin is attributed to the costs of repairs and process enhancements made to a variety of machines crucial to the production of the Company's disposable breath alcohol detectors and the PIFA and PIFA PLUSS Heparin/PF4 rapid assays, along with the indirect labor costs associated with such activities. The completion of these tasks has improved production performance and efficiency and increased the Company's overall manufacturing capacity.

#### General and Administrative Expenses

Six months ended June 30, 2013 and 2012

General and administrative expenses in the six months ended June 30, 2013 totaled \$675,689, a 9% decrease as compared to the same period of 2012. The most significant difference is the write-off of a long-term note receivable of \$151,569, the outstanding balance for products supplied under the en(10) licensing agreement dating from 2010. The write-off was part of the June 2012 licensing and supply agreement with Chubeworkx which, among other things, discharged all prior agreements and all liabilities arising from prior transactions. The current accounts receivable arose from product purchases in 2013 and are within credit terms as of June 30, 2013.

Year 2012 compared to Year 2011

General and administrative expenses in the year ended December 31, 2012, totaled \$1,493,707, which was a 53% decrease as compared to \$3,188,137 for the year ended 2011. The decrease was due to the fact that in 2011 the Company incurred bad debt expense of \$1,650,185 where as in 2012 this expense was only \$9,047. The bad debt expense of \$1,650,185 in 2011 represented an increase in the allowance for doubtful accounts for a long-term receivable due from a foreign customer who entered bankruptcy proceedings in 2011 and thus collection was doubtful. This receivable was written off during the six months ended June 30, 2012 with a corresponding reduction in the allowance. In addition, the Company saved \$66,200 by phasing out its previously outsourced Investor Relations firm and bringing such tasks in-house.

## Sales and Marketing Expenses

Six months ended June 30, 2013 and 2012

Sales and marketing expenses in the six months ended June 30, 2013 totaled \$410,008, an 18% increase as compared to the same period in 2012. This increase is related to sales commissions and the payment of royalties on the breathalyzer products.

Year 2012 compared to Year 2011

Sales and marketing expenses in the year ended December 31, 2012, totaled \$638,732, which was a 10% decrease as compared to \$707,790 for the year ended 2011. The savings was a result of a reduction in the size of the internal sales force, through attrition.

## Research and Development

Six months ended June 30, 2013 and 2012

Research and development expenses in the six months ended June 30, 2013 totaled \$522,132, which was a 7% increase as compared to the same period in 2012. This increase in cost was primarily due to required repairs and maintenance for the Company's laboratory equipment.

#### Year 2012 compared to Year 2011

Research and development expenses in the year ended December 31, 2012 totaled \$900,380, which was a 1% increase as compared to the same period in 2011. This increase was due to expanded development of the METRON single-use ketone test for the medically-assisted weight loss and health & wellness industries.

#### Other Income and Expense

Six months ended June 30, 2013 and 2012

Other income increased for the six months ended June 30, 2013 over the same period in 2012, primarily as a result of income from two notable events. On June 13, 2013, ABI sold its interest in (en)10, the Company's exclusive CHUBE distributor based in the UK, to Chubeworkx for \$100,000; and a realized gain of \$99,710, representing the difference between the sale price and carried value of the interest. We have determined that the sale of our interest was an independent transaction, unrelated to the extension of the licensing agreement to include North America. In addition, the Company recognized \$91,286 in other income from the net proceeds gained from ABI's insurer demutualizing upon receiving a payment of such amount representing our share of the demutualization as determined by the insurer. Other items, including interest, shipping and handling fees and other miscellaneous income amounted to \$115,543 as of June 30, 2013 as compared to \$22,797 as of June 30, 2012. On April 8, 2011, the Company reacquired technology from a customer at a calculated fair value of \$2,062,410 (the long-term receivable of \$2,290,538 less \$155,311 in deferred revenue and \$72,817 of future value impairment associated with the receivable).

Year 2012 compared to Year 2011

Other income and expenses for the year ended December 31, 2012, decreased to income of \$51,751, compared to an income of \$287,481 in 2011. Other items, including interest, shipping and handling fees and other miscellaneous income declined to a total \$44,892 as of June 30, 2012 compared to \$317,109 as of June 30, 2012. The decline was partially offset by an increase in income due to foreign currency transactions in the Company's favor.

#### Income Taxes

During 2012, the Company was approved by the State of New Jersey to sell a portion of its state tax benefits that existed as of December 31, 2011, pursuant to the Technology Tax Certificate Transfer Program. The Company received net proceeds of \$167,408 in 2012 (2011: \$297,890) as a result of the sale of the tax benefits.

The Company has had recurring tax losses and it has determined that it is not probable that the Company will be able to utilize its net operating loss carry-forwards and other tax attributes in the future. Accordingly, the Company has not recorded any deferred tax assets as of December 31, 2012 and December 31, 2011.

As of December 31, 2012 and 2011, the Company had Federal net operating loss carry forwards of approximately \$46,500,000 and \$44,000,000, respectively, expiring through the year ending 31 December 2032. As of December 31, 2012 and 2011, the Company had New Jersey state net operating loss carry forwards of approximately \$5,600,000 and \$6,100,000, respectively, expiring the year ending 31 December 2019.

The principal components of unrecognized deferred tax assets consisted of the following as of December 31, 2012 and December 31, 2011:

## Unrecogonized Deferred Tax Assets

	Years Ended December 31,				
	2012		2011		
Reserves and other	\$	921,068	\$	922,702	
Net operating loss carry-forwards	\$	16,149,472	\$	15,039,711	
Valuation Allowance	\$	(17,070,540)	\$	(15,962,413)	
Total unrecognized deferred tax assets:	\$		\$		

The reconciliation of income taxes using the statutory U.S. income tax rate and the benefit from income taxes for the years ended December 31, 2012 and December 31, 2011 are as follows

# Tax Rates & Benefits

	Years Ended December 31		
	2012	2011	
Statutory U.S. Federal Income Tax Rate	(34.0)%	(34.0)%	
New Jersey State income taxes, net of U.S.			
Federal Benefit	(6.0)%	(6.0)%	
Change in Valuation Allowance	34.0%	32.3%	
Net benefit from sale of state income tax benefits	(6.0)%	(7.7)%	

#### **Liquidity and Capital Resources**

For the year ended December 31, 2012, the Company generated a net loss of \$2,557,820. As of December 31, 2012, the Company has an accumulated deficit of \$80,194,353 and had cash and cash equivalents totaling \$633,022.

Currently, our primary focus is to expand the domestic and international distribution of our PIFA Heparin/PF4 rapid assays and support Chubeworkx international distribution of its CHUBE private-labeled breath alcohol detectors.

The Company continues initial commercialization tasks for METRON and VIVO, as well as development activities for its PIFA PLUSS® Infectious Disease single-use assays, Breath Ketone "Check", and Breath PulmoHealth "Check" products, including advancement of the steps required for FDA clearance or CE marking in the EU where necessary.

We expect to continue to incur losses from operations for the near-term and these losses could be significant as we incur product development, clinical and regulatory activities, contract consulting and other product development and commercialization related expenses. We believe that our current working capital position will be sufficient to meet our estimated cash needs for at least 12 months following the consummation of this offering. The Company is pursuing additional financing opportunities; however, there can be no assurance that the Company will be able to obtain sufficient additional financing on terms acceptable to the Company, if at all. We are closely monitoring our cash balances, cash needs and expense levels. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might result in the possible inability of the Company to continue as a going concern.

We expect that our primary expenditures will be to continue development of PIFA PLUSS ® Infectious Disease single-use assays, Breath Ketone "Check" and Breath PulmoHealth "Check" products and enroll patients in clinical trials to support performance claims, generate studies in peer-reviewed journals to support product marketing, and provide data for the FDA 510(k) clearance / CE certifications processes when required. We will also continue to support commercialization and marketing activities of in-line products (PIFA Heparin/PF4 rapid assays, PIFA PLUSS ® PF4, breath alcohol detectors, METRON and VIVO)) in the US and internationally. Based upon our experience, clinical trial and related regulatory expenses can be significant costs. Steps to achieve commercialization of emerging products will be an ongoing and evolving process with expected improvements and possible subsequent generations being evaluated for commercialized and emerging tests. Should we be unable to achieve FDA clearance for products that require such regulatory "approval", develop performance characteristics for rapid tests that satisfy market needs, or generate sufficient revenue from commercialized products, we would need to rely on other business or product opportunities to generate revenue and costs that we have incurred for the patents may be deemed impaired.

We may consider entering into agreements with ISO-certified contract manufacturers which would allow the Company to meet the regulatory requirements for product sales in large, international markets (e.g. India). We may also consider acquisitions of development technologies or products, if opportunities arise that we believe fit our business strategy and would be appropriate from a capital standpoint.

Capital expenditures, primarily for production, laboratory and facility improvement costs for remainder of the year ending December 31, 2013 are anticipated to total approximately \$250,000. As per the Company's lease agreement, the owner of the facility will be handling the majority of facility upgrades, and we anticipate financing any production and laboratory capital expenditures through working capital.

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

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

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

# **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

#### **Operating Activities**

ABI's net cash consumed by operating activities totaled \$1,024,584 during the six months ended June 30, 2013. Cash was consumed by the loss of \$200,962, less non-operating gains of \$190,996 plus a non-cash adjustment of \$176,285 for depreciation and amortization of non-current assets. For the six months ended June 30, 2013, decreases in license fees receivables, inventories, and other assets of \$608,505 provided cash, primarily related to routine changes in operating activities. A net increase in trade and other receivables of \$1,115,985 consumed cash from operating activities. Additional cash was consumed by operations from a net decrease of approximately \$301,431 in deferred revenue and trade and other payables and legal settlements payable.

ABI's net cash consumed by operating activities was \$999,166 during the year ended December 31, 2012. Cash was consumed by the loss of \$2,557,820, less non-cash expenses of \$561,623 for provisions for bad debt, write-off of notes receivable, establishment of an inventory reserve for obsolescence and depreciation and amortization of non-current assets. For the year ended December 31, 2012, decreases in trade and other receivables, and other assets generated cash of \$382,724. There was a \$334,178 increase in inventories in the year ended December 31, 2012, primarily due to increases in the production of CHUBE breath alcohol tubes. At year-end 2012, there was also an increase of \$948,485 in trade and other payables, legal settlement liabilities, and deferred revenue.

Net cash consumed by operating activities was \$2,452, 312 during the year ended December 31, 2011. Cash was consumed by the loss of \$3,626,944, less net non-cash expenses of \$2,055,109, including provision for bad debt totaling \$1,650,185, non-cash share based compensation totaling \$27,766, \$377,448 for depreciation and amortization of noncurrent assets, and a non-cash increase in the equity position in (en)10 in the amount of \$290. For the year ended December 31, 2011, a \$479,548 increase in inventories, trade and other receivables, and other assets consumed cash. Additional cash was consumed by operations from a net decrease of \$400,929 in trade and other payables.

# **Critical Accounting Policies**

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

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

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

Intangible Assets: Intangible assets primarily represent legal and filing costs associated with obtaining patents on the Company's new discoveries or acquiring patents for diagnostic technologies or tests that will enhance the Company's product portfolio. The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person's breath, blood, urine and saliva. Propriety protection for the Company's products, technology and process is important to its competitive position. To date, the Company has received eight patents from the United States Patent Office (7,896,167, 8,097,171, 7,285,246, 7,837,936, 8,003,061, 8,425,859, 5,565,366 and 5,827,749). Other patents have been granted through the European patent Convention in Japan (4,885,134 and 4,931,821). Patents are in the national phase of prosecution in many PCT participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the U.S., European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

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

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

The testing resulted in no patent impairment charges during the six months ended June 30, 2013, as well as for the years ended December 31, 2012 and 2011 respectively.

On April 8, 2011, the Company re-acquired technology from a customer at a calculated fair value of \$2,062,410 (the long-term receivable of \$2,290,538 less \$155,311 in deferred revenue and \$72,817 of future value impairment associated with the receivable.)

# **Long-Lived Assets:**

# Recognition and measurement

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Cost includes expenditure that is directly attributable to the acquisition of the asset. When parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment. Gains and losses on disposal of an item of property, plant and equipment are determined by comparing the proceeds from disposal with the carrying amount of property, plant and equipment and are recognized net within "other income" in profit or loss.

# **Revenue Recognition**

The Company's revenue is recognized when products are shipped or delivered to unaffiliated customers. The Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) 605, provides guidance on the application of generally accepted accounting principles to select revenue recognition issues. The Company has concluded that its revenue recognition policy is appropriate and in accordance with FASB ASC 605. Revenue is recognized under sales, license and distribution agreements only after the following criteria are met: (i) there exists adequate evidence of the transactions; (ii) delivery of goods has occurred or services have been rendered; and (iii) the price is not contingent on future activity and (iv) collectability is reasonably assured.

#### Stock-based Compensation

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

# Recently Issued and Adopted Accounting Pronouncements

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

# Reclassifications

Certain prior period amounts in the accompanying financial statements have been reclassified to conform to the presentation used in 2012.

# Quantitative and Qualitative Disclosure About Market Risk

#### General

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

## **Interest Rates**

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

#### BUSINESS

#### Overview

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

All of ABI's 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, neuropsychiatry, oncology and infectious diseases / bioagent detection, as well as for on- and off-the-job alcohol safety initiatives.

ABI 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 ABI's FDA-cleared rapid diagnostic tests that help facilitate targeted diagnoses and real-time treatment. We also believe that ABI's rapid diagnostic tests surpass most other current diagnostic products with their flexibility, speed, ease-of-use, readability, low cost and accuracy. In minutes, detection of disease states and medical conditions can be performed on single-patient specimens, without sacrificing accuracy.

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

- cost pressures/efficiency of healthcare delivery;
- need for tools for pharmaceutical companies to monitor side effects of medicines/new agents in development;
- 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.

## **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 increasing baby booming population across the globe. Other major drivers for the growth of the in vitro diagnostic ("IVD") industry is a rise in the number of diseases like respiratory and hospital-acquired infections and a rise in the chronic diseases such as diabetes, hypertension, cardiovascular diseases, and cancer. both an increasing understanding of the molecular processes underlying many disease states and the opportunity for clinicians to quickly incorporate that targeted information into treatment decisions (e.g. companion testing). According to an article published on in vitro diagnostics by Medical Device and Diagnostic Industry ("MDDI") online in March 2013, in the past, the in vitro diagnostics industry has focused on developing tests that require significant time, skill, and often costly, specialized equipment. Patient specimens often had to be collected remotely and processed in a central laboratory with test results sent to a physician at a later date. This general protocol is not particularly well-adapted to the practice of medicine in a cost-effective, timely manner. The pressures on public health budgets and falling profits among third party payors such as insurers, necessitates an alternative approach to disease management. 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 centers market.

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

ABI designed its products based on single-use assay platforms with straightforward test procedures that can be completed in minutes. In the healthcare setting, the Company's clinical laboratory products can be utilized near or at the point-of-care and do not require the use of expensive equipment or a highly trained or specialized staff. As a result, an individual's 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. ABI believes that the products that emerge from ABI's technology platforms address the needs of the evolving healthcare delivery system that is moving patient care closer to or in the home.

In a June 6, 2013 article "Global In Vitro Diagnostics Markets Outpace Pharma Industry Growth" by Frost & Sullivan's 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's. The Company's main presence is in the United States, but recently executed distribution and licensing agreements have initiated ABI's strategic move to the China and European Union marketplaces.

#### Strategy

ABI's 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. ABI utilizes its existing platform technologies to internally develop its new products as the Company's proprietary methods.

ABI 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.

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

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

ABI's 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 tubes through which test subjects can easily blow for several seconds. In the United States, the MPC Biosensor Technology is protected by two United States patents (7,285,246; 7,837,936), covering all MPC Biosensor products such as CHUBE, Breath Ketone "Check and the "Breath PulmoHealth "Check" suite of products, with an additional patent pending.

# 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. ABI's PIFA® Technology is currently protected by two United States patents (5,565,366; 5827749) and one international Patent (4,931,821) covering all PIFA tests such as Heparin, Malaria and Chlamydia. An additional US patent and one international patent are pending.

# **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. ABI has two United States patents (8,003,061; 8,425,859) for this technology covering our Tri-Cholesterol Test.

## minDNATM Technology

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

# Product Portfolio

ABI 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, ABI's commercialized and emerging product portfolio incorporate 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 will be segmented by platform.

ABI 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 Adminstration ("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, ABI's 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 payor. In addition, in the developing world, the portability and ease-of-use of such point-of-care tests can serve to drastically improve the level of disease screening and subsequent patient care. We believe the benefits of our technology platforms are therefore well-suited to the diagnostic demands of countries in the developing world that seek to deliver modern medical diagnosis 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 a quality management system ("QMS-Compliant"). ABI 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 set forth our marketed and current pipeline products indentifies the appropriate "prescription use" or "OTC" designation and whether the required clearance has been obtain

Not FDA

Our marketed and emerging products include:

Product	Platform	Market/Pipeline	Not FDA- regulated; QMS- Compliant Only	FDA Clearance Required Prescription Use/OTC	FDA Clearance Status Obtained/Needed	Description
BreathScan <sup>®</sup> /CHUBE <sup>™</sup>	MPC	Marketed		OTC	Obtained	Disposable breath alcohol detector
BreathScan <sup>®</sup> 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 <sup>TM</sup>	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
VIVO	MPC	Marketed	X			Non-invasive, quantitative measurement of biological markers for oxidative stress that relates to cellular damage
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 <sup>®</sup> Infectious Diseases	PIFA	Pipeline		Prescription Use	Obtained	Rapid tests for a variety of infectious diseases, especially those that are prevalent outside of the United States
seraSTAT <sup>®</sup>	seraStat	Marketed		Prescription Use	Obtained	Rapid Blood Cell Separator, marketed under the brand name seraSTAT <sup>®</sup> , 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

# MPC Biosensor Technology

 $The \ Company's \ MPC \ Biosensor \ breath \ condensate \ testing \ platform \ forms \ the \ basis \ of \ a \ number \ of \ ABI's \ marketed \ and \ pipeline \ products.$ 

## **Breath Alcohol Franchise**

BreathScan<sup>®</sup> 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, Chubeworkx and its indirect subsidiary (en)<sup>10</sup> Global Limited ("en10"), in partnership with the Company, 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 March 2013, a 2012 law mandating most motorists driving in France to equip their vehicles with two, "NF-Marked" breath alcohol detectors took effect. As a result, the Company's breathalyzers, under the Chubeworkx private label brand, CHUBE, can now be marketed to the approximately 34 million French nationals who own motorized vehicles and a portion of the estimated 81 million foreign visitors entering France annually by automobile. In fact it is estimated that at least 1.6 millioncars, motorcycles and

recreational vehicles are transported on the Eurotunnel train through the Channel Tunnel each year between England and France, while more vehicles make the same trip via ferry via the English Channel waterway. In addition, the Company's breath alcohol detector technology has been granted Australian Standard certification trademark, which cleared the commercial pathway for product sales in Australia, New Zealand, and South Africa that view certification as a requirement for market entrance through its distribution relations with Chubeworkx and en10. Chubeworkx sales and marketing initiatives also currently extend into the UK. On June 13, 2013, the Company announced that it was extending the Chubeworkx License and Supply Agreement to allow the marketing and distribution of the "BE CHUBE" program and its related product in North America to facilitate a worldwide sales and marketing initiative.

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 US 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. ABI's distribution relationship with Chubeworkx also is expected to encompass a private-labeled version of BreathScan® PRO within its global distribution plan.

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, ABI has used its proprietary, easy-to-use platform to design disposable breath tubes that measure ketone (acid) production associated with fat-burning (METRON™) and oxidative stress levels that relate to cellular damage and the development of many preventable diseases (VIVO™). Initial marketing activities have commenced for these products and they are heading toward full 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 either 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.

ABI is continuing its clinical development of the Breath Ketone "Check" disposable breath tube for two clinical indications: (i) the diagnosis of ketoacidosis in diabetics, and (ii) the management of senile dementia and Alzheimer's disease patients.

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.

An additional clinical indication for the Breath Ketone "Check" test is as an aid in the management of senile dementia and Alzheimer's disease. There is no known cure for these neurological conditions, which slowly progress over years to decrease cognitive function. Moreover, the cost to the healthcare system to provide care for these patients is significant. However, recent advances in neuroscience indicate that these diseases can be greatly slowed, and in some cases the progression can stop, if the patient is maintained in a state of ketosis. Ketosis results from a diet low in carbohydrates that promotes the production of ketones in the bloodstream, and is a milder form of ketoacidosis. Because these patients are often confused or unreliable, it is important to ensure that they maintain a state of ketosis to keep the disease in check. This can be accomplished through routine monitoring with Breath Ketone "Check".

ABI is also putting research and development resources to the development of 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. ABI has chosen to target this trio of conditions as their impact on global health is staggering:

- · 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 is 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.

ABI 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 ABI 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 an earlier version of the Breath Ketone "Check" as being in compliance with CE requirements in the EU, and intends to pursue the same designation for the emerging version, as well as for each product in the Breath PulmoHealth "Check" trio once the appropriate technical file is assembled.

MPC Biosensor technology is currently protected by two United States patents (7,285,246; 7,837,936).

# <u>PIFA</u> <u>Rechnology</u>

The core products marketed under the PIFA® platform are the PIFA® Heparin/PF4 Rapid Assay, PIFA PLUSS® PF4, and a variety of rapid Infectious Disease screening tests which target markets in the developing world.

PIFA® Heparin/PF4 Rapid Assay and PIFA PLUSS® PF4 remain the only FDA-cleared rapid manual assays that quickly determines 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 ABI's Heparin/PF4 devices, is paramount to effective, clinical decision making. In the US alone, approximately 12 million patients are exposed to Heparin annually and 1% to 5% of tardiac 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 was fully commercialized in the U.S. in 2008, improving the standard of care in HIT-testing with its result delivered in less than ten minutes after the patient sample has been prepared. Traditional methods required the use of expensive equipment, specialized laboratory personnel and approximately 4 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. In November2012, the Company introduced PIFA PLUSS PF4 to U.S. hospitals to further improve the rate at which healthcare professionals can obtain a HIT-antibody result.

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

Since the appropriate regulatory clearances have been obtained in the United States for these products, the Company does not anticipate needing to fund additional clinical trials to facilitate product marketing domestically. In addition, the current technical file that has been assembled for seraSTAT ® and PIFA PLUSS PF4 ® will also be used to support ABI's 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 greater 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.

ABI's PIFA <sup>®</sup> technology provides a testing format that meets the aforementioned criteria. The Company can quickly apply the PIFA PLUSS<sup>®</sup> 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, especially those that are prevalent outside of the United States including the following:

- · chagas disease
- chlamydia
- cytomegalovirus
- · dengue fever
- · hepatitis B surface antigen
- · hepatitis C
- human immunodeficiency virus (HIV 1+2)
- · infectious mononucleosis\*
- · lyme disease
- malaria
- · syphilis

In addition, PIFA technology has been applied to a rapid blood typing card used to assess donor-patient blood grouping compatibility in minutes, to help facilitate fresh whole blood transfusions in triage situations. The "Battlefield Blood Transfusion Card" is designed to enhance combat casualty care or provide remote healthcare facilities in underdeveloped countries with critical patient-donor information, especially when blood requirements outpace blood supplies. As with the Company's Infectious Disease products, current business activities will focus on opportunities in international markets. As such, clinical trials to support FDA 510(k) clearances or CE self-certification will not be required. The Company intends to determine the clinical data needed to market products specifically within the developing world, once it completes the assessment of distribution options within the region.

PIFA® technology is currently protected by two United States patents (5,565,366; 5,827,749) and one international patent (JP 4,931,821).

# **REA Technology**

ABI's 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 lypoprotein ("HDL") cholesterol levels, and by a simply calculation, approximates their low density lypoprotein ("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 accessed 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 ABI 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 two United States patents (8,003,061; 8,425,859).

# Sample Preparation Technology

# Rapid Blood Cell Separation Technology

In addition to the Company's testing platforms, ABI's recently patented Rapid Blood Cell Separation ("Separator") Technology, marketed under the brand name seraSTAT <sup>®</sup>, 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. seraSTAT is currently integrated into PIFA PLUSS PF4 devices, and will be utilized in the infectious disease products currently under development. ABI may consider partnerships with other medical device companies, functioning as an Original Equipment Manufacturer ("OEM"), as the benefits of the seraSTAT applied 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 ABI's 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 Technologyis currently protected by two United States patents (7,896,167; 8,097,171) and one international patent) (JP 4,885,134).

## Competition

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

#### **Our Current Target Markets**

Given that, according to the HIT Report, 50% of cardiac surgery patients develop antibodies that have been found to be the major determinant in the pathogenesis of HIT, the HIT-testing market largely resides within the clinical hospital laboratories of medical facilities that perform major cardiac surgeries such as coronary artery bypass graft (CABG) procedures. 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. ABI has also instituted an innovative teleconference program that trains laboratory professionals on the PIFA and PIFA PLUSS product profiles and with product in-hand, walks them through the straightforward test procedures. This training is intended to turn interest into immediate action and drives home the ease-of-use of the products. Individuals that participate in remote training usually start the verification process to bring one or both of the assays in-house, within a 4-week cycle. Internationally, ABI provides comprehensive training to its distributor partners to enable them to implement the same selling and technical training strategies.

# 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 (the 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. During the year ended December 31, 2012 and the six months ended June 30, 2013, three suppliers accounted for 43% and 56%, respectively of the Company's total purchases. This makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

#### Distribution

We distribute our products through direct and indirect channels of distribution. We have well-developed indirect distribution channels in the U.S. with Cardinal Health 200, Inc. and Fisher Healthcare for the Company's PIFA Heparin/PF4 assays. Effective May 1, 2007 we entered into a distribution agreement (as subsequently amended the "Cardinal Health Agreement") with Cardinal Health 200, Inc. ("Cardinal Health"). The Cardinal Health Agreement grants Cardinal Health the non-exclusive right to distribute PIFA Herapin / PF4 Rapid Assays. Pricing terms for each product are included in the Cardinal Agreement and vary depending on product and volume of the order. The Cardinal Health Agreement automatically renews for successive twelve month unless either party (a) upon 30days written notice if either party commits or suffers any act of bankruptcy or insolvency, or fails to cure any material breach of the provisions of the agreement within 30 days after written notice of such breach, or (b) upon 90 days written notice with or without cause. On June 15, 2010 we entered into a distribution agreement with Fisher Healthcare, a Division of Fisher Scientific Company L.L.C. (as subsequently amended, the "Fisher Agreement"). The Fisher Agreement grants non-exclusive rights for Fisher Healthcare to distribute PIFA Heparin/PF4 Rapid Assays, Heparin/PF4 serum panels, and BreathScan disposable breath alcohol detectors in the United States. Under the Fisher Agreement we are required to fill all orders placed by Fisher Healthcare and do not have the right to decline such orders. We must notify Fisher Healthcare of any proposed price increase at least 120 days prior to the effective date of such increase. Payment terms are net 45 days from the date of receipt of an accurate invoice, and Fisher Healthcare will not be in default if payments are made within five (5) days of the due date. The initial term of the agreement was June 15, 2010 through May 31, 2012 and included initial pricing terms for each product that varied depending on t

The relationships with Cardinal Health and Fisher provide us with access to the majority of U.S. hospitals. During the year ended December 31, 2012 and for the six months ended sales to Cardinal Health, Inc. and Fisher Healthcare accounted for 57% and 20% of the Company's revenue, respectively. For the six months ended June 30, 2013 Chubeworkz accounted for 67% of our revenue. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated. 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. 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 China in the current fiscal year.

With respect to the Company's breath alcohol franchise, historically ABI focused its commercial attention within the on-the-job safety / human resources sector. Access was and currently is largely achieved through designated BreathScan<sup>®</sup> distributors and limited arrangements in which the Company serves in an OEM capacity. On June 19, 2012, ABI entered into License and Supply Agreement (the "License and Supply Agreement") with Sono International Limited ("SIL"), BreathScan International (Guersney) Limited and BreathScan International Limited pursuant to which the Company granted SIL an exclusive license to market and distribute private-labeled versions of ABI's disposable breath alcohol detectors, to be supplied by the Company, outside the United States of America, Canada and Mexico. On June 12, 2013, the Company entered into an amended License and Supply Agreement (the "Amended License and Supply Agreement") with Chubeworkx Guernsey Limited (as successor to SIL), (EN)10 (Guernsey) Limited (formerly BreathScan International Limited). Under the Amended License and Supply Agreement, among other obligations, Chubeworkx is required to provide product purchase forecasts and maintain minimum order volumes. Chubeworkx is required to pay invoices in full within 90 days of delivery. Chubeworkx shall pay the Company \$0.30 per product unit sold to Chubeworkx for the duration of the agreement. The initial term of the agreement is three (3) years. The term will, unless mutually agreed by the Company and Chubeworkx in writing, automatically renew on a three year rolling basis. Chubeworkx may terminate the agreement at any time after the initial term in whole or in part by giving the Company not less than six months written notice.

We believe that the Amended License and Supply Agreement represents a significant shift in ABI's breath alcohol product strategy. Chubeworkx extensive "BE CHUBE" promotional program, which recently launched in the EU, is helping to transform the way people from among the most at-risk populations view alcohol consumption and emphasize the importance of proactive testing with their private-labeled CHUBE breath alcohol detectors. While the majority of this marketing has been aimed at the French market, with all drivers on French roads, including foreign passport holders and drivers of foreign vehicles legally required to carry at least one un-used NF Approved disposable breathalyzer kit, Chubeworkx, through en10, also has active sales and marketing initiatives in the UK, South Africa and Australia. The Amended License and Supply Agreement expanded the marketing and distribution of the "BE CHUBE" program worldwide using the ABI breathalyzer. We believe that our decision to expand Chubeworkx reach into North America will facilitate a global presence and likely demand for ABI-manufactured private-label disposable breathalyzers. Chubeworkx's partnerships within Asia and Africa may also serve to expand the demand for the Company's PIFA PLUSS® Infectious Disease assays as well. To date, the Company has not dedicated extensive production resources toward this product line as demand by the US Government within the GSA contracting system has been minimal. With the expected expansion into the international market with a focus on the developing world, it is anticipated that selling opportunities for infectious disease rapid assays will increase.

We currently do not have a strong presence in many emerging markets. We have however, developed a distribution relationship with Novotek Therapeutics Inc. ("Novotek"), a Beijing-based pharmaceutical and *in vitro* diagnostic business development corporation. The multi-year agreement assigns exclusive sales and marketing rights to Novotek to make ABI's Particle ImmunoFiltration Assay ("PIFA") products available in Mainland China once market clearance is obtained (anticipated 2013). We are seeking to enter into additional agreements that will enable us to enter other international markets in the current fiscal year. Through our expanded distribution relationship with Chubeworkx, we anticipate pursuing business opportunities in Africa and other parts of Asia in the future. The Company is in the process of solidifying relationships with distributors in the UK for these assays, with selling expected to commence in the fourth quarter of 2013.

# 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 ABI logo is a registered trademark in the U.S. Other registered trademarks include: BreathScan<sup>®</sup>, PIFA PLUSS<sup>®</sup>, seraSTAT<sup>®</sup>, HealthTest<sup>®</sup>, and Be a Hero, Get Their Keys<sup>®</sup>.

The following table summarizes the US and international utility patents that currently protect ABI's intellectual property; the core and emerging products to which they relate are also noted:

<b>Description</b>	Jurisdiction	Utility Patent No.	Type of Protection	Expiration Date	Product(s) To Which They Relate
blood separator and method of separating fluid fraction from whole blood	US	7,896,167	Manufacture	9/7/2026	seraSTAT®; PIFA PLUSS® PF4; PIFA PLUSS® Infectious Diseases Rapid Assays
blood separator and method of separating fluid fraction from whole blood	US	8,097,171	Manufacture	8/5/2025	seraSTAT®; rapid blood cell separator also integrated into PIFA PLUSS® PF4 and PIFA PLUSS® Infectious Diseases Rapid Assays
blood separator and method of separating fluid fraction from whole blood	Japan	4,885,134	Manufacture	8/5/2025	seraSTAT®; rapid blood cell separator also integrated into PIFA PLUSS® PF4 and PIFA PLUSS® Infectious Diseases Rapid Assays
hand-held fluid analyzer	US	7,285,246	Manufacture	11/19/2025	Breath Ketone "Check"®; Breath PulmoHealth "Check"® suite of products; BreathScan®; BreathScan® PRO; CHUBE <sup>TM</sup> ; METRON <sup>TM</sup> ; VIVO <sup>TM</sup>
hand-held fluid analyzer	US	7,837,936	Manufacture	9/12/2024	Breath Ketone "Check"®; Breath PulmoHealth "Check"® suite of products; BreathScan®; BreathScan® PRO; CHUBE <sup>TM</sup> ; METRON <sup>TM</sup> ; VIVO <sup>TM</sup>
kits and ligand assay plates using two-tiered separation for detection of immunoreagent particles	US	5,565,366	Manufacture	5/25/2014	PIFA® Heparin/PF4 Rapid Assay; PIFA PLUSS® PF4; PIFA PLUSS® Infectious Diseases Rapid Assays
ligand assay method	US	5,827,749	Manufacture	10/11/2016	PIFA® Heparin/PF4 Rapid Assay; PIFA PLUSS® PF4; PIFA PLUSS® Infectious Diseases Rapid Assays
methods and kits for detecting heparin/platelet factor 4 antibodies	Japan	4,931,821	Manufacture	10/4/2025	PIFA® Heparin/PF4 Rapid Assay; PIFA PLUSS® PF4
test strip card	US	8,003,061	Manufacture	5/6/2024	Tri-Cholesterol "Check"®
test strip card	US	8,425,859	Manufacture	5/6/2024	Tri-Cholesterol "Check"®

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.		

ABI's Tri-Cholesterol "Check", PIFA Heparin/PF4 Rapid Assay, BreathScan PRO alcohol detection system, and an earlier version of the Breath Ketone "Check" are CEmarked for sale in the EU for professional use. The CE-mark must be affixed to a product that 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 ABI's 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 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 any required FDA clearance for all of our current products that require 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. PMA approval process based upon 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 number of arrangements 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 la

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

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

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

#### Foreign Regulation

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

# 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**

As of August 5, 2013, we employed 27 full-time equivalent employees, contractors or consultants, which include, seven in research and development, four in general and administrative, four in sales and marketing and twelve 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 is a party to a collective bargaining agreement. We believe that we have good relations with our employees.

#### **Properties**

Our corporate headquarters which houses our research and development, engineering, manufacturing, operations and support personnel, is located in Thorofare, New Jersey, in an office consisting of a total of 17,000 square feet. For the past ten years, the Company has leased this facility at this location. The current lease term is effective from January 1, 2013 through December 31, 2019 with an annual rent of \$132,000.

We believe our current facilities are sufficient for our current needs and will be adequate, or that suitable additional or substitute space will be available on commercially reasonable terms, for the foreseeable future.

#### Legal Proceedings

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

As of August 5, 2013, the Company does not have any litigation matters pending.

#### MANAGEMENT

#### **Executive Officers and Directors**

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

Name	Age	Position
Thomas A. Nicolette	62	Chief Executive Officer, Director, Principal Financial Officer, President
Raymond F. Akers, Jr. PhD	55	Executive Chairman of the Board of Directors, Secretary
Gary Rauch	57	Controller and Treasurer
Tom Knox**	72	Independent Director
Brandon Knox**	34	Independent Director(1)
Gavin Moran**	43	Independent Director

<sup>\*\*</sup>It is intended that these named persons, who will meet the requirements of "independence" under the pertinent NASDAQ rules.

(1) Mr. Brandon Knox will be appointed as a director upon the effectiveness of the registration statement of which this prospectus forms a part.

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

Thomas A. Nicolette, age 62, has been our President since February 2007 and our Chief Executive Officer since April 2008. Mr. Nicolette has been a member of the Board since May 2006. Mr. Nicolette has served as the principal of Nicolette Consulting Group Limited, a business management consulting firm, since founding it in 1984. From 1997 through 2012 Mr. Nicolette was the Corporate Secretary, Treasurer and director of Sentech EAS Corp., a designer and manufacturer of electronic security systems for retail, commercial and industrial firms. From 2003 through 2006, Mr. Nicolette was the director of international business development for November AG a developer of methods of authentication for anti-counterfeiting based in Germany. From 2001 to 2004, Mr. Nicolette served as Chairman of Exaqt Sa de CV a manufacturer and installer of electronic security systems. From 2001 through 2003, Mr. Nicolette served as Executive Director of Tri-Mex Group Limited, a developer of monitoring and response solutions to protect high value or hazardous cargo. Mr. Nicolette served as President, Chief Executive Officer and Director of DNA Technologies, Inc., a holder of patented technology providing solutions for counterfeiting, forgery and product diversion, from 2000 through 2003. From 1995 through 2001, Mr. Nicolette was the President, Chief Executive Officer and director of Sentry Technology Corporation which owned Knogo North America, Inc. and Video Sentry Corporation, designers and manufacturers of electronic articles surveillance systems and closed circuit television systems worldwide. Also, Mr. Nicolette served as President, Chief Executive Officer and director of Knogo Corporation, a New York Stock Exchange listed multi company and purveyor of electronic articles surveillance, from 1986 through 1994.

Mr. Nicolette is a graduate of Michigan State University School of Criminal Justice.

The Company believes that Mr. Nicolette's experience in management of various public companies, capital raising strategy, financial planning and the U.S. markets will assist the Company's development and maintenance of a sound financial strategy going forward.

Raymond F. Akers Jr., Ph.D., age 55, has been Executive Chairman of the Board since December 31, 2009 and was appointed Secretary on August 5, 2013. Dr. Akers founded the Company in 1989. He has over 25 years of experience in the diagnostics industry having co-founded Drug Screening Systems, Inc., a publicly listed company, in 1987, and Akers Medical Technology Inc. in 1984. He was Chief Executive Officer and vice president of research and development of Drug Screening Systems, Inc. until the sale of that company in 1989 and served as President and Chief Executive Officer of Akers Medical Technology Inc. until 1987.

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

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

Gary Rauch, age 57, has over 35 years of experience in accounting, financial and information systems consulting, discrete manufacturing, distribution and administration. Mr. Rauch has been the Company's controller since March, 2010 and was appointed treasurer on August 5, 2013. Mr. Rauch also founded DataSys Solutions, LLC in 2004 and is currently the managing member. DataSys Solutions LLC specializes in financial and information systems consulting and technical support services. From July, 2002 through March, 2010, Mr. Rauch was the controller for Cold Star, Inc., a manufacturer of dairy dispensing equipment and a dairy products distributor. Mr. Rauch also worked for six years as consulting manager with Deloitte & Touche providing financial system selection, development and implementation services for their small to middle market clients.

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

Thomas J. Knox, age 72, was appointed to our board of directors effective July 1, 2013. Mr. Knox is currently the Chief Executive Officer of Knox Consulting Group, an advisory and investment firm, as well as Chairman of ORB Automotive Corporation, Ltd. (appointed in 2011), a company focused on the development and manufacture of various components used in the Chinese automotive industry including adhesives and rubber molds. In May of 2007, Mr. Knox was a candidate for Mayor of Philadelphia. From April 2004 to April 2006, Mr. Knox was the Chief Executive Officer of United Healthcare of Pennsylvania, a division of United Healthcare, Inc., the largest health insurance provider in the world. From 1999 to 2004, Mr. Knox was Chairman of the Board and Chief Executive Officer of Fidelity Insurance Group, Inc., a Maryland and Pennsylvania licensed group life and health insurance provider. From 1988 through June 2000, Mr. Knox was the Chairman of the board and Chief Executive Officer of Crusader Holding Corporation, a NASDAQ listed company which was the owner of a multi-branch bank serving the greater Philadelphia area. Mr. Knox is a Chartered Life Underwriter (CLU) and Chartered Financial Consultant (ChFC), and is active in Philadelphia politics having held the position of Deputy Mayor for the Office of Management and Productivity from 1993 to 1999. Mr Knox also currently serves as the Chairman of INDECS Corp, a full service health benefit third party administrator affiliated with Aetna Corporation. From 1999 through the present, Mr. Knox has been a director of Historic Philadelphia Incorporated. Mr. Knox was a candidate for Governor or Pennsylvania from 2008 to 2010

The Company believes that Mr. Knox extensive expertise in health care and finance will assist the Company's strategic planning and operations.

Brandon Knox, age 34, has agreed to become a member of the board upon the effectiveness of the registration statement of which this prospectus forms a part. Mr. Knox has been a wealth advisor at Raymond James in Philadelphia since December 2012. His practice focuses on investment and estate solutions for high net worth families and individuals as well as public and private institutions both locally and nationally. Prior to joining Raymond James, Mr. Knox was a wealth advisor at Morgan Stanley from July 2008 to October 2012. From 2006 to 2008, Mr. Knox served as Deputy Finance Director for the Philadelphia mayoral campaign of his Father, Thomas Knox. In this role he concentrated on the organization and management of campaign fundraising efforts as well as the planning and execution of campaign events and off-site functions. Mr. Knox was a Leasing Associate for SSH Realty in Philadelphia from 2005 to 2007 handling lease negotiations for both commercial tenants and landlords. Mr. Knox holds a BS in Economics from West Chester University and an MBA in Financial Management from Drexel University. Mr. Knox sits on the Board of Directors of The Committee of Seventy and is a member of the Drexel University Presidents Leadership Council and the Archdiocese of Philadelphia's OSD Advisory Council.

Mr. Knox holds a B.S. in Economics from West Chester University and an M.B.A. in Financial Management from Drexel University's LeBow College of Business.

The Company believes that Mr. Knox vast experience with corporate finance and financial management will make him an ideal board member helping the Company to manage its finances as it continues its growth.

Gavin Moran, age 43, has previously worked for Shell International as a Trader, rotating through different departments including shell chemicals, marketing, finance and International Trading from 1988 to 1995. Mr. Moran held a trading role as a beneficial shareholder at Trafigura Ltd, a Trading Manager based in South Africa and London responsible for all the group's middle distillate activities and also jointly responsible for trading activities in East Africa and Far East, from 1995 to 2008 and since April 2010 a trading role as a beneficial shareholder at Sono International Ltd responsible for group's commercial activities, investments and strategy, based in Ghana and London.

The Company believes that the Mr. Moran's extensive experience in marketing and finance will assist the Company's growth strategy and development as a public company.

#### Chubeworkx Purchase Agreement/Voting Agreement

On June 19, 2013, the Company and Chubeworkx entered into a purchase agreement (the "Chubeworkx Purchase Agreement") pursuant to which Chubeworkx purchased 80,000,000 shares of the Company's common shares for an aggregate purchase price of \$1,600,000. As further consideration to induce Chubeworkx to enter into the Chubeworkx Purchase Agreement, the Company, Chubeworkx and Mr. Tom Knox entered into a voting agreement (the "Voting Agreement") whereby Mr. Knox and Chubeworkx agreed to vote their respective shares pursuant to the terms of the Voting Agreement. Amongst other things, The Company, Mr. Knox and Chubeworkx agreed as follows:

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

The Voting Agreement shall terminate and be of no further force or effect immediately prior to the consummation of this offering; provided, however, that the parties thereto acknowledge and agree that the termination of the Voting Agreement shall not occur until after the board of directors of the Company has already granted final approval of this offering and the issuance of shares of common stock in connection therewith.

Pursuant to the Voting Agreement, Chubeworkx was granted the right to appoint one director to the Company's board. Chubeworkx nominated Gavin Moran as its representative on the board and Mr. Moran was so appointed effective July 1, 2013.

#### **Family Relationships**

Tom Knox and Brandon Knox are father and son, respectively. There are no other family relationships among any of our directors or executive officers.

# Board Composition and Committees and Director Independence

As of the date of this prospectus, our board of directors will consist of four members: Thomas A. Nicolette, Raymond F. Akers, Jr. PhD, Thomas Knox and Gavin Moran. Mr. Brandon Knox shall be appointed to the board of directors upon the effectiveness of the registration statement of which this prospectus forms a part. The directors will serve until our next annual meeting and until their successors are duly elected and qualified. The Company defines "independent" as that term is defined in Rule 5605(a)(2) of the NASDAQ listing standards.

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

#### **Board Committees**

Upon effectiveness of the registration statement of which this prospectus forms a part, our board of directors will establish an audit committee, a compensation committee and a nominating and corporate governance committee. Each committee will have its own charter, which will be available on our website at <a href="https://www.akersbiosciences.com">www.akersbiosciences.com</a>. Information contained on our website is not incorporated herein by reference. As of the date of this prospectus, each of the board committees will have the composition and responsibilities described below.

#### Audit Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, we will have a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act of 1934, as amended (the Exchange Act"). The members of our Audit Committee will, upon effectiveness of the registration statement of which this prospectus forms a part, be Tom Knox, Gavin Moran and Brandon Knox. Each of these Committee members is "independent" within the meaning of Rule 10A-3 under the Exchange Act and the NASDAQ Stock Market Rules. Our board has determined that Tom Knox is an "audit committee financial expert", as such term is defined in Item 407(d)(5) of Regulation S-K. Tom Knox will serve as Chairman of our Audit Committee.

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

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

#### **Compensation Committee**

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our Compensation Committee will be Tom Knox, Gavin Moran and Brandon Knox. Each such member is "independent" within the meaning of the NASDAQ Stock Market Rules. In addition, each member of our Compensation Committee qualifies as a "non-employee director" under Rule 16b-3 of the Exchange Act. Our Compensation Committee assists the board of directors in the discharge of its responsibilities relating to the compensation of the board of directors and our executive officers. Tom Knox will serve as Chairman of our Compensation Committee.

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

- · reviewing and approving on an annual basis the corporate goals and objectives with respect to compensation for our Chief Executive Officer;
- · reviewing, approving and recommending to our board of directors on an annual basis the evaluation process and compensation structure for our other executive officers;
- determining the need for an the appropriateness of employment agreements and change in control agreements for each of our executive officers and any other officers recommended by the Chief Executive Officer or board of directors;
- · providing oversight of management's decisions concerning the performance and compensation of other company officers, employees, consultants and advisors;
- · reviewing our incentive compensation and other equity-based plans and recommending changes in such plans to our board of directors as needed, and exercising all the authority of our board of directors with respect to the administration of such plans;
- · reviewing and recommending to our board of directors the compensation of independent directors, including incentive and equity-based compensation; and
- · selecting, retaining and terminating such compensation consultants, outside counsel or other advisors as it deems necessary or appropriate.

## Nominating and Corporate Governance Committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, the members of our Nominating and Corporate Governance Committee will be Tom Knox, Gavin Moran and Brandon Knox. Each such member is "independent" within the meaning of the NASDAQ Stock Market Rules. The purpose of the Nominating and Corporate Governance Committee is to recommend to the board nominees for election as directors and persons to be elected to fill any vacancies on the board, develop and recommend a set of corporate governance principles and oversee the performance of the board. Mr. Gavin Moran will serve as Chairman of our Nominating and Corporate Governance Committee.

The Committee's responsibilities include:

- recommending to the board of directors nominees for election as directors at any meeting of stockholders and nominees to fill vacancies on the board;
- considering candidates proposed by stockholders in accordance with the requirements in the Committee charter;
- · overseeing the administration of the Company's Code of Ethics;
- · reviewing with the entire board of directors, on an annual basis, the requisite skills and criteria for board candidates and the composition of the board as a whole;

- the authority to retain search firms to assist in identifying board candidates, approve the terms of the search firm's engagement, and cause the Company to pay the engaged search firm's engagement fee;
- · recommending to the board of directors on an annual basis the directors to be appointed to each committee of the board of directors;
- · overseeing an annual self-evaluation of the board of directors and its committees to determine whether it and its committees are functioning effectively; and
- · developing and recommending to the board a set of corporate governance guidelines applicable to the Company.

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

#### Code of Ethics

Upon effectiveness of the registration statement of which this prospectus forms a part, our board of directors will adopt a Code of Business Ethics and Conduct (the "Code of Ethics") which constitutes a "code of ethics" as defined by applicable SEC rules and a "code of conduct" as defined by applicable NASDAQ rules. We shall require all employees, directors and officers, including our principal executive officer and principal financial officer to adhere to the Code of Ethics in addressing legal and ethical issues encountered in conducting their work. The Code of Ethics shall require that these individuals avoid conflicts of interest, comply with all laws and other legal requirements, conduct business in an honest and ethical manner and otherwise act with integrity. The Code of Ethics shall contain additional provisions that apply specifically to our Chief Executive Officer, Chief Financial Officer and other finance department personnel with respect to accurate reporting.

#### Management-Non-Executive Director Compensation

There were no non-executive directors for the fiscal year ended December 31, 2012.

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

#### **EXECUTIVE COMPENSATION**

The compensation provided to our "named executive officers" for 2012 2011 and 2011 is set forth in detail in the Summary Compensation Table and other tables and the accompanying footnotes and narrative that follow this section. This section explains our executive compensation philosophy, objectives and design, our compensation-setting process, our executive compensation program components and the decisions made for compensation in respect of 2012 for each of our named executive officers.

Our named executive officers who appear in the 2012 Summary Compensation Table are:

Thomas A. Nicolette President and Chief Executive Officer Raymond F. Akers, Jr., PhD Executive Chairman, Secretary Controller, Treasurer

# Summary Compensation Table

The following table summarizes information regarding the compensation awarded to, earned by or paid to, our Chief Executive Officer, and our only other most highly compensated executive officers who earned in excess of \$100,000 during 2012 and 2011 and 2010. We refer to these individuals in this prospectus as our named executive officers.

			Cash	Stock	Option		All Other	
		Salary	Bonus	Awards	Awards	Co	mpensation	Total
Name and Principal Position	Year	(\$)	(\$)	(\$)	(\$)		(\$)	(\$)
Raymond F. Akers, Jr. PhD	2012	\$ 350,000	0	0	0	\$	7,800(1) \$	357,800
Executive Chairman, Secretary	2011	\$ 345,285	0	0	0	\$	7,800(1) \$	353,085
	2010	\$ 295,000	0	0	0	\$	7,800(1) \$	320,800
Thomas A. Nicolette	2012	0	0	0	0	\$	335,004(2) \$	335,004
Chief Executive Officer, President	2011	0	0	0	0	\$	333,506(2) \$	333,506
	2010	0	0	0	0	\$	284,400(2)	284,400
Gary M Rauch, Controller, Treasurer	2012	0	0	0	0	\$	67,500(3) \$	67,500
	2011	0	0	0	0	\$	41,700(3) \$	41,700
	2010	0	0	0	0	\$	36,150(3) \$	36,150

- (1) Other compensation for Mr. Akers consisted of a car allowance.
- (2) Thomas A. Nicolette is not an employee of the Company and is paid a fee pursuant to his consultant agreement. Fees paid to Mr. Nicolette are recorded as other compensation.
- (3) Gary M. Rauch is not an employee of the Company and is paid a fee pursuant to his consultant agreement. Fees paid to Mr. Rauch are recorded as other compensation.

# Compensation-Setting Process/ Role of Our Compensation Committee

During 2012, our board of directors was responsible for overseeing our executive compensation program, establishing our executive compensation philosophy and programs, and determining specific executive compensation, including cash and equity. Upon effectiveness of the registration statement of which this prospectus forms a part, we intend to establish a compensation committee, the members of which shall be Tom Knox, Gavin Moran and Brandon Knox, with Tom Knox serving as Chairman. Unless otherwise stated, the discussion and analysis below is based on decisions by the board of directors.

During 2012, our board of directors considered one or more of the following factors when setting executive compensation, as further explained in the discussions of each compensation element below:

- the experiences and individual knowledge of the members of our board of directors regarding executive compensation, as we believe this approach helps us to compete in hiring and retaining the best possible talent while at the same time maintaining a reasonable and responsible cost structure;
- · corporate and/or individual performance, as we believe this encourages our executive officers to focus on achieving our business objectives;
- · the executive's existing equity award and stock holdings; and
- internal pay equity of the compensation paid to one executive officer as compared to another that is, that the compensation paid to each executive should reflect the importance of his or her role to the company as compared to the roles of the other executive officers, while at the same time providing a certain amount of parity to promote teamwork.

With our transition to being a company listed on NASDAQ, our compensation program following this offering may, over time, vary significantly from our historical practices. For example, we expect that following this offering, in setting executive compensation, the new compensation committee may review and consider, in addition to the items above, factors such as the achievement of predefined milestones, tax deductibility of compensation, the total compensation that may become payable to executive officers in various hypothetical scenarios, the performance of our common stock and compensation levels at public peer companies.

# Executive Compensation Program Components Base Salary

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

Base salaries for our executive officers were established primarily based on individual negotiations with the executive officers when they joined us and reflect the scope of their anticipated responsibilities, the individual experience they bring, the board members' experiences and knowledge in compensating similarly situated individuals at other companies, our then-current cash constraints, and a general sense of internal pay equity among our executive officers.

The board does not apply specific formulas in determining base salary increases. In determining base salaries for 2012 for our continuing named executive officers, no adjustments were made to the base salaries of any of our named executive officers as the board determined, in their independent judgment and without reliance on any survey data, that existing base salaries, taken together with other elements of compensation, provided sufficient fixed compensation for retention purposes.

#### Outstanding Equity Awards at Fiscal Year-End 2012

The following table presents information regarding outstanding options held by our named executive officers as of December 31, 2012:

		Option Awards				
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)		Option Expiration date	
					September 28,	
Thomas A.(1) Nicolette	3,000,000	_	\$	0.32	2017	
	500,000		\$	0.18	January 8, 2019	
					September 28,	
Raymond(2) F. Akers, Jr. PhD	3,000,000	_	\$	0.32	2017	
	500,000	_	\$	0.18	January 8, 2019	
Gary Rauch	_	_		_	· · · · —	
Total	_	_		_	_	

- 1. Thomas A. Nicolette was granted (i) warrants to purchase the 3,000,000 shares of the Company's common stock at an exercise price of \$0.32 and (ii) warrants to purchase 500,000 shares of the Company's common stock at an exercise price of \$0.18 per share. These warrants were all cancelled in 2013.
- 2. Raymond F. Akers, Jr., was granted (i) warrants to purchase 3,000,000 shares of the Company's common stock at an exercise price of \$0.32 and (ii) warrants to purchase 500,000 shares of the Company's common stock at an exercise price of \$0.18 per share. These warrants were all cancelled in 2013.

# Outstanding Equity Awards at Fiscal Year-End 2012 — Incoming Directors upon Effective Date

There were no outstanding Equity Awards at Fiscal Year-End 2012.

#### Compensation Risk Assessment

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

# Potential Payments upon Termination or Change in Control

Raymond F. Akers, Jr. PhD is covered by an employment agreement which calls for potential payments upon termination or change in control, see summary on such agreements below.

## **Employment Agreements**

Effective January 12, 2011, the Company and Mr. Raymond F. Akers Jr., PhD, our Executive Chairman, entered into a three (3) year (the "Term") employment agreement (the "Employment Agreement"). Mr. Akers shall be responsible for the duties attendant with such position as an executive officer of the Company and is required to devote all of his working time, attention and energies to the affairs of the Company and to use his best efforts to promote its best interests. Mr. Akers shall be paid a base salary of \$350,000 (the "Base Salary"), payable in intervals consistent with other executive officers of the Company but in no event less than on a monthly basis. Mr. Akers shall also be entitled to benefits made available to executive officers of the Company, including, but not limited to, participation in incentive compensation plans, pensions and other retirement plans, hospitalization, surgical, dental, major medical coverage and short and long term disability, vacation and sick leave. The Company is required to reimburse of all his reasonable and necessary travel including a car allowance, entertainment or other related expenses incurred by him in carrying out his duties and responsibilities under the Employment Agreement.

In the event that Mr. Akers's employment is terminated by the Company for cause (as defined below) the Company shall pay Mr. Akers his unpaid base salary (excluding bonus compensation) through the month in which the termination occurs. The term "cause" shall mean the entering of a plea of guilty or nolo contendere by Mr. Akers or the conviction of Mr. Akers for a felony or any other criminal act involving moral turpitude.

In the event that Mr. Akers's employment is terminated by the Company for any reason other than death, disability or cause (as such terms are defined in the Employment Agreement, other than in connection with a change in control) the Company shall pay Mr. Akers a severance and non-competition payment equal to the sum of (i) an amount equal to the Base Salary for the remainder of the Term, plus (ii) an amount equal to the Bonus Compensation earned by the Employee in respect of the last full fiscal year immediately preceding the year of termination multiplied by the number of months remaining in the Term divided by twelve.

Mr. Akers may elect to end his employment with the Company for any reason at any time. Should Mr. Akers end his employment with the Company voluntarily prior to the expiration of the Term, he shall be entitled to his unpaid base salary through the month in which the voluntary termination occurs. For one year following his resignation or termination, Mr. Akers will not work for or provide any services in any capacity to any competitor and will not solicit any of the Company's customers or accounts.

# Consulting Agreements

## **Nicolette Consulting Group Limited**

Effective January 12, 2011, the Company and Nicolette Consulting Group Limited ("NGC") entered into a three (3) year (the "Term") consulting services agreement (the "Consulting Agreement") whereby Mr. Thomas A. Nicolette, Managing Director of NGC, shall serve the Company in the capacity of Chief Executive Officer. Mr. Nicolette is responsible for the duties attendant with his position as Chief Executive Officer of the Company and is required to devote all of his working time, attention and energies to the affairs of the Company and to use his best efforts to promote its best interests. In consideration for such services, NGC is paid a monthly fee (the "Monthly Fee") of \$27,916.67. The Company is required to reimburse NGC for all approved, reasonable and necessary travel, entertainment or other related expenses up to \$10,000 per month (the "Approved Expenses") incurred in carrying out duties and responsibilities under the Consulting Agreement. NGC must submit appropriate, written, audit-worthy documentation to the Company supporting Approved Expenses (including receipts) and the Company must authorize the same, which shall not be unreasonably withheld.

In the event that NGC or Mr. Nicolette is terminated by the Company for cause (as defined below), the Company is required to pay NGC any unpaid Monthly Fee or Approved Expenses earned but unpaid through the termination date. The term "cause" shall mean (a) Mr. Nicolette's conviction or guilty plea admitting guilt of any felony; (ii) the deliberate engaging by NGC or Mr. Nicolette in fraud or embezzlement which is demonstrably proven and materially injurious to the Company; or (iii) NGC's or Mr. Nicolette's refusal to observe or perform any of the terms and provisions of the Consulting Agreement, which refusal remains uncured following thirty (30) days prior written notice from the Company.

In the event that the Consulting Agreement is terminated without cause the Company shall pay NGC any unpaid Monthly Fee or Approved Expenses earned but unpaid through the termination date.

The Company, NGC and NGC's personnel, including Mr. Nicolette, have agreed to indemnify each other from and against any and all claims, liabilities losses, damages, and expenses incurred, arising in connection with any litigation related to services performed under the Consulting Agreement.

The relationship created by the Consulting Agreement is one of an independent contractor. Neither NGC nor its personnel, including Mr. Nicolette, are entitled to any rights and or benefits that the Company provides for the Company's employees (including any employee pension, health, vacation pay, sick pay or other fringe benefits offered by the Company under plan or practice) by virtue of the services being rendered by NGC or otherwise.

During the Term, NGC and Mr. Nicolette shall not provide services to any direct competitor of the Company.

#### **DataSys Solutions, LLC**

Effective January 11, 2012, the Company and DataSys Solutions, LLC ("DS") entered into a two (2) year (the "Term") consulting services agreement (the "DS Consulting Agreement") whereby Mr. Gary M. Rauch, Managing Member of DS, shall serve the Company in the capacity of Controller and/or other such positions designated by the Company's CEO. Mr. Rauch is responsible for the duties attendant with his position as Controller of the Company and/or other such positions designated by the Company's CEO and is required to devote all of his working time, attention and energies to the affairs of the Company and to use his best efforts to promote its best interests. In consideration for such services, DS is paid an annual fee of \$67,500 in compensation payable in twelve monthly installments of \$5,625 for seventeen (17) days per month devoted to the engagement (the "DS Monthly Fee"). The Company is required to reimburse DS for all reasonable expenses directly attributable to and incurred in connection with the engagement with prior approval by the CEO.

The Company may terminate the DS Consulting Agreement for cause (as defined below) by action of its CEO, without notice and without liability. The term "cause" shall mean (a) Mr. Rauch's conviction, guilty plea, plea of nolo contender, or entering into any other plea admitting guilt of any felony; (ii) the deliberate engaging by DS or Mr. Rauch in fraud or embezzlement which is demonstrably proven and materially injurious to the Company; or (iii) DS's or Mr. Rauch's refusal to observe or perform any of the terms and provisions of the DS Consulting Agreement, or services thereunder.

The Company or DS may terminate the DS Consulting Agreement for any reason without cause, upon ninety (90) days advance written notice.

In the event that the DS Consulting Agreement is terminated without cause the Company shall pay DS any unpaid DS Monthly Fee or approved expenses earned but unpaid through the termination date.

The Company, DS and DS's personnel, including Mr. Rauch, have agreed to indemnify each other from and against any and all claims, liabilities losses, damages, and expenses incurred, arising in connection with any litigation related to services performed under the DS Consulting Agreement.

During the Term, DS and Mr. Rauch shall not provide services to any direct competitor of the Company.

# **Confidentiality Agreements**

All employees, including Mr. Akers, Mr. Nicolette and Mr. Rauch have signed agreements that contain confidentiality provisions or have signed a confidentiality agreement (the "Confidentiality Agreement") with the Company to keep confidential all proprietary information of the Company including, but not limited to, (i) product designs and formulations, and other technical information and data, (ii) operations, training and technical manuals and specifications, (iii) physical security systems, (iv) names, addresses and phone numbers of customers, prospects and contacts, (v) confidential and proprietary information of customers and their clients, (vi) pricing policies, marketing strategies, product strategies and methods of operation, (vii) budgets and other nonpublic financial information, and (viii) expansion plans, management policies, and other business strategies and policies.

Additionally, under the Confidentiality Agreement, all employees are required to promptly communicate to the Company, in writing when requested, all techniques, concepts, methods and ideas, other technical information, marketing strategies, and other ideas and creations pertaining to the Company's business which are conceived or developed by that employee, alone or with others, at any time during their employ with the Company. All employees acknowledged that all such ideas, creations and inventions are works for hire and are property of the Company.

# Employee Stock Incentive Plans

The Company intends to adopt, upon effectiveness of the registration statement of which this prospectus forms a part, the 2013 Stock Incentive Plan (the "Plan") which will provide for the issuance of options/shares equal to % of the total outstanding shares after the consummation of offering. The % calculation shall be made on the first trading day of a new fiscal year.

The purpose of the Plan is to provide additional incentive to those officers, employees, consultants and non-employee directors of the Company and its parents, subsidiaries and affiliates whose contributions are essential to the growth and success of the Company's business. The 2013 Plan may be administered by the board or a board-appointed committee.

Eligible recipients of option awards are employees, officers, consultants or directors (including non-employee directors) of the Company or of any parent, subsidiary or affiliate of the Company. The board has the authority to grant to any eligible recipient any options, restricted stock or other awards valued in whole or in part by reference to, or otherwise based on, our common shares.

The provisions of each option granted need not be the same with respect to each option recipient. Option recipients shall enter into award agreements with us, in such form as the board shall determine.

The Plan shall be administered by either the board of directors or a committee consisting of two or more independent, non-employee and outside directors (the 'Committee''). In the absence of such a Committee, the Board of the Company shall administer the Plan.

Each Option shall contain the following material terms:

- (i) the purchase price of each share of Common Stock with respect to Incentive Options shall be determined by the Committee at the time of grant, shall not be less than 100% of the Fair Market Value (defined as the closing price on the final trading day immediately prior to the grant on the principal exchange or quotation system on which the Common Stock is listed or quoted, as applicable) of the Common Stock of the Company, provided that if the recipient of the Option owns more than ten percent (10%) of the total combined voting power of the Company, the exercise price shall be at least 110% of the Fair Market Value;
- (ii) The purchase price of each share of Common Stock purchasable under a Non-qualified Option shall be at least 100% of the Fair Market Value of such share of Common Stock on the date the Non-qualified Option is granted, *unless* the Committee, in its sole and absolute discretion, determines to set the purchase price of such Non-qualified Option below Fair Market Value.
- (iii) the term of each Option shall be fixed by the Committee, provided that such Option shall not be exercisable more than five (5) years after the date such Option is granted, and provided further that with respect to an Incentive Option, if the recipient owns more than ten percent (10%) of the total combined voting power of the Company, the Incentive Option shall not be exercisable more than five (5) years after the date such Incentive Option is granted;
- (iv) subject to acceleration in the event of a Change of Control of the Company (as further described in the Plan), the period during which the Options vest shall be designated by the Committee or, in the absence of any Option vesting periods designated by the Committee at the time of grant, shall vest and become exercisable in equal amounts on each fiscal quarter of the Company through the four (4) year anniversary of the date on which the Option was granted;

- (vi) no Option is transferable and each is exercisable only by the recipient of such Option except in the event of the death of the recipient; and
- (vii) with respect to Incentive Options, the aggregate Fair Market Value of Common Stock exercisable for the first time during any calendar year shall not exceed \$100,000.

Each award of Restricted Stock is subject to the following material terms:

- (i) no rights to an award of Restricted Stock are granted to the intended recipient of Restricted Stock unless and until the grant of Restricted Stock is accepted within the period prescribed by the Committee;
  - (ii) Restricted Stock shall not be delivered until they are free of any restrictions specified by the Committee at the time of grant;
  - (iii) recipients of Restricted Stock have the rights of a stockholder of the Company as of the date of the grant of the Restricted Stock;
  - (iv) shares of Restricted Stock are forfeitable until the terms of the Restricted Stock grant have been satisfied or the employment with the Company is terminated; and
  - (v) the Restricted Stock is not transferable until the date on which the Committee has specified such restrictions have lapsed.

# CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements, the following is a description of transactions to which we were a participant or will be a participant to, in which:

- the amounts involved exceeded or will exceed the lesser of 1% of our total assets or \$120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

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 30,000,000 million shares of the Company's common stock for a purchase price of \$450,000. Additionally, Mr. Knox received, 10,000,000 shares of the Company's Series A Cumulative Preferred Stock (the Series A Preferred Stock") in consideration for a \$225,000 promissory note issued to the Company by Mr. Knox. The note bears interest at the rate of 3% per annum. The Series A Preferred Stock pays a \$0.00135 dividend per annum. The Series A Preferred Stock are convertible at any time into common shares, at the rate of 5 common shares for each preferred share, for an additional payment of \$0.05 per converted share. This conversion price, when added to the purchase price per share, is equivalent to \$0.0145 per common share. For so long as the Series A Preferred Stock is outstanding, the holders of the Series A Preferred Stock, 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.

On June 12, 2013, the Company entered into a purchase agreement with Chubeworkx Guernsey Limited ("Chubeworkx") whereby the Company sold all of its equity interest, 20 ordinary shares, in (EN)10 (Guersney) Limited to Chubeworkx for a purchase price of \$100,000.

On December 19, 2012, Chubeworkx placed an order for 3,500,000 Breathalyzers for a purchase price of \$1,050,000 or \$0.30 per unit. On April 19, 2013, Chubeworkx placed an order for 1,400,000 Breathalyzers for a purchase price of \$420,000 or \$0.30 per unit. As of June 30, 2013, all of the units for these orders have been shipped. As of the date of this prospectus the Company has received an aggregate of \$468,000 for these orders and has an account receivable of \$967,000 from Chubeworkx.

Compensation arrangements for our directors and named executive officers are described elsewhere in this prospectus.

#### Policy on Future Related Party Transactions

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

#### PRINCIPAL STOCKHOLDERS

The following table sets forth, as of September 30, 2013, information regarding beneficial ownership of our capital stock by:

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

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including options that are currently exercisable or exercisable within 60 days of August 5, 2013. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all shares of common stock shown that they beneficially own, subject to community property laws where applicable.

Our calculation of the percentage of beneficial ownership prior to this offering is based on 279,515,666 shares of our common stock issued and outstanding as of August 5, 2013.

Common stock subject to stock options currently exercisable or exercisable within 60 days of August 5, 2013, are deemed to be outstanding for computing the percentage ownership of the person holding these securities and the percentage ownership of any group of which the holder is a member but are not deemed outstanding for computing the percentage of any other person.

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

	Voting Rights held Prior to this Offering <sup>(1)</sup>	Percentage of Ownership as of September 30	Percentage Immediately following the Offering
Name of Beneficial Owner:			
5% Stockholders:			
Chubeworkx Guernsey Limited (3)	80,000,000	24.28%	
John Harvey	14,600,000	4.43%	
Named Executive Officers and Directors:			
Thomas A. Nicolette	6,000,538	1.82%	
Raymond F. Akers, Jr. Phd	-		
Tom Knox(2)	65,000,000	19.73%	
Brandon Knox	7,500,000	2.28%	
Gavin Moran	-	-	-
Gary Rauch	75,000	0.02%	
All executive officers and directors as a group (6 persons)	78,575,538	23.85%	

<sup>(1)</sup> of shares issued and outstanding and including in relation to each person, convertible securities that are currently exercisable or exercisable within 60 days of August 5, 2013 by that person

<sup>(2)</sup> Represents (i) 15,000,000 shares of common stock and (ii) 50,000,000 shares of common stock, subject to adjustment, issuable upon conversion of Series A Preferred Stock. Each one share of Series A Preferred Stock has voting rights equal to the number of shares into which it may be converted.

(3) Mark Massey is the Chairman of Chubeworkx Guernsey Limited and has beneficial ownership of the shares

#### DESCRIPTION OF SECURITIES

#### General

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the bylaws that will be in effect upon the closing of this offering. Copies of these documents will be filed with the Securities and Exchange Commission as exhibits to the registration statement of which this prospectus forms a part. The descriptions of the common stock reflect changes to our capital structure that will be in effect upon the closing of this offering.

Upon the closing of this offering, our authorized capital stock will consist of 550,000,000 shares, of which 500,000,000 will be common stock, without par value and 50,000,000 shall be preferred stock without par value. As of August 5, 2013, we had outstanding 279,515,666 shares of common stock and 10,000,000 shares of our Series A Cumulative Convertible Preferred Stock, par value \$.001 per share (the "Series A Preferred Stock"). Mr. Thomas J. Knox holds all of our Series A Preferred Stock.

#### Common Stock

# **Voting Rights**

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

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all of our directors. Our amended and restated certificate of incorporation and bylaws to be effective upon the closing of this offering will 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, issued and outstanding 10,000,000 shares of Series A Cumulative Preferred Stock (the "Series A Preferred Stock"). Mr. Thomas Knox currently holds all of the Series A Preferred Stock and has agreed to convert such shares into 50,000,000 shares of common stock immediately prior to the consummation of this offering.

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 5 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. This conversion price, when added to the purchase price per share is equivalent to \$0.0145 per share of commons stock (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 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 August 5, 2013, we had 310,344 shares issuable upon exercise of outstanding warrants and shares issuable upon the exercise of the Underwriters' 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.

#### Transfer Agent and Registrar

Upon the closing of this offering, the U.S. transfer agent and registrar for our common stock will be VStock Transfer, LLC 77 Spruce Street, Suite 201 Cedarhurst, NY 11516.

#### SHARES ELIGIBLE FOR FUTURE SALE

Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

There has been no public market for our common stock in the United States prior to this offering. Our common stock has traded on AIM since May 2002. For further information regarding the trading of our common stock on AIM following the offering, see "Our common stock traded in the United Kingdom".

Based on the number of shares outstanding as of , 2013, upon the closing of this offering shares of common stock will be issued and outstanding, assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options or warrants. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below.

shares of our common stock outstanding after this offering are restricted securities as such term is defined in Rule 144 under the Securities Act and/or are subject to lock-up agreements with us as described below. Following the expiration of the lock-up period, restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under the Securities Act, as described in greater detail below.

#### Rule 144

In general, under Rule 144 as currently in effect, a person who has beneficially owned restricted shares of our common stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we have been subject to the Securities Exchange Act of 1934, as amended, periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares of our common stock for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to volume restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering assuming no exercise of the underwriters' over-allotment option, based on the number of shares of common stock outstanding as of , 2013; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Provided, in each case, that we have been subject to and are current with the Exchange Act periodic reporting requirements for at least 90 days before the sale. Sales by affiliates must also comply with the manner of sale and notice provisions of Rule 144.

#### **Rule 701**

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers, directors or consultants who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under "Underwriting" and will become eligible for sale at the expiration of those agreements.

Employees can only sell vested shares. Employees who do not hold vested shares, including shares subject to options, upon expiration of these selling restrictions will not be able to sell shares until they vest.

# Lock-Up Arrangements

We have agreed with the underwriter that for a period of six months following the date of this prospectus, we will not offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of, or hedge, any shares of our common stock or any securities convertible into or exchangeable for shares of our common stock, subject to specified exceptions. The Underwriter may, in its sole discretion, waive this prohibition. The restriction is not applicable to shares issuable upon conversion or exercise of any existing securities.

The restricted period described in the preceding paragraph will be extended if:

- · during the last 17 days of the restricted period we issue a release regarding earnings or regarding material news or events relating to us; or
- prior to the expiration of the restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the period, in which
  case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release
  or the occurrence of the material news or material event.

In addition, all officers and directors and their affiliates have agreed not to sell any shares beneficially owned by them for a period of 90 days from the effective date of this Registration Statement. For a more complete discussion of our stock incentive plans, see the section titled "Underwriting — Lock-up Agreements".

#### Registration Rights

There are no shareholders who have any right to request registration of their shares.

# Our common stock traded on AIM in the United Kingdom

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

# The AIM Rules

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

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

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

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

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

# Disclosure and Transparency Rules

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

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

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

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

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

- temporary delays that may arise because the transfer books for the common stock are closed;
- · obligations to pay fees, taxes and similar charges that would arise; or
- · restrictions imposed because of laws or regulations applicable to shares of common stock in the United States or the United Kingdom.

#### UNDERWRITING

Aegis Capital Corp. is acting as the sole book-running manager of the offering and as representative of the underwriters, or the "Representative." We have entered into an underwriting agreement, dated, [\_\_\_\_] 2013, 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 and not jointly agreed to purchase from us, at the public offering price per share less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name of Underwriter	Number of Shares
Aegis Capital Corp	
Total	

The underwriters are committed to purchase all the shares of common stock offered by us other than those covered by the option to purchase additional shares 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, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, 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.

Over-allotment Option. 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 (15% of the shares sold in this offering) from us to cover over-allotments, if any. If the underwriters exercise all or part of this option, they will purchase shares covered by the option at the public offering price per share that appears on the cover page of this prospectus, less the underwriting discount. 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 \$\\$\$.

Discount. 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.

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

The underwriters propose to offer the shares offered by us to the public at the public offering price per share set forth on the cover of this prospectus. In addition, the underwriters may offer some of the shares 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 paid an expense deposit of \$50,000 to the Representative, which will be applied against the out-of-pocket accountable expenses that will be paid by us to the underwriters in connection with this offering. The underwriting agreement, however, provides that in the event the offering is terminated, the \$50,000 expense deposit paid to the Representative will be returned to the extent that offering expenses are not actually incurred in accordance with FINRA Rule 5110(f)(2)(C).

We have agreed to pay the Representative's a non-accountable expense allowance equal to 1% of the public offering price of the shares (excluding shares that we may sell to the underwriters to cover over-allotments). We have also agreed to pay the Representative's expenses relating to the offering, including (a) all fees, expenses and disbursements relating to background checks of our officers and directors in an amount not to exceed \$5,000 per individual; (b) reimbursement for reasonable fees of representative's legal counsel up to \$50,000; (c) all fees, expenses and disbursements relating to the registration, qualification or exemption of securities offered under the securities laws of foreign jurisdictions designated by the underwriters; (d) the costs associated with post-closing advertising up to \$ (e) the costs of commemorative momentos and Lucite tombstones up to \$\_\_\_\_ (f) upon successfully completing this offering, \$21,775 for the underwriters' use of Ipreo's book-building, prospectus tracking and compliance software for this offering; (g) upon successfully completing this offering, up to \$20,000 of the Representative's actual accountable road show expenses for the offering.

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

Discretionary Accounts. The underwriters do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

Lock-Up Agreements. Pursuant to certain "lock-up" agreements, we, our executive officers and directors, and certain significant holders of our outstanding shares of common stock on a fully diluted basis (including shares underlying options, warrants and convertible securities) have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic risk of ownership of, directly or indirectly, engage in any short selling of any common stock or securities convertible into or exchangeable or exercisable for any common stock, whether currently owned or subsequently acquired, without the prior written consent of the underwriter, for a period of three (3) months from the date of effectiveness of the offering.

The lock-up period described in the preceding paragraph will be automatically extended if: (1) during the last 17 days of the restricted period, we issue an earnings release or announce material news or a material event; or (2) prior to the expiration of the lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the lock-up period, in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the date of the earnings release, unless the Representative waives this extension in writing; provided, however, that this lock-up period extension shall not apply to the extent that FINRA has amended or repealed NASD Rule 2711(f)(4), or has otherwise provided written interpretive guidance regarding such rule, in each case, so as to eliminate the prohibition of any broker, dealer, or member of a national securities association from publishing or distributing any research report, with respect to the securities of an emerging growth company (as defined in the JOBS Act) prior to or after the expiration of any agreement between the broker, dealer, or member of a national securities association and the emerging growth company or its shareholders that restricts or prohibits the sale of securities held by the emerging growth company or its shareholders after the initial public offering date.

Underwriters' Warrants. We have agreed to issue to the underwriters' representative warrants to purchase up to a total of shares of common stock. The warrants are exercisable at \$ per share (125% of the public offering price) commencing on a date which is one year from the effective date of the offering under this prospectus supplement and expiring on a date which is no more than five years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H). The warrants have been deemed compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The Representative (or permitted assignees under the Rule) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will it engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from effectiveness. In addition, the warrants provide for registration rights upon request, in certain cases. We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants or the offering in compliance with FINRA Rule 5110(f)(2)(H)(iv). The piggyback registration right provided will not be greater than five years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(v). We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant ex

Right of First Refusal. Subject to certain limited exceptions, until twenty four (24) months from the effective date of the offering, the Representative has a right of first refusal to purchase for its account or to sell for our account, or any subsidiary or successor, any securities of our company or any such subsidiary or successor which we or any subsidiary or successor may seek to sell in public or private equity and public debt offerings during such twenty four (24) month period. The Representative will not have more than one opportunity to waive or terminate the right of first refusal in consideration of any payment or fee.

Electronic Offer, Sale and Distribution of Shares. A prospectus 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 prospectuses 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 in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

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 which 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 overallotment 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 overallotment option and, therefore, have a naked short 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 of common stock or preventing or retarding a decline in the market price of our shares of 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 for 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 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 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, or the 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 14 May 1999 ("Regulation no. 11971") as amended ("Qualified Investors"); and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the 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 (Comissã do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to 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.

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#### LEGAL MATTERS

Lucosky Brookman LLP will render a legal opinion as to the validity of the shares of the common stock to be registered hereby. Certain legal matters in connection with this offering will be passed upon for the underwriters by Blank Rome LLP.

# **EXPERTS**

Our financial statements as of and for the years ended December 31, 2012 and 2011 included in this prospectus have been audited byMorisonCogen LLP independent certified public accountants, to the extent and for the periods set forth in their report appearing elsewhere herein, and are included in reliance on such report given upon the authority of said firm as experts in auditing and accounting.

#### WHERE YOU CAN FIND MORE INFORMATION

As of the effective date, we will file annual, quarterly and current reports, proxy statements and other information with the SEC. We have also filed with the SEC under the Securities Act a registration statement on Form S-1 with respect to the common stock offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all the information set forth in the registration statement or the exhibits and schedules which are part of the registration statement, portions of which are omitted as permitted by the rules and regulations of the SEC. Statements made in this prospectus regarding the contents of any contract or other document are summaries of the material terms of the contract or document. With respect to each contract or document filed as an exhibit to the registration statement, reference is made to the corresponding exhibit. For further information pertaining to us and the common stock offered by this prospectus, reference is made to the registration statement, including the exhibits and schedules thereto, copies of which may be inspected without charge at the Public Reference Room of the SEC at 100 F Street, N.E., Washington, D.C. 20549 on official business days during the hours of 10 a.m. to 3 p.m.. Copies of all or any portion of the registration statement may be obtained from the SEC at prescribed rates. Information on the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The web site can be accessed at <a href="http://www.sec.gov">http://www.sec.gov</a>. The internet address of the Company is <a href="http://www.sec.gov">http://www.sec.gov</a>. The internet address of the Company is <a href="http://www.sec.gov">http://www.sec.gov</a>. In formation contained on our website is not a part of, and is not incorporated into, this prospectus, and the inc

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# December 31, 2012 and December 31, 2011 (Audited)

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# AKERS BIOSCIENCES, INC. AND SUBSIDIARIES Condensed Consolidated Balance Sheets June 30, 2013 and December 31, 2012

	(u	2013 naudited)	2012 (audited)	
ASSETS				
Current Assets				
Cash and Cash Equivalents	\$	1,553,884	\$ 633,022	
Trade Receivables (net)		163,907	101,213	
Trade Receivables – Related Party		1,041,388	10,013	
Other Receivables		26,413	4,497	
Notes Receivable – Related Party		-	225,000	
License Fee Receivable – Related Party		-	450,000	
Inventories (net)		867,811	987,853	
Other Assets		29,435	67,898	
Total Current Assets		3,682,838	2,479,496	
Non-Current Assets				
Property, plant and equipment, net		263,855	240,014	
Intangible assets, net		2,563,923	2,693,209	
Other Assets		4,282	4,572	
Ollici Assets		4,202	4,372	
Total Non-Current Assets		2,832,060	2,937,795	
Total Assets	<u>\$</u>	6,514,898	\$ 5,417,291	
LIABILITIES				
Current Liabilities				
Trade and Other Payables	\$	1,006,282	\$ 1,082,504	
Other Payables – Related Party		-	58,542	
Deferred Revenue – Related Party		805,555	972,222	
		,	,	
Total Current Liabilities		1,811,837	2,113,268	
Total Liabilities		1,811,837	 2,113,268	
EQUITY				
Convertible Preferred Stock, No par value,				
50,000,000 shares authorized, 10,000,000 shares				
issued and outstanding as of June 30, 2013 and				
December 31, 2012.		225,000	225,000	
Common Stock, No par value, 500,000,000 shares				
authorized, 279,515,666 and 199,515,666 issued				
and outstanding as of June 30, 2013 and December				
31, 2012		84,873,376	83,273,376	
Accumulated Deficit		(80,395,315)	(80,194,353)	
Total Equity		4,703,061	 3,304,023	
		,,	- , ,	
Total Equity and Liabilities	\$	6,514,898	\$ 5,417,291	

# AKERS BIOSCIENCES, INC. AND SUBSIDIARIES Condensed Consolidated Statements of Operations Six months ended June 30, 2013 and 2012 (unaudited)

	2013		2012
Revenues:	 		
Product Revenue	\$ 2,272,418	\$	787,194
License Revenue	366,667		-
Total Revenue	2,639,085		787,194
Cost of Sales:			
Product Cost of Sales	(1,409,384)		(469,335)
	 		,
Gross Profit	1,229,701		317,859
Administrative Expenses	675,689		743,549
Sales and Marketing Expenses	410,008		348,618
Research and Development Expenses	522,132		487,874
Amortization of Non-Current Assets	129,286		104,734
Loss from Operations	(507,414)		(1,366,916)
Other Income/Expenses			
Gain on sale of equity investment	(99,710)		-
Foreign Currency Transaction (Income)/Expense	87		(5,860)
Gain from demutualization of insurance carrier	(91,286)		-
Other Income	 (115,543)		(22,797)
Total Other Income	 (306,452)		(28,657)
Loss Before Income Taxes	(200,962)		(1,338,259)
Income Tax Benefit/(Expense)	 -		<u>-</u>
Net Loss	\$ (200,962)	\$	(1,338,259)
Basic & diluted loss per common share	\$ (0.00)	\$	(0.01)
	 (****)	Ť	(4,4,4)
Weighted average basic & diluted common			
shares outstanding	206,587,489		169,415,666
Side S Guistalians	 200,387,489		107,413,000

# AKERS BIOSCIENCES, INC. AND SUBSIDIARIES Condensed Consolidated Statement of Changes in Stockholders' Equity Six months ended June 30, 2013

	P	nvertible referred Stock	Common Stock	A	accumulated Deficit	Total Equity
Balance at December 31, 2012 (audited)	\$	225,000	\$ 83,273,376	\$	(80,194,353)	\$ 3,304,023
Net loss for the period		-	-		(200,962)	(200,962)
Sale of common shares		-	1,600,000		-	1,600,000
Balance at June 30, 2013 (unaudited)	\$	225,000	\$ 84,873,376	\$	(80,395,315)	\$ 4,703,061

# AKERS BIOSCIENCES, INC. AND SUBSIDIARIES Condensed Consolidated Cash Flow Statements Six months ended June 30, 2013 and 2012 (unaudited)

	2013	2012
Cash flows from operating activities		
Net loss for the period	\$ (200,962)	\$ (1,338,259)
Adjustments to reconcile net loss to net cash used by operating activities		
Provisions for bad debts	-	8,913
Write-off of note receivable	-	148,900
Gain on sale of equity investment	(99,710)	-
Reversal of old trade payables	(91,905)	-
Gain from demutualization of insurer	(91,286)	-
Depreciation and amortization of non-current assets	176,285	161,287
Changes in assets and liabilities		
(Increase)/decrease in trade receivables	(62,694)	69,008
Increase in trade receivables – related party	(1,031,375)	(2,659)
(Increase)/decrease in other receivables	(21,916)	260,436
Decrease in license fees receivable – related party	450,000	-
(Increase)/decrease in inventories	120,042	(49,803)
Decrease in other assets	38,463	68,102
Increase/(decrease) in trade and other payables	97,607	(108,265)
Decrease in other payables – related party	(58,542)	-
Increase/(decrease) in legal settlement liabilities	(81,924)	79,810
Decrease in deferred revenue – related party	(166,667)	
Net cash used in operating activities	(1,024,584)	(702,530)
Cash flows from investing activities		
Purchases of property, plant and equipment	(70,840)	(7,325)
Proceeds from sale of equity investment	100,000	-
Proceeds from demutualization of insurance carrier	91,286	
Net cash provided from/(used in) investing activities	120,446	(7,325)
		(1,020)
Cash flows from financing activities		
Proceeds from note receivable – related party for Series A Convertible		
Preferred Stock	225,000	-
Proceeds from issuance of common shares	1,600,000	<del>_</del>
Net cash provided from financing activities	1,825,000	
Net increase/(decrease) in cash and cash equivalents	920,862	(709,855)
Cash and cash equivalents at beginning of year	633,022	1,192,805
Cash and cash equivalents at end of period	\$ 1,553,884	\$ 482,950
The second secon	ψ 1,555,66 <del>1</del>	402,730

#### AKERS BIOSCIENCES, INC. AND SUBSIDIARIES Notes to Consolidated Financial Statements

#### Note 1 - Nature of Business

#### (a) Reporting Entity

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information. Accordingly, they do not include all the information and disclosures required by GAAP for complete financial statements. Operating results for the six months ended June 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. In the opinion of management, the unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation. These unaudited condensed consolidated financial statements and related notes should be read in conjunction with the consolidated financial statements and notes for the year ended December 31, 2012 included in this Registration Statement on Form S-1.

The consolidated financial statements include two dormant subsidiaries, Akers Acquisition Sub, Inc. and Bout Time Marketing Corporation. All material intercompany transactions have been eliminated upon consolidation.

#### (b) Nature of Business

The Company commenced research and development operations in September 1989, and until 2005 had devoted substantially all its efforts to establishing the new business.

The Company's primary focus is the development and sale of disposable diagnostic testing devices that can be performed in minutes, to facilitate time sensitive therapeutic decisions. The Company's main products are a disposable breathalyzer test that measures the blood alcohol content of the user, a rapid test detecting the antibody causing an allergic reaction to Heparin and a disposable breathalyzer test that measures Free Radical activity in the human body. When the Company enters into an agreement with a new distributor it requires an upfront licensing fee to be paid for the right to sell the Company's products in specific markets.

#### Note 2 - Basis of Presentation

#### (a) Statement of Compliance

The consolidated financial statements of the Company are prepared in U.S. Dollars and in accordance with accounting principles generally accepted in the United States of America (US GAAP).

# (b) Use of Estimates and Judgments

The preparation of financial statements in conformity with US GAAP requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. In particular, information about significant areas of estimation, uncertainty and critical judgments in applying accounting policies that have the most significant effect on the amounts recognized in the financial statements is included in the following notes for preferred stock, allowances for doubtful accounts, inventory write-downs, impairment of intangible assets and valuation of share based payments.

Notes to Consolidated Financial Statements

#### (c) Functional and Presentation Currency

These consolidated financial statements are presented in U.S. Dollars, which is the Company's functional currency. All financial information presented in U.S. Dollars has been rounded to the nearest dollar. Foreign Currency Transaction Gains or Losses, resulting from loans and cash balances denominated in Foreign Currencies, are recorded in the statement of operations.

#### (d) Comprehensive Income

The Company follows Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) 220 in reporting comprehensive income (loss). Comprehensive income is a more inclusive financial reporting methodology that includes disclosure of certain financial information that historically has not been recognized in the calculation of net income. Since the Company has no items of other comprehensive income (loss), comprehensive income (loss) is equal to net income (loss).

# Note 3 - Significant Accounting Policies

#### (a) Trade Receivable, Trade Receivable - Related Party and Allowance for Doubtful Accounts

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

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

As of June 30, 2013 and December 31, 2012, allowances for doubtful accounts were \$- and \$-. Allowances charged for doubtful accounts amounted to \$- for the six months ended June 30, 2013 and 2012.

Notes to Consolidated Financial Statements

# (b) Shipping and Handling Fees and Costs

The Company charges actual shipping plus a handling fee to customers, which amounted to \$22,584 and \$21,651 for the six months ended June 30, 2013 and 2012. These fees are classified as other income in the statement of operations. Shipping and other related delivery costs, including those for incoming raw materials are classified as part of the cost of net revenue, which amounted to \$58,789 and \$35,953 for the six months ended June 30, 2013 and 2012.

#### (c) Concentration of Credit Risk

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

Substantially all of the Company's cash and cash equivalents are maintained with Bank of America, NA. The funds are insured by the FDIC up to a maximum of \$250,000, but are otherwise unprotected. The Company placed \$1,550,540 and \$630,337 with this institution as of June 30, 2013 and December 31, 2012. No losses have been incurred in these accounts.

Concentration of credit risk with respect to trade receivables exists as approximately 89% of its revenue for the six months ended June 30, 2013 is generated by three customers. These customers accounted for 96% of trade receivable as of June 30, 2013. In order to limit such risks, the Company performs ongoing credit evaluations of its customers' financial condition.

# (d) Basic and Diluted Earnings per Share of Common Stock

Basic earnings per common share are based on the weighted average number of shares outstanding during the periods presented. Diluted earnings per share are computed using the weighted average number of common shares plus dilutive common share equivalents outstanding during the period. Potential common shares that would have the effect of increasing diluted earnings per share are considered anti-dilutive for the six months ended June 30, 2013 and 2012 as net losses were recorded in both periods.

#### (e) Recently Adopted Accounting Pronouncements

As of June 30, 2013, and for the period then ended, there were no recently adopted accounting pronouncements that had a material effect on the Company's financial statements.

# (f) Recently Adopted Accounting Pronouncements not Yet Adopted

As of June 30, 2013, there are no recently issued accounting standards not yet adopted which would have a material effect on the Company's financial statements.

Notes to Consolidated Financial Statements

# (g) Subsequent Events

FASB ASC 855-10, Subsequent Events, establishes general standards of accounting and disclosure of events that occur after the consolidated balance sheet date but before the date the consolidated financial statements are available to be issued. Subsequent events have been evaluated through July 26, 2013, the date that the consolidated financial statements were available to be issued.

# Note 4 - Note Receivable - Related Party

The note of \$225,000 was issued to the Company in connection with the subscription of 10,000,000 series A convertible preferred stock entered into on September 14, 2012 (Note 12). It is due September 14, 2027 and has an interest rate of 3% per annum. For the six months ended June 30, 2013 and 2012, interest income of \$1,054 and \$- was recorded. The note was fully settled in cash on February 26, 2013.

# Note 5 - License Fee Receivable - Related Party

On June 19, 2012, the Company entered into a 3-year exclusive License & Supply Agreement with Chubeworkx Guernsey Limited (as a successor to SONO International Limited) ("Chubeworkx") for the purchase and distribution of ABI's proprietary breathalyzers outside North America (Note 15). Chubeworkx agreed to pay a licensing fee of \$1,000,000. The final payment of \$450,000 was received on March 6, 2013.

On June 14, 2013, Chubeworkx became a shareholder of the Company (Note 12).

#### Note 6 - Inventories

Inventories at June 30, 2013 and December 31, 2012 consisted of the following:

	2013	2012
Raw Materials	\$ 432	,714 \$ 516,497
Sub-Assemblies	449	,840 464,740
Finished Goods	17	,257 38,616
Reserve for Obsolescence	(32	,000) (32,000)
	\$ 867	\$ 987,853

For the six months ended June 30, 2013 and 2012 no charges were made to cost of goods sold for obsolete inventory.

# Note 7 - Property, Plant and Equipment

For the six months ended June 30, 2013 and 2012 depreciation expense was \$46,999 and \$56,552.

# Note 8 - Intangible Assets

For the six months ended June 30, 2013 and 2012 amortization expense was \$129,286 and \$104,734.

Notes to Consolidated Financial Statements

#### Note 9 - Trade and Other Pavables

Trade and other payables as of June 30, 2013 and December 31, 2012 are as follows:

	 2013	2012
Trade Payables	\$ 650,892	\$ 608,836
Other Payables	330,390	366,744
Legal Settlement Payable	25,000	106,924
	\$ 1,006,282	\$ 1,082,504

Trade and other payables are non-interest bearing and are normally settled on 30 - 60 day terms. The legal settlement is non-interest bearing and has a term of 12 equal monthly installments, which commended on October 31, 2012.

The legal settlements payable comprises two arbitration settlements as follows:

(a) On January 9, 2012, the Company was notified of an action to recover unpaid royalties for the exclusive use of a patent used in the production of our MPC Biosensor products (MicroParticle Catalyzed Biosensor). The dispute related to the method used to calculate royalty payments and the scope of the products involved involved for the period dated March 17, 2007 through March 19, 2012.

On April 23, 2012, the Company agreed to an arbitration settlement of \$137,791. The settlement is to be paid over 12 months, with an initial payment of \$50,000 and 11 equal payments of \$7,981. As of June 30, 2013 and December 31, 2012 the amount due was \$- and \$31,924.

The Company recorded an amount of \$131,376 in Sales and Marketing expenses in 2011. The Company recorded \$- and \$6,425 in Sales and Marketing expense for the six months ended June 30, 2013 and 2012.

(b) On January 11, 2012, the Company was notified of a demand for arbitration from Trinity Biotech Manufacturing Limited related to the distributor agreement between the parties dated June 19, 2008.

On October 15, 2012, the Company agreed to an arbitration settlement of \$118,000. The settlement is to be paid over 13 months, with an initial payment of \$18,000 and 12 equal payments of \$8,333. As of June 30, 2013 and December 31, 2012 the amount due was \$25,000 and \$75,000.

The Company recorded \$- and \$118,000 in Administrative expense for the six months ended June 30, 2013 and 2012.

# Note 10 - Deferred Revenue - Related Party

Deferred revenue represents the unearned revenue from the 3-year exclusive License and Supply Agreement with Chubeworkx Guernsey Limited (Note 15) for the purchase and distribution of ABI's proprietary breathalyzer that was signed in June, 2012. The first order for the proprietary breathalyzers was received in December 2012 for 3,500,000 units and another order was received in April 2013 for 1,400,000 units. All the units have been shipped as of June 30, 2013. The license revenue is being recognized monthly on a straight line basis over the 3-year term of the agreement.

# Note 11 - Share-based Payments

# (a) Stock Warrants

The Company has issued warrants to various employees, consultants and members of the Board of Directors of the Company for their services either in connection with the Company's ongoing efforts to raise capital or the development of the Company's products. In addition, the Company has granted warrants to lenders in connection with the issuance of debt. Each warrant granted may be exchanged for a prescribed number of shares of common stock. The warrants expire at various dates through January 2019.

	20		2012			
				Weighted Average		
	Warrants	Ex	xercise Price	Warrants	Ex	ercise Price
Outstanding at January 1	7,365,344	\$	0.31	9,365,344	\$	0.40
Granted during period	-		-	-		-
Forfeited during period	-		-	-		-
Exercised during period	-		-	-		-
Expired during period	<u>-</u>		<u>-</u>	(2,000,000)		0.71
Outstanding at June 30	7,365,344	\$	0.31	7,365,344	\$	0.31

The Company has adopted two option plans that permit the granting of options to purchase shares of common stock. The plans provide for the granting of both incentive stock options ("Incentive Stock Plan"), as defined in Section 422 of the U.S. Internal Revenue Code (the "Code"), and options defined by Section 422 of the Code ("Non-qualified options").

Notes to Consolidated Financial Statements

The plans are administered by a Compensation Committee, which is appointed by the Board of Directors, who grants all options and determines their terms. Options are non-transferable and are only granted to employees, officers and directors, and advisors or consultants who agree to be employed or to provide services to the Company for a period of at least one year after the grant date. The maximum term of any option under the plans is ten years, and generally vest over three years.

# (b) Stock options

Qualified option holders may exercise their options at their discretion through various dates ending November 2014. Each option granted may be exchanged for a prescribed number of shares of common stock.

# Employee's Plan - Qualified Options

Zimproyee s 1 min	20	20	012			
		Weighted Average				
	<u>Options</u>	ions Exercise Price Opti		Options	Exc	ercise Price
Outstanding at January 1	246,700	\$	0.27	446,700	\$	0.27
Granted during period	-		-	-		-
Forfeited during period	-		-	(200,000)		0.27
Exercised during period	-		-	-		-
Expired during period	(246,700)		0.27	-		-
Outstanding at June 30	_	\$	_	246,700	\$	0.27

# Director's Plan

	20	013		20	2012				
			Weighted Average						
	Options	_]	Exercise Price	Options	Exercise Price				
Outstanding at January 1	55,000	\$	2.00	880,500	\$	0.45			
Granted during year	-		-	-		-			
Forfeited during year	-		-	-		-			
Exercised during year	-		-	-		-			
Expired during year	<u> </u>		<u>-</u>	(825,500)		0.34			
Outstanding at June 30	55,000	\$	2.00	55,000	\$	2.00			

The options and warrants issued under the above three plans were valued using a Black Scholes option pricing model on the date of measurement.

A summary of warrants and stock options outstanding and exercisable as of June 30, 2013 follows:

				Outstanding	Exercisable Weighted Average Life	Weighted Average Exercise		Weiş	ghted Average Exercise
	I	LOW	High	Shares	Remaining	Price	Shares		Price
Director's Plan	\$	2.00	\$ 2.00	55,000	1.37	\$ 2.00	55,000	\$	2.00
Warrants		0.18	0.89	7,365,344	4.05	0.31	7,365,344		0.31
Employee's Plan		0.00	0.00	0	0.00	0.00	0		0.00
				8,420,344			8,420,344		

# Note 12 - Equity

The holders of common shares are entitled to one vote per share at meetings of the Company. Holders of Series A convertible preferred shares are entitled to five votes per share at meetings of the Company.

Notes to Consolidated Financial Statements

At June 30, 2013 and December 31, 2012, the Company has an undeclared dividend due to series A convertible preferred shareholders in the amount of \$10,745 and \$3,995.

On June 14, 2013 the Company, in a private placement to ChubeWorkx, issued 80,000,000 common shares for \$1,600,000.

As of June 30, 2013 the Company has reserved shares of its common stock as follows:

	2013
Reserves for:	
Convertible Preferred Stock	50,000,000
Outstanding Warrants	7,365,344
Outstanding Directors Options	55,000
Total Reserves	58,420,344

The following is a reconcilement of the movement of shares of Series A Convertible preferred stock (preferred stock) and common stock:

	Author	rized	Issued			
	Preferred	Common	Preferred	Common		
	Stock	Stock	Stock	Stock		
Balance at December 31, 2012	50,000,000	500,000,000	10,000,000	199,515,666		
Shares Issued:						
June 14, 2013	<u>-</u>	<del>_</del>	<del>_</del>	80,000,000		
Balance at June 30, 2013	50,000,000	500,000,000	10,000,000	279,515,666		

# Note 13 - Loss per share

The calculation of basic and diluted loss per share at June 30, 2013 and 2012 was based on the loss attributable to common shareholders of \$200,962 and \$1,338,259. The basic and diluted weighted average number of common shares outstanding for 2013 and 2012 was 206,587,489 and 169,415,666.

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

Potential common shares consist of preferred stocks, options and warrants. Diluted net loss per common share was the same as basic net loss per common share for the six months ended June 30, 2013 and 2012 since the effect of preferred stocks, options and warrants would be anti-dilutive due to the net loss attributable to the common shareholders for the periods. Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were as follows: series A convertible preferred stock – 50,000,000 (2012: nil), employee and consulting stock options – 55,000 (2012: 642,500); warrants 7,365,344 (2012: 7,365,344).

Notes to Consolidated Financial Statements

# Note 14 - Income Tax Expense

There is no income tax benefit for the losses for the six months ended June 30, 2013 and 2012 since management has determined that the realization of the net deferred tax asset is not assured and has created a valuation allowance for the entire amount of such benefits.

The Company's policy is to record interest and penalties associated with unrecognized tax benefits as additional income taxes in the statement of operations. As of January 1, 2013, the Company had no unrecognized tax benefits, or any tax related interest of penalties. There were no changes in the Company's unrecognized tax benefits during the six months ended June 30, 2013 related to unrecognized tax benefits. With few exceptions, the U.S. and state income tax returns filed for the tax years ending on December 31, 2009 and thereafter are subject to examination by the relevant taxing authorities.

#### Note 15 - Related Party Transactions

On January 12, 2011, the Company entered into a consulting agreement with Nicolette Consulting Group Limited (NCG) for a period of three years under which the Company must pay NCG \$27,917 per month in fees and up to \$10,000 in reimbursement for monthly expenses (2013: \$50,000; 2012: \$50,000) for the services of Mr. Nicolette as President and Chief Executive Officer of the Company. The total amount of consulting fees accrued for NCG as of June 30, 2013 and December 31, 2012 was \$- and \$58,542 and is shown as Other Payables – Related Party in the Condensed Consolidated Balance Sheet.

On March 17, 2010, in exchange for an exclusive licensing agreement, ABI received a 20 percent equity stake in BreathScan International Ltd (BIL). During 2012, BreathScan International Limited changed its name to en(10) Guernsey Limited ("en(10)"). Thomas A. Nicolette, President and Chief Executive Officer of ABI, was also appointed to en(10)'s Board of Directors. The equity stake is accounted for using the equity method of accounting in accordance with the Financial Accounting Standards Board Accounting Standards Codification. The equity investment was initially recorded at cost, which was nil. During the six months ended June 30, 2013 and 2012 no profit or loss is recorded for en(10)'s results as en(10) recorded a net loss and ABI is not required to equity account any losses in excess of its carrying value on the books. On June 13, 2013 the Company sold its interest in en(10) to ChubeWorkx for \$100,000. A realized gain of \$99,710 is recognized for the disposal of the investment in the statement of operations for the six months ended June 30, 2013.

On June 19, 2012, the Company entered into a 3 year exclusive License & Supply Agreement with Chubeworkx Guernsey Limited (as successor to SONO International Limited) ("Chubeworkx") for the purchase and distribution of ABI's proprietary breathalyzers outside North America. Chubeworkx is the 80% shareholder in en(10) Guernsey Limited, described above. Chubeworkx paid a licensing fee of \$1,000,000, of which \$166,667 and \$- was recognized as income for the six months ended June 30, 2013 and 2012, with the deferral to be recognized over the remaining term of the agreement (Note 5).

Notes to Consolidated Financial Statements

Included in total revenue for the six months ended June 30, 2013 and 2012 are \$1,551,340 and \$2,659 from Chubeworkx Guernsey Limited, a major shareholder of the Company.

Included in trade receivables – related party as of June 30, 2013 and December 31, 2012 are amounts due from Chubeworkx Guernsey Limited, a major shareholder of the Company of \$1,041,388 and \$10,013. The amount due is non-interest bearing, unsecured and has a term of 90 days generally.

#### Note 16 - Major Customers

During the six months ended June 30, 2013, two customers each generated more than 10% of the Company's revenue. In aggregate, sales to these customers accounted for 83% of the Company's revenue. As of June 30, 2013, the amount due from these two customers was \$1,130,089. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

# Note 17 - Major Suppliers

During the six months ended June 30, 2013, two suppliers each accounted for more than 10% of the Company's purchases. In aggregate, these suppliers accounted for 56% of the Company's total purchases. As of June 30, 2013, the amount due to these two suppliers was \$145,978. This makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

# Note 18 - Other Income

Other income consists of interest income, shipping and handling fees and other miscellaneous income items. As of June 30, 2013 and 2012, the other income consists of the following:

	2013		2012		
Interest Income	\$ 1,0	54	\$ 370		
Shipping & Handling Fees	22,5	84	21,651		
Miscellaneous Income	91,9	05	776		
Total:	\$ 115,5	43	\$ 22,797		

# Note 19 - Subsequent Events

On July 1, 2013, the Company announced the appointment of Gavin Moran and Thomas Knox as Non-Executive members of the Company's Board of Directors

On August 5, 2013, the Company cancelled common stock warrants to purchase 7,000,000 shares of common stock and outstanding options to purchase 55,000 shares of common stock.

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Akers Biosciences, Inc. and Subsidiaries (the "Company") as of December 31, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such an opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Akers Biosciences, Inc. and Subsidiaries at December 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ Morison Cogen LLP

Bala Cynwyd, Pennsylvania July 23, 2013

# AKERS BIOSCIENCES, INC. AND SUBSIDIARIES Consolidated Balance Sheets December 31, 2012 and 2011

	2012		2011
ASSETS			
Current Assets			
Cash and Cash Equivalents	\$ 633,022	\$	1,192,805
Trade Receivables (net)	101,213		205,547
Trade Receivables – Related Party	10,013		21,842
Other Receivables	4,497		263,436
Note Receivable – Related Parties	225,000		148,900
License Fee Receivable – Related Party	450,000		-
Inventories (net)	987,853		685,675
Other Current Assets	67,898		84,567
Total Current Assets	2,479,496		2,602,772
Non-Current Assets			
Property, plant and equipment, net	240,014		341,433
Intangible assets, net	2,693,209		2,951,781
Other Assets	4,572		4,572
Total Non-Current Assets	2,937,795		3,297,786
Total Assets	\$ 5,417,291	\$	5,900,558
LIABILITIES			
Current Liabilities	ф. 1 00 <b>0 5</b> 0 A	Φ.	604.150
Trade and Other Payables	\$ 1,082,504	\$	694,158
Other Payables – Related Party	58,542		20,625
Deferred Revenue – Related Party	972,222		-
Total Current Liabilities	2,113,268		714,783
Total Liabilities	2,113,268		714,783
			, ,,,,,,
EQUITY			
Convertible Preferred Stock, No par value,			
50,000,000 shares authorized, 10,000,000 and -			
shares issued and outstanding as of December			
31, 2012 and 2011	225,000		-
Common Stock, No par value, 500,000,000	220,000		
shares authorized, 199,515,666 and 169,415,666			
issued and outstanding as of December 31, 2012			
and 2011	83,273,376		82,822,308
Accumulated Deficit	(80,194,353	)	(77,636,533)
Total Equity	3,304,023		5,185,775
Total Liabilities and Equity	\$ 5,417,291	\$	5,900,558

# AKERS BIOSCIENCES, INC. AND SUBSIDIARIES Consolidated Statements of Operations Years ended December 31, 2012 and 2011

2012 2011 Revenues: Product Revenue 1,494,585 1,785,068 \$ \$ License Revenue 27,778 Total Revenue 1,522,363 1,785,068 Cost of Sales: Product Cost of Sales (1,007,951)(956,620) Gross Profit 514,412 828,448 Administrative Expenses 1,493,707 3,188,137 Sales and Marketing Expenses 638,732 707,790 Research and Development Expenses 900,380 888,976 Non-Cash Share Based Compensation 27,766 Amortization of Non-Current Assets 258,572 228,094 Loss from Operations (2,776,979)(4,212,315)Other Income/Expenses Foreign Currency Transaction (Income)/Expense (6,859) 29,628 Other (Income)/Expense (44,892)(317,109)Total Other Expense/(Income) (51,751) (287,481) (2,725,228) (3,924,834) Loss Before Income Taxes Income Tax Benefit 297,890 167,408 Net Loss (2,557,820)(3,626,944) Basic & diluted loss per common share (0.01)(0.02)Weighted average basic & diluted common shares outstanding 178,316,486 163,519,502

# AKERS BIOSCIENCES, INC. AND SUBSIDIARIES Consolidated Statement of Changes in Stockholders' Equity Years ended December 31, 2012 and 2011

	 Convertible Preferred Stock	_	Common Stock		Accumulated Deficit	_	Total Equity
Balance at December 31, 2010	\$ -	\$	79,515,496	\$	(74,009,589)	\$	5,505,907
Net loss for the year	-		-		(3,626,944)		(3,626,944)
Fair value of warrants issued for compensation Issuance of shares			27,766				27,766
Exercise of warrants	-		3,017,746 261,300		-		3,017,746 261,300
Balance at December 31, 2011	-	_	82,822,308	_	(77,636,533)		5,185,775
Net loss for the year	-		-		(2,557,820)		(2,557,820)
Issuance of shares	225,000		451,068		-		676,068
Balance at December 31, 2012	\$ 225,000	\$	83,273,376	\$	(80,194,353)	\$	3,304,023

# AKERS BIOSCIENCES, INC. AND SUBSIDIARIES Consolidated Cash Flow Statements Years ended December 31, 2012 and 2011

	 2012		2011
Cash flows from operating activities			
Net loss for the year	\$ (2,557,820)	\$	(3,626,944)
Adjustments to reconcile net loss to net cash used by operating activities:			
Provisions for bad debts	9,047		1,650,185
Write-off of note receivable	148,900		-
Provision for inventory obsolescence	32,000		-
Non-cash equity position in BreathScan Int'l	-		(290)
Reversal of old trade payables	-		(172,331)
Non-cash share based compensation	-		27,766
Depreciation and amortization of non-current assets	371,676		377,448
Changes in assets and liabilities			
(Increase)/decrease in trade receivables	95,287		(191,908)
(Increase)/decrease in trade receivables – related party	11,829		(21,465)
(Increase)/decrease in other receivables	258,939		(263,436)
(Increase) in inventories	(334,178)		(52)
(Increase)/decrease in other assets	16,669		(2,687)
Increase/(decrease) in trade and other payables	281,422		(228,598)
Increase/(decrease) in other payables – related party	37,917		-
Increase in legal settlement liabilities	106,924		-
Increase in deferred revenue – related pary	 522,222		-
Net cash used in operating activities	(999,166)		(2,452,312)
Tee cash used in operating activities	 (999,100)	_	(2,432,312)
Cash flows from investing activities			
Purchases of property, plant and equipment	 (11,685)		(57,179)
Net cash used in investing activities	(11,685)		(57,179)
	(==,0.00)		(3,7272)
Cash flows from financing activities			
Proceeds from issuance of common stock	451,068		3,017,746
Proceeds from issuance of warrants	 <u> </u>		261,300
Net cash provided by financing activities	451.060		2 270 046
Net cash provided by infancing activities	 451,068		3,279,046
Net (decrease)/increase in cash and cash equivalents	(559,783)		769,555
Cash and cash equivalents at beginning of year	1,192,805		423,250
Cash and cash equivalents at end of year	\$ 633,022	\$	1,192,805
Supplemental Disclosure of Cash Flow Information			
Non-cash financing activities			
Exchange of a long-term receivable, less impingement and			
deferred revenue for patent rights	\$	\$	2 062 410
1 0	-		2,062,410
Issuance of convertible preferred stock for note receivable – related party	\$ 225,000	\$	-
License fee receivable – related party included in deferred revenue – related party	\$ 450,000	\$	_

#### Note 1 - Nature of Business

#### (a) Reporting Entity

The accompanying audited financial statements have been prepared by Akers Biosciences, Inc. ("ABI" or the "Company"), a company domiciled in the United States of America. The address of the Company's registered office is 201 Grove Road, West Deptford, New Jersey, 08086. The Company is incorporated in the United States of America under the laws of the State of New Jersey.

The consolidated financial statements include two dormant subsidiaries, Akers Acquisition Sub, Inc. and Bout Time Marketing Corporation. All material intercompany transactions have been eliminated upon consolidation.

#### (b) Nature of Business

The Company commenced research and development operations in September 1989, and until 2005 had devoted substantially all its efforts to establishing the new business.

The Company's primary focus is the development and sale of disposable diagnostic testing devices that can be performed in minutes, to facilitate time sensitive therapeutic decisions. The Company's main products are a disposable breathalyzer test that measures the blood alcohol content of the user, a rapid test detecting the antibody causing an allergic reaction to Heparin and a disposable breathalyzer test that measures Free Radical activity in the human body. When the Company enters into an agreement with a new distributor it requires an upfront licensing fee to be paid for the right to sell the Company's products in specific markets

# Note 2 - Basis of Presentation

# (a) Statement of Compliance

The consolidated financial statements of the Company are prepared in U.S. Dollars and in accordance with accounting principles generally accepted in the United States of America (US GAAP).

# (b) Use of Estimates and Judgments

The preparation of financial statements in conformity with US GAAP requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. In particular, information about significant areas of estimation, uncertainty and critical judgments in applying accounting policies that have the most significant effect on the amounts recognized in the financial statements is included in the following notes for preferred stock, allowances for doubtful accounts, inventory write-downs, impairment of intangible assets and valuation of share based payments.

Notes to Consolidated Financial Statements

#### (c) Functional and Presentation Currency

These consolidated financial statements are presented in U.S. Dollars, which is the Company's functional currency. All financial information presented in U.S. Dollars has been rounded to the nearest dollar. Foreign Currency Transaction Gains or Losses, resulting from loans and cash balances denominated in Foreign Currencies, are recorded in the statement of operations.

#### (d) Comprehensive Income

The Company follows Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) 220 in reporting comprehensive income (loss). Comprehensive income is a more inclusive financial reporting methodology that includes disclosure of certain financial information that historically has not been recognized in the calculation of net income. Since the Company has no items of other comprehensive income (loss), comprehensive income (loss) is equal to net income (loss).

# Note 3 - Significant Accounting Policies

#### (a) Cash and Cash Equivalents

Cash and cash equivalents comprise cash balances. The Company considers all highly liquid investments, which include short-term bank deposits (up to 3 months from date of deposit) that are not restricted as to withdrawal date or use, to be cash equivalents. Bank overdrafts are shown as part of trade and other payables in the balance sheet.

# (b) Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, receivables and trade and other payables. The carrying value of cash and cash equivalents, trade receivables and trade and other payables approximate their fair value because of their short maturities. The Company believes the carrying amount of its note receivable approximates its fair value based on rates and other terms.

# (c) Trade Receivables, Trade Receivables - Related Party and Allowance for Doubtful Accounts

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

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

Notes to Consolidated Financial Statements

As of December 31, 2012 and 2011, allowances for doubtful accounts were \$\\$- and \$\\$1,655,582\$. Allowances charged for doubtful accounts amounted to \$\\$9,047 as of December 31, 2012 and \$\\$1,650,185 for December 31, 2011. The bad debt expense of \$\\$1,650,185 in 2011 represents an increase in the allowance for doubtful accounts due from a foreign customer who entered bankruptcy proceedings in 2011 and thus collection was doubtful. The receivable was written off in 2012 with a corresponding reduction in the allowance.

#### (d) Concentration of Credit Risk

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

Substantially all of the Company's cash and cash equivalents are maintained with Bank of America, NA. The funds are insured by the FDIC up to a maximum of \$250,000, but are otherwise unprotected. The Company placed \$630,337 and \$1,190,120 with this institution as of December 31, 2012 and 2011. No losses have been incurred in these accounts.

Concentration of credit risk with respect to trade receivables exists as approximately 63% (2011: 53%) of its revenue is generated by three customers. These customers accounted for 59% and 72% of trade receivables as of December 31, 2012 and 2011 In order to limit such risks, the Company performs ongoing credit evaluations of its customers financial condition.

#### (e) Inventories

Inventories are measured at the lower of cost or market. The cost of inventories is based on the weighted-average principle, and includes expenditures incurred in acquiring the inventories, production or conversion costs and other costs incurred in bringing them to their existing location and condition. In the case of manufactured inventories and work in progress, costs include an appropriate share of production overheads based on normal operating capacity.

#### (f) Property, Plant and Equipment

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Costs include expenditures that are directly attributable to the acquisition of the asset.

Gains and losses on disposal of an item of property, plant and equipment are determined by comparing the proceeds from disposal with the carrying amount of property, plant and equipment and are recognized within "other income" in the statement of operations.

Depreciation is recognized in profit and loss on the accelerated basis over the estimated useful lives of the property, plant and equipment. Leased assets are depreciated over the shorter of the lease term or their useful lives.

Notes to Consolidated I maneral Statem

The estimated useful lives for the current and comparative periods are as follows:

	Useful Life (in years)
Plant and equipment	5-12
Furniture and fixtures	5-10
Computer equipment & software	3-5

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

# (g) Intangible Assets

#### (i) Patents and Trade Secrets

The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person's breath, blood, urine and saliva. Propriety protection for the Company's products, technology and process is important to its competitive position. To date, the Company has received nine patents from the United States Patent Office (7,896,167, 8,097,171, 7,285,246, 7,837,936, 8,003,061, 8,425,859, 5,565,366, 5,231,035 and 5,827,749). Other patents have been granted through the European patent Convention (EP 0556202), in Germany (69126142.3) and in Japan (2,628,792, 4,885,134 and 4,931,821). Patents are in the national phase of prosecution in many Patent Cooperation Treaty participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the U.S., European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

# (ii) Patent Costs

Costs associated with applying for patents are capitalized as patent costs. Once the patents are approved, the respective costs are amortized over their estimated useful lives (maximum of 17 years) on a straight-line basis. Patent pending costs for patents that are not approved are charged to operations the year the patent is rejected.

In addition, patents may be purchased from third parties. The costs of acquiring the patent are capitalized as patent costs if it represents a future economic benefit to the Company. Once a patent is acquired it is amortized over its remaining useful life.

# (iii) Other Intangible Assets

Other intangible assets that are acquired by the Company, which have definite useful lives, are measured at cost less accumulated amortization and accumulated impairment losses.

Notes to Consolidated Financial Statements

#### (iv) Amortization

Amortization is recognized on a straight-line basis over the estimated useful lives of intangible assets, other than goodwill, from the date that they are available for use. The estimated useful lives for the current and comparative periods are as follows:

	Useful Life
	(in years)
Patents and trademarks	12-17
Customer lists	5

#### (h) Recoverability of Long Lived Assets

In accordance with FASB ASC 360-10-35 "Impairment or Disposal of Long-lived Assets", long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable or that the useful lives of those assets are no longer appropriate. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment.

The Company determines the existence of such impairment by measuring the expected future cash flows (undiscounted and without interest charges) and comparing such amount to the carrying amount of the assets. An impairment loss, if one exists, is then measured as the amount by which the carrying amount of the asset exceeds the discounted estimated future cash flows. Assets to be disposed of are reported at the lower of the carrying amount or fair value of such assets less costs to sell. Asset impairment charges are recorded to reduce the carrying amount of the long-lived asset that will be sold or disposed of to their estimated fair values. Charges for the asset impairment reduce the carrying amount of the long-lived assets to their estimated salvage value in connection with the decision to dispose of such assets.

#### (i) Revenue Recognition

In accordance with FASB ASC 605, the Company recognizes revenue when (i) persuasive evidence of a customer or distributor arrangement exists, (ii) a retailer, distributor or wholesaler receives the goods and acceptance occurs, (iii) the price is fixed or determinable, and (iv) collectability of the revenue is reasonably assured. Subject to these criteria, the Company recognizes revenue from product sales when title passes to the customer based on shipping terms. The Company does not accept returns nor offer chargebacks or rebates. License fee revenue is recognized on a straight-line basis over the term of the license agreement.

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

Notes to Consolidated Financial Statements

#### (j) Income Taxes

The Company follows FASB ASC 740 when accounting for income taxes, which requires an asset and liability approach to financial accounting and reporting for income taxes. Deferred income tax assets and liabilities are computed annually for temporary differences between the financial statements and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense or benefit is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

#### (k) Shipping and Handling Fees and Costs

The Company charges actual shipping plus a handling fee to customers, which amounted to \$41,728 and \$47,231 for December 31, 2012 and 2011. These fees are classified as other income in the statement of operations. Shipping and other related delivery costs, including those for incoming raw materials are classified as part of the cost of net revenue, which amounted to \$72,305 and \$54,664 for December 31, 2012 and 2011.

#### (I) Research and Development Costs

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

#### (m) Stock-based Payments

The Company accounts for stock-based compensation under the provisions of FASB ASC 718, Compensation—Stock Compensation, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. The Company estimates the fair value of stock-based awards on the date of grant using the Black-Scholes model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over shorter of the period over which services are to be received or the vesting period.

The Company accounts for stock-based compensation awards to non-employees in accordance with FASB ASC 505-50, Equity-Based Payments to Non-Employees. Under FASB ASC 505-50, the Company determines the fair value of the stock warrants or stock-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

All issuances of stock warrants or other equity instruments to non-employees as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued. The Company estimates the fair value of stock-based awards on the date of grant using the Black-Scholes model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the period which services are to be received.

Notes to Consolidated Financial Statements

#### (n) Basic and Diluted Earnings per Share of Common Stock

Basic earnings per common share are based on the weighted average number of shares outstanding during the periods presented. Diluted earnings per share are computed using the weighted average number of common shares plus dilutive common share equivalents outstanding during the period. Potential common shares that would have the effect of increasing diluted earnings per share are considered anti-dilutive for the years ended December 31, 2012 and 2011 as net losses were recorded in both years.

# (o) Recently Adopted Accounting Pronouncements

The Company does not believe that any accounting standards and guidance with an effective date during the year ended December 31, 2012 had a significant impact on the Company's consolidated financial statements and the disclosures presented in the consolidated financial statements.

# (p) Recently Adopted Accounting Pronouncements not Yet Adopted

As of December 31, 2012, there are no recently issued accounting standards not yet adopted which would have a material effect on the Company's financial statements.

# (q) Subsequent Events

FASB ASC 855-10, Subsequent Events, establishes general standards of accounting and disclosure of events that occur after the consolidated balance sheet date but before the date the consolidated financial statements are available to be issued. Subsequent events have been evaluated through July 23, 2013, the date that the consolidated financial statements were available to be issued.

#### Note 4 - Note Receivable - Related Parties

The note of \$225,000 was issued to the Company in connection with the subscription of 10,000,000 series A convertible preferred stock entered into on September 14, 2012 (Note 12). It is due September 14, 2027 and has an interest rate of 3% per annum. For the year ended December 31, 2012, interest income of \$1,997 was recorded. The note was fully settled in cash on February 26, 2013 and hence the note is recorded as a receivable instead of being shown as a contra account against the preferred stock as of December 31, 2012.

The \$148,900 at December 31, 2011 represents the impaired balance of the 2010 note from BreathScan International Ltd for products related to the licensing agreement dated March 17, 2010. This note was written-off on June 19, 2012 as part of the 3 year exclusive License & Supply agreement with Chubeworkx Guernsey Limited (as a successor to SONO International Limited) ("Chubeworkx").

#### Note 5 - License Fee Receivable - Related Party

On June 19, 2012, the Company entered into a 3-year exclusive License & Supply Agreement with Chubeworkx for the purchase and distribution of ABI's proprietary breathalyzers outside North America (Note 15). Chubeworkx agreed to pay a licensing fee of \$1,000,000. As of December 31, 2012, the Company has received \$550,000 with the balance due with the final award of the *NF Marque* ("NF Mark"). The final fee of \$450,000 was received on March 6, 2013.

On June 14, 2013 Chubeworkx became a shareholder of the Company (Note 18).

# Note 6 - Inventories

Inventories at December 31, 2012 and 2011 consists of the following categories:

	2012	2011
Raw Materials	\$ 516,497	\$ 265,859
Sub-Assemblies	464,740	398,528
Finished Goods	38,616	21,288
Reserve for Obsolescence	(32,000)	-
	\$ 987,853	\$ 685,675

For the years ended December 31, 2012 and 2011 \$32,000 and \$- was charged to cost of goods sold for obsolete inventory.

# Note 7 - Property, Plant and Equipment

Property, plant and equipment as of December 31, 2012 and 2011 and the movements for the years then ended are as follows:

	 2012	2011		
Computer Equipment	\$ 100,405	\$	100,405	
Computer Software	22,930		22,930	
Office Equipment	50,049		50,049	
Furniture & Fixtures	29,939		29,939	
Machinery & Equipment	1,021,061		1,009,376	
Molds & Dies	603,957		603,957	
Leasehold Improvements	222,594		222,594	
	2,050,935		2,039,250	
Less				
Accumulated Depreciation	1,810,921		1,697,817	
	,			
	\$ 240,014	\$	341,433	

During the years ended December 31, 2012 and 2011 depreciation expense was \$113,104 and \$149,354.

# Note 8 - Intangible Assets

Intangible assets as of December 31, 2012 and 2011 and the movements for the years then ended are as follows:

	_	Patents & rademarks	(	stributor & Customer lationships	Totals		
Cost or Deemed Cost							
At December 31, 2010	\$	1,789,084	\$	1,270,639	\$	3,059,723	
Additions		2,062,410		-		2,062,410	
Disposals		-		-			
At December 31, 2011		3,851,494		1,270,639		5,122,133	
Accumulated Amortization							
At December 31, 2010		678,672		1,263,586		1,942,258	
Amortization Charge		221,041		7,053		228,094	
Disposals		_		_			
At December 31, 2011		899,713		1,270,639		2,170,352	
Net Book Value							
At December 31, 2010		1,110,412		7,053		1,117,465	
At December 31, 2011		2,951,781				2,951,781	
Cost or Deemed Cost							
At December 31, 2011		3,851,494		1,270,639		5,122,133	
Additions		-		-		-	
Disposals		-		-		-	
At December 31, 2012		3,851,494		1,270,639		5,122,133	
Accumulated Amortization							
At December 31, 2011		899,713		1,270,639		2,170,352	
Amortization Charge		258,572		-		258,572	
Disposals		_		_			
At December 31, 2012		1,158,285		1,270,639		2,428,924	
Net Book Value							
At December 31, 2011		2,951,781				2,951,781	
At December 31, 2012	\$	2,693,209	\$		\$	2,693,209	

On April 8, 2011 the Company entered into an agreement with Pulse Health, LLC ("Pulse") to purchase all Technology relating to non-invasive exhaled breath testing which Pulse acquired from ABI in December, 2008. In exchange for this technology, ABI released Pulse from any obligation to make further payments under the Technology Transfer Agreement, which currently total \$2,217,721. The fair value of the acquired patent was determined to be \$2,062,410 which was equal to the consideration paid. There was no income or expense recorded as part of this transaction.

During the years ended December 31, 2012 and 2011 amortization expense was \$258,572 and \$228,094.

# Note 9 - Trade and Other Payables

Trade and other payables as of December 31, 2012 and 2011 are as follows:

	2012	2011
Trade Payables	\$ 608,836	\$ 205,463
Other Payables	366,744	357,319
Legal Settlement Payable	106,924	131,376
	\$ 1,082,504	\$ 694,158

Trade and other payables are non-interest bearing and are normally settled on 30-60 day terms. The legal settlement is non-interest bearing and has a term of 12 equal monthly installments, which commended on October 31, 2012.

The legal settlements payable comprises two arbitration settlements as follows:

(c) On January 9, 2012, the Company was notified of an action to recover unpaid royalties for the exclusive use of a patent used in the production of our MPC Biosensor products (MicroParticle Catalyzed Biosensor). The dispute related to the method used to calculate royalty payments and the scope of the products involved for the period dated March 17, 2007 through March 19, 2012.

On April 23, 2012, the Company agreed to an arbitration settlement of \$137,791. The settlement is to be paid over 12 months, with an initial payment of \$50,000 and 11 equal payments of \$7,981. As of December 31, 2012 the amount due was \$31,924.

The Company recorded an amount of \$131,376 in Sales and Marketing expenses in 2011. Upon agreement of the settlement on April 23, 2012, an additional amount of \$6,425 was accrued and recorded as Sales and Marketing expenses in 2012.

(d) On January 11, 2012, the Company was notified of a demand for arbitration from Trinity Biotech Manufacturing Limited related to the distributor agreement between the parties dated June 19, 2008.

On October 15, 2012, the Company agreed to an arbitration settlement of \$118,000. The settlement is to be paid over 13 months, with an initial payment of \$18,000 and 12 equal payments of \$8,333. As of December 31, 2012 the amount due was \$75,000.

The Company recorded \$118,000 in Administrative expense in 2012.

# Note 10 - Deferred Revenue - Related Party

Deferred revenue represents the unearned revenue from the 3-year exclusive License and Supply Agreement with Chubeworkx Guernsey Limited (Note 15) for the purchase and distribution of ABI's proprietary breathalyzer that was signed in June, 2012. The first order for the proprietary breathalyzers was received in December 2012 for 3,500,000 units. The license revenue is being recognized monthly on a straight line basis over the 3-year term of the agreement.

#### Note 11 - Share-based Payments

#### (a) Stock Warrants

The Company has issued warrants to various employees, consultants and members of the Board of Directors of the Company for their services either in connection with the Company's ongoing efforts to raise capital or the development of the Company's products. In addition, the Company has granted warrants to lenders in connection with the issuance of debt. Each warrant granted may be exchanged for a prescribed number of shares of common stock. The warrants expire at various dates through January 2019.

	20	)12		2011			
		Weighted Average					
	Warrants Exercise Price		Warrants	Exercise Price			
Outstanding at January 1	9,365,344	\$	0.40	9,915,344	\$	0.42	
Granted during year	-		-	4,650,000		0.06	
Forfeited during year	-		-	-		-	
Exercised during year	-		-	(4,650,000)		0.06	
Expired during year	(2.000,000)		0.71	(550,000)		0.83	
Outstanding at December 31	7,365,344	\$	0.31	9,365,344	\$	0.40	

The Company has adopted two option plans that permit the granting of options to purchase shares of common stock. The plans provide for the granting of both incentive stock options ("Incentive Stock Plan"), as defined in Section 422 of the U.S. Internal Revenue Code (the "Code"), and options defined by Section 422 of the Code ("Non-qualified options").

Notes to Consolidated Financial Statements

The plans are administered by a Compensation Committee, which is appointed by the Board of Directors, who grants all options and determines their terms. Options are non-transferable and are only granted to employees, officers and directors, and advisors or consultants who agree to be employed or to provide services to the Company for a period of at least one year after the grant date. The maximum term of any option under the plans is ten years, and generally vest over three years.

# (b) Stock options

Qualified option holders may exercise their options at their discretion through various dates ending November 2014. Each option granted may be exchanged for a prescribed number of shares of common stock.

# Employee's Plan

Employee's Flan	20		Weighted Average	2011 Weighted Average			
	8			Options	Exercise Price		
Outstanding at January 1	446,700	\$	0.27	470,700	\$	0.27	
Granted during year	-		-	-		-	
Forfeited during year	(200,000)		0.27	(24,000)		0.27	
Exercised during year	-		-	-		-	
Expired during year	-		-	-		-	
Outstanding at December 31	246,700	\$	0.27	446,700	\$	0.27	

#### Director's Plan

Director S Liun	20	20	2011 Weighted Average				
	Options	Ex	xercise Price	Options	Exercise Price		
Outstanding at January 1	880,500	\$	0.45	1,134,500	\$	0.76	
Granted during year	-		-	-		-	
Forfeited during year	-		-	-		-	
Exercised during year	-		-	-		-	
Expired during year	(825,500)		0.34	(254,000)		1.90	
Outstanding at December 31	55,000	\$	2.00	880,500	\$	0.45	

The options and warrants issued under the above three plans were valued using a Black Scholes option pricing model on the date of measurement. The weighted average measurement date fair value for the 650,000 warrants granted in 2011 was \$0.05 per warrant. There were no options or warrants granted during 2012.

The following weighted average assumptions were used in valuing the awards:

	2012	2011
Expected option term	n/a	5 years
Expected volatility	n/a	71.33%
Expected divident yeild	n/a	-
Risk free interest rate	n/a	2.11%

Notes to Consolidated Financial Statements

A summary of warrants and stock options outstanding and exercisable as of December 31, 2012 follows:

					Outstanding Weighted Average Life	Weighted Average Exercise		Exercisable Weighted Average Exercise
	I	Low	High	Shares	Remaining	Price	Shares	Price
Director's Plan	\$	2.00	\$ 2.00	55,000	1.87	\$ 2.00	55,000	\$ 2.00
Warrants		0.18	0.89	7,365,344	4.55	0.31	7,365,344	0.31
Employee's Plan		0.27	0.27	246,700	0.27	0.27	246,700	0.27
		,		8,667,044			8,667,044	

# Note 12 - Equity

The holders of common shares are entitled to one vote per share at meetings of the Company. Holders of Series A convertible preferred shares are entitled to five votes per share at meetings of the Company.

At December 31, 2012, the Company has an undeclared dividend due to series A convertible preferred shareholders in the amount of \$3,995 (2011: nil).

On January 12, 2011, the Company issued 50,000 common shares to an investor for \$5,230.

On February 10, 2011, the Company issued 50,000,000 common shares in a secondary offering. The transaction was recorded at the net proceeds value. The expenses related to the share sale are detailed below.

# **Secondary Share Offering**

	\$	\$
Gross Proceeds:		3,200,000
Broker Commission	160,000	
Finance Fees	16,000	
Legal Fees	11,076	
Expenses	408	
Total Expenses		187,484
Net Proceeds:		3,012,516

On February 10, 2011 as part of the secondary offering, directors and employees of the Company received and immediately exercised warrants, with a two day expiration term, for 4,000,000 common shares for total proceeds of \$254,800. No compensation expense was recorded upon the issuance of the warrants since the exercise price was equal to the share price of the secondary offering.

On March 9, 2011, the Company granted two employees a total of 650,000 warrants as compensation. The warrants had an exercise price of \$0.01, expiration term of five years and vest immediately. The warrants were valued at \$27,766, fair value, and expensed immediately.

On March 9, 2011, two employees exercised options for a total of 650,000 common shares for \$6,500.

On July 7, 2012, the Company issued 100,000 common shares to an investor for \$1,068.

Notes to Consolidated Financial Statements

On September 14, 2012, the Company, in a private placement to an investor, issued 30,000,000 common shares for \$450,000 and 10,000,000 series A convertible preferred shares to an investor for a promissory note of \$225,000 (Note 4). The series A convertible preferred shares have the following rights:

<u>Voting Rights.</u> Preferred stockholders have voting rights equal to the number of common shares stockholder would own upon conversion of shares of preferred stock. The preferred stock is convertible into 50,000,000 shares of common stock.

<u>Dividends</u>. The holders of the Convertible Preferred Stock are entitled to receive preferential dividends at a rate of \$0.00135 per share. Such dividends compound annually and are fully cumulative and have priority to any dividends on common stock.

<u>Liquidation Preferences</u>. The holders of the Convertible Preferred Stock are entitled to receive liquidation preferences for payment of any dividends due the holders. After payment of the liquidation preferences, the remaining assets, if any, are to be distributed to the holders of the Convertible Preferred Stock and common stock on a pro rata basis.

<u>Conversion</u>. One share of the Convertible Preferred Stock is convertible into five shares of the Company's common stock at the option of the holder. In order to convert, the holders of the Convertible Preferred Stock must make a one-time payment to the Company of \$500,000.

The Convertible Preferred Stock is recorded as equity in accordance with FASB ASC 480. In accordance with FASB ASC 815, it was determined that the conversion feature was not required to be bifurcated from the equity host.

On December 20, 2012 the Company increased its authorized number of preferred stock to 50,000,000 and its authorized number common stock to 500,000,000

As of December 31, 2012 the Company has reserved shares of its common stock as follows:

	2012
Reserves for:	
Convertible Preferred Stock	50,000,000
Outstanding Warrants	7,365,344
Outstanding Employee Options	246,700
Outstanding Directors Options	55,000
Total Reserves	57,667,044

Notes to Consolidated Financial Statements

The following is a reconcilement of the movement of shares of Series A Convertible Preferred stock (preferred stock) and common stock.

	Authorized Preferred Stock	Issued Common Stock	Preferred Stock	Common Stock
Balance at December 31, 2010	15,000,000	200,000,000	-	114,715,666
Shares Issued:				
January 12, 2011	-	-	-	50,000
February 10, 2011	-	-	=	54,000,000
March 9, 2011	-	-	-	650,000
Balance at December 31, 2011	15,000,000	200,000,000	-	169,415,666
Shares Issued:				
July 7, 2012	-	-	-	100,000
September 14, 2012	-	-	10,000,000	30,000,000
Increase in Authorization:				
December 20, 2012	35,000,000	300,000,000	-	-
Balance at December 31, 2012	50,000,000	500,000,000	10,000,000	199,515,666

#### Note 13 - Loss per share

The calculation of basic and diluted loss per share at December 31, 2012 and 2011 was based on the loss attributable to common shareholders of \$2,557,820 and \$3,626,924. The basic and diluted weighted average number of common shares outstanding for 2012 and 2011 was 178,316,486 and 163,219,502.

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

Potential common shares consist of preferred stocks, options and warrants. Diluted net loss per common share was the same as basic net loss per common share for the years ended December 31, 2012 and 2011 since the effect of preferred stocks, options and warrants would be anti-dilutive due to the net loss attributable to the common shareholders for the years. Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were as follows: series A convertible preferred stock – 50,000,000 (2011: nil), employee and consulting stock options – 301,700 (2011: 1,327,200); warrants 7,365,344 (2011: 9,365,344).

# Note 14 - Income Tax Expense

The Company's income tax benefit is as follows:

	2012	2011
Net State Income Tax Benefit	\$ 167,408	\$ 297,890
Total:	\$ 167,408	\$ 297,890

During 2012, the Company was approved by the State of New Jersey to sell a portion of its state tax benefits that existed as of December 31, 2011, pursuant to the Technology Tax Certificate Transfer Program. The Company received net proceeds of \$167,408 in 2012 (2011: \$297,890) as a result of the sale of the tax benefits, which has been included when received as an income tax benefit in the consolidated statement of operations.

Notes to Consolidated Financial Statements

The Company has had recurring tax losses and the Company has determined that it is not probable that the Company will be able to utilize its net operating loss carry-forwards and other tax attributes in the future. Accordingly, the Company has not recorded any deferred tax assets as of December 31, 2012 and 2011.

As of December 31, 2012 and 2011, the Company had Federal net operating loss carry forwards of approximately \$46,500,000 and \$44,000,000, expiring through the year ending December 31, 2032. As of December 31, 2012 and 2011, the Company had New Jersey state net operating loss carry forwards of approximately \$5,600,000 and \$6,100,000, expiring through the year ending December 31, 2019.

The principle components of the deferred tax assets and related valuation allowances as of December 31, 2012 and 2011 are as follows:

	2012	2011
Reserves and other	\$ 921,068	\$ 922,702
Net operating loss carry-forwards	16,149,472	15,039,711
Valuation Allowance	(17,070,540)	(15,962,413)
Total unrecognized deferred tax assets:	\$ -	\$ -

The reconciliation of income taxes using the statutory U.S. income tax rate and the benefit from income taxes for the years ended December 31, 2012 and 2011 are as follows:

	2012	2011
Statutory U.S. Federal Income Tax Rate	(34.0%)	(34.0%)
New Jersey State income taxes, net of U.S.		
Federal Benefit	(6.0%)	(6.0%)
Change in Valuation Allowance	34.0%	32.3%
Net benefit from sale of state income tax		
benefits	(6.0%)	(7.7%)

The valuation allowance for deferred tax assets as of December 31, 2012 and 2011 was \$17,070,540 and \$15,962,413. The change in the total valuation for the years ended December 31, 2012 and 2011 was an increase of \$1,108,127 and a decrease of \$4,250,495. In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the net operating losses and temporary differences become deductible. Management considered projected future taxable income and tax planning strategies in making this assessment. The value of the deferred tax assets was offset by a valuation allowance, due to the current uncertainty of the future realization of the deferred tax assets.

The Company's policy is to record interest and penalties associated with unrecognized tax benefits as additional income taxes in the statement of operations. As of January 1, 2012, the Company had no unrecognized tax benefits and no charge during 2012, and accordingly, the Company did not recognize any interest or penalties during 2012 related to unrecognized tax benefits. There is no accrual for uncertain tax positions as of December 31, 2012.

Notes to Consolidated Financial Statements

The Company files U.S. income tax returns and a state income tax return. With few exceptions, the U.S. and state income tax returns filed for the tax years ending on December 31, 2009 and thereafter are subject to examination by the relevant taxing authorities.

#### Note 15 - Related Party Transactions

On January 12, 2011, the Company entered into a consulting agreement with Nicolette Consulting Group Limited (NCG) for a period of three years under which the Company must pay NCG \$27,917 per month in fees and up to \$10,000 in reimbursement for monthly expenses (2012: \$100,000; 2011: \$110,000) for the services of Mr. Nicolette as President and Chief Executive Officer of the Company. The total amount of consulting fees accrued for NCG as of December 31, 2012 and 2011 was \$58,542 and \$20,625 and is shown as Other Payables – Related Party in the Consolidated Balance Sheet.

On March 17, 2010, in exchange for an exclusive licensing agreement, ABI received a 20 percent equity stake in BreathScan International Ltd (BIL). During 2012, BreathScan International Limited changed its name to en(10) Guernsey Limited ("en(10)"). Thomas A. Nicolette, President and Chief Executive Officer of ABI, was also appointed to en(10)'s Board of Directors. The equity stake is accounted for using the equity method of accounting in accordance with the Financial Accounting Standards Board Accounting Standards Codification. The equity investment was initially recorded at cost, which was nil. During 2011, the Company recognized \$290 in Other Income for the Company's share of en(10)'s net profit or loss. During 2012 no profit or loss is recorded for en(10)'s results as en(10) recorded a net loss and ABI is not required to equity account any losses in excess of its carrying value on the books.

On June 19, 2012, the Company entered into a 3 year exclusive License & Supply Agreement with Chubeworkx Guernsey Limited (as successor to SONO International Limited) ("Chubeworkx") for the purchase and distribution of ABI's proprietary breathalyzers outside North America. Chubeworkx is the 80% shareholder in en(10) Guernsey Limited, described above. Chubeworkx paid a licensing fee of \$1,000,000, of which \$27,778 was recognized as income in 2012 with the deferral to be recognized over the remaining term of the agreement (Note 5).

Revenue from Chubeworkx for the years ended December 31, 2012 and 2011 were \$12,673 and \$21,465.

# Note 16 - Commitments

The Company leases its facility in West Deptford, New Jersey under an operating lease with annual rentals of \$130,200 plus common area maintenance (CAM) charges. The lease, which took effect on January 1, 2008, reduced the CAM charges allowing the Company to reach their own agreements with utilities and other maintenance providers.

On January 7, 2013, the Company extended its lease agreement for a term of 7 years, expiring December 31, 2019. Under the terms of the lease, The Company will pay \$132,000 per year.

Notes to Consolidated Financial Statements

	Ye	ar	Years		Years
		1	2-5		6-7
201 Grove Road Lease	\$	132,000 \$	528,000	\$	264,000

Rent expense, including related CAM charges for the years ended December 31, 2012 and 2011 were \$160,207 and \$167,189.

#### Note 17 - Other Income

Other income consists of interest income, shipping and handling fees and other miscellaneous income items. As of December 31, 2012 and 2011 the earnings were as follows:

	2012	2011
Interest Income	\$ 2,366	\$ 95,419
Shipping & Handling Fees	41,738	47,230
Miscellaneous Income	788	174,460
Total:	\$ 44,892	\$ 317,109

#### Note 18 - Subsequent events

On February 27, 2013, the Company announced that its proprietary disposable breath alcohol detectors have been granted the final award of the NF Marque ("NF Mark") number 18/01. The NF Mark allows the breathalyzers to be sold in and around France under the brand name CHUBE by ABI's UK based partner, (en)10 Guernsey Limited.

On April 10, 2013, the Company announced the receipt of the second order from ChubeWorkx for 1.4 million disposable breathalyzers which in combination with the initial 3.5 million unit order received in December 2012, brings the total order to-date under the License and Supply Agreement to 4.9 million units.

On June 13, 2013, the Company announced an extension of the License and Supply Agreement with Chubeworkx to include worldwide marketing and distribution of the "Be CHUBE" program using the ABI breathalyzer.

On June 13, 2013, the Company announced that Chubeworkx has agreed to subscribe for 80,000,000 new common shares in the Company for a total price of \$1,600,000. The proceeds were received by the Company on June 14, 2013. In addition, the parties have entered into a share purchase agreement in which ABI will sell its 20% interest in (en)10 to Chubeworkx for \$100,000. A realized gain of \$99,710 will be recognized in 2013 for the sale of the asset.

On June 13, 2013, the Company announced its intention to change its by-laws to insure that unanimous approval shall be required by the Board of Directors for any issuance by the Company of any new shares of capital stock or any instruments convertible into share of capital stock.

On July 1, 2013, the Company announced the appointment of Gavin Moran and Thomas Knox as Non-Executive members of the Company's Board of Directors.



**METRON™** measures ketone production associated with desired fat-burning due to weight loss or an increase in exercise



Breath Ketone "Check" assists diabetics in assessing if they have a severe level of ketone (acid) build up that can cause a medical emergency called ketoacidosis





Breath PulmoHealth "Check"® suite of assays detect various biomarkers related to pulmonary health, namely Asthma, COPD and Lung Cancer

**VIVO™** measures key biological indicators of oxidative stress related to cellular damage







PIFA PLUSS® PF4 prepares the blood sample & determines if a patient exposed to the blood thinner, Heparin, may be developing a life- and limb threatening drug allergy

# Shares of Common Stock



# **PROSPECTUS**

# **Aegis Capital Corp**

# PART II INFORMATION NOT REQUIRED IN PROSPECTUS

# ITEM 13. Other Expenses of Issuance and Distribution.

The expenses (other than underwriting discounts and expenses) payable by us in connection with this offering are as follows:

	Amount
SEC registration fee	\$ 2,480
FINRA fee	\$ 3,228.13
NASDAQ listing fee	-
Printing and mailing expenses	-
Accounting fees and expenses	-
Legal fees and expenses	
Transfer agent fees and expenses	*
Miscellaneous	*
Total expenses	-

All expenses are estimated except for the SEC fee, the FINRA fee and the NASDAQ listing fee.

#### ITEM 14. Indemnification of Directors and Officers.

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

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

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

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

<sup>\*</sup> To be completed by amendment

# ITEM 15. Recent Sales of Unregistered Securities.

During the last three completed fiscal years and to date in the current fiscal year, we sold the following unregistered securities:

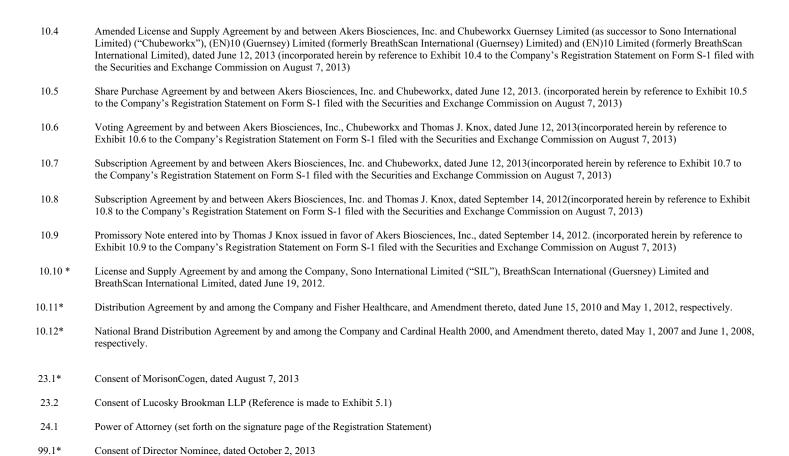
Issuance	# Of Shares	
On June 13, 2013, the Company sold 80,000,000 shares of its common stock for a purchase price of \$1,600,000 to Chubeworkx.	80,000,000	June 13, 2013
On September 14, 2012, the Company sold 30,000,000 shares of its common stock for a purchase price of \$450,000 to Thomas Knox	30,000,000	September 14, 2012
On September 14, 2012, the Company sold 10,000,000 shares of Series A preferred stock for \$225,000 to Thomas Knox.	10,000,000	September 14, 2012
On July 7, 2012, the Company sold 100,000 shares of its common stock to an investor for \$1,068	100,000	July 7, 2012
On March 9, 2011, two employees exercised options for 650,000 shares of common stock for \$6,500	650,000	March 9, 2011
On February 10, 2011, the Company sold 50,000,000 shares of commons stock in a secondary public offering for a total of \$3,012,516	50,000,000	February 10, 2011
On February 10, 2011, employees exercised options for 4,000,000 shares of common stock for \$254,800 as part of the secondary public offering.	4,000,000	February 10, 2011
On January 12, 2011, the Company sold 50,000 shares of common stock to an investor for \$5,230	50,000	January 12, 2011
On March 19, 2010, the Company issued a warrant for 310,344 shares of common stock, exercisable immediately, at an exercise price of \$0.46 per share, expiring March 19, 2015 to Daniel Stewart & Company in exchange for services provided.	310,344	March 19, 2010

No underwriters were involved in the foregoing sales of securities. The issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 701 promulgated under Section 3(b) of the Securities Act or Regulation S promulgated under the Securities Act. The recipients of securities in some but not all such transactions represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the stock certificates and option agreements issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

# ITEM 16. Exhibits and Financial Statement Schedules.

(a)

Exhibit Number	Description of Exhibit
1.1†	Form of Underwriting Agreement
3.1	Amended & Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013)
3.2	Amendment to Certificate of Incorporation dated June 2, 2008 (incorporated herein by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013)
3.3	Amendment to Certificate of Incorporation, Certificate of Designation of Series A Preferred Stock, dated September 21, 2012. (incorporated herein by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013)
3.4	Amendment to Certificate of Incorporation dated January 22, 2013 (incorporated herein by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013)
3.5	Amended and Restated By-laws dated August 5, 2013(incorporated herein by reference to Exhibit 3.5 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013)
4.1†	Form of Underwriters' Warrant
5.1†	Opinion of Lucosky Brookman LLP
10.1	Employment Agreement, dated January 12, 2011 between Raymond F. Akers, Jr. Phd and Akers Biosciences, Inc. and letter of amendment dated August 3, 2013. (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013)
10.2	Consulting Agreement between Akers Biosciences, Inc. and Nicolette Consulting Group, dated January 12, 2011(incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013)
10.3	Consulting Agreement between Akers Biosciences, Inc. and DataSys Solutions, LLC, dated Janury 1, 2012. (incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013)



Unless otherwise indicated, exhibits were previously filed with this registration statement.

- \* Filed herewith.
- † To be filed by amendment.
  - (b) Financial Statement Schedules

No financial statement schedules have been provided because the information is not required or is shown either in the financial statements or the notes thereto.

# ITEM 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting certificates in such denominations and registered in such names as required by underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) For purposes of determining any liability under the Securities Act, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (§ 230.430A of this chapter), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Thorofare, State of New Jersey, on October 7, 2013.

# AKERS BIOSCIENCES, INC.

/s/Thomas A. Nic	olette
Thomas A. Nic	olette
Chief Executive O	fficer
(Principal Executive Of	ficer)
(Principal Financial Of	ficer)

POWER OF ATTORNEY: KNOW ALL PERSONS BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints Thomas A. Nicolette and Raymond F. Akers, Jr., Phd and each of them, his or her true and lawful attorneys-in-fact and agents with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and to sign any registration statement for the same offering covered by the Registration Statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his, her or their substitute or substitutes, may lawfully do or cause to be done or by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates stated.

Signature	Title	Date
/s/ Thomas A. Nicolette	Chief Executive Officer, President and Director	October 7, 2013
Thomas A. Nicolette	(Principal Executive Officer and Principal Financial Officer)	
/s/ Raymond F. Akers Jr., Phd Raymond F. Akers Jr. Phd	Executive Chairman and Director	October 7, 2013
/s/Gary Rauch Gary Rauch	Controller	October 7, 2013
/s/Thomas A. Knox Thomas A. Knox	Director	October 7, 2013
/s/ Gavin Moran Gavin Moran	Director	October 7, 2013
	II-6	

EXECUTION COPY

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# **Licence and Supply Agreement**

between

Akers Biosciences, Inc.

and

Sono International Limited

and

BreathScan International (Guernsey) Limited

and

BreathScan International Limited

relating to products utilising certain breath condensate technology

Simmons & Simmons



Simmons & Simmons LLP CityPoint One Ropemaker Street London EC2Y 958 United Kingdom T +44 20 7628 2020 F +44 20 7628 2070 DX Box No 12

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#### THIS AGREEMENT is dated 19 June 2012 (the "Effective Date") and made

#### BETWEEN:

- (1) <u>AKERS BIOSCIENCES. INC...</u> (the "Supplier"), registered in the state of New Jersey, USA and having its principal place of business at 201 Grove Road, Thorofare, New Jersey 08086, USA;
- (2) <u>SONO INTERNATIONAL LIMITED</u>, (the "Customer"), registered in England and Wales as company number 07121719 and having its registered office at 2nd Floor, 37 lxworth Place, London, United Kingdom, SW3 3QH;
- (3) BREATHSCAN INTERNATIONAL (GUERNSEY) LIMITED ("BSI Guernsey"), registered in Guernsey and having its principal place of business located at 18-20 Le Pollet, St Peter Port, Guernsey, GY1 1WH; and
- (4) **BREATHSCAN INTERNATIONAL LIMITED** ("BSIL"), registered in England and Wales as company number 07159500 and having its registered office at Richmond Terrace, 49 London Road, Tunbridge Wells, Kent, United Kingdom, TN1 1DT.

#### **BACKGROUND:**

- (A) The Supplier carries on the business of manufacturing and selling the Products.
- (B) The Supplier entered into the Existing Agreements with BSI Guernsey and BSIL regarding the exclusive distribution of Products.
- (C) The Supplier, BSI Guernsey and BSIL now wish to terminate the Existing Agreements and the Customer now wishes to buy, and the Supplier now wishes to supply, the Products and Components, on the terms and conditions set out in this Agreement.

#### AGREED TERMS:

#### 1. Interpretation

1.1 The definitions and rules of interpretation in this clause apply in this Agreement.

"ADR Notice" has the meaning given in clause 27.1.

"Ampoules" means the ampoules listed in Part III of Schedule 2.

"Brand Development and Marketing Agreement" means the agreement to be entered into between Supplier and the BreathScan International Group under which the BreathScan International Group will develop brand value for the breath condensate technology and develop the associated well being programmes and applied technologies for behaviour and attitude shifts for governments, corporates, retailers and consumers.

"BreathScan International Group" means the Group of companies including BSI Guernsey and BSIL.

"Business Day" mean a day (other than a Saturday, Sunday or public holiday) when banks in London and New Jersey are open for business.

"Components" means the Ampoules, Indicator Reagents and Filter Plugs, packaged loose and in bulk.

"Conditions Precedent" means the conditions set out in clause 3.

"Conditions Precedent Notice Date" means the date on which the Customer notifies the Supplier that all Conditions Precedent have been satisfied (or waived) in accordance with clause 3.

"Confidential Information" has the meaning given in clause 20.

"Delivery" means completion of delivery of an Order in accordance with clause 10.2 or clause 10.5(A).

"Delivery Date" means the date specified for delivery of an Order in accordance with clause 8.3.

"Delivery Location" means the Supplier's manufacturing facility at 201 Grove Road, Thorofare, New Jersey 08086 USA.

"Dispute" has the meaning given in clause 27.1.

"Dispute Notice" has the meaning given in clause 27.1.

"Distribution Agreement" means the distribution agreement(s) to be entered into between the Customer and the BreathScan International Group on or around the Effective Date in connection with the distribution of the Products.

"Existing Agreements" means the agreements listed in schedule 5.

"Field" means any use, including relating to the operation of vehicles, employer screening programmes and the armed forces, but excluding use by the US Military.

"Filter Plugs" means those filter plugs listed in Part I of Schedule 2 and any other filter plugs manufactured from time to time by or for the Supplier or any member of the Supplier's Group.

"Force Majeure Event" has the meaning given in clause 24.

"Group" means in relation to a company, that company, its subsidiaries, its holding companies and their subsidiaries.

"Independent Expert' means a person appointed In accordance with clause 15.

"Indicator Reagents" means those indicator reagents listed in Part II Schedule 2 and any other reagents manufactured from time to time by or for the Supplier or any member of the Supplier's Group.

"Initial Term" means the initial term of the Agreement as defined in clause 3.

"Intellectual Property Rights" means all patents, rights to inventions, utility models, copyright and related rights, trade marks, service marks, trade, business and domain names, rights in trade dress or get-up, rights in goodwill or to sue for passing off, unfair competition rights, rights in designs, rights in computer software, database right, topography rights, moral rights, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications for and renewals or extensions of such rights, and all similar or equivalent rights or forms of protection in any part of the world.

"Licensed Know How" means unpublished research and development information, unpatented inventions, unpublished technical data and trade secrets that are necessary or desirable for manufacturing, importing, offering for sale, selling, distributing, using, advertising or labelling the Products or the Components.

"Licensed Patents" means all patents and patent applications owned or controlled by the Supplier or a member of the Supplier's Group, including those patents and patent applications identified in Part 1 of Schedule 4.

"Licensed Trade Marks" means all trade mark registrations and applications, and unregistered rights, for BREATHSCAN and the BREATHSCAN logo which are owned or controlled by the Supplier or a member of the Supplier's Group, including the trade mark registration identified in Part II of Schedule 4.

"Loans" means loans to be made available by the Customer to the BreathScan International Group on or around the Effective Date.

"Minimum Purchase Amount(s)" has the meaning given in clause 6.

"Month" means a calendar month.

"NF Approval" means Norme Francaise approval by the Laboratoire National de Metrologie et d'Essai (as delegated by the Association Franyaise de la Normalisation) confirming that the Products comply with applicable French product standards (including, French standard NF X20702 of July 2007 and/or European standard NF EN 15964 of April 2011).

"Order" means an order for Products submitted by the Customer in accordance with clause 8.

"Order Number" means the reference number to be applied to an Order by the Supplier in accordance with clause 8.4.

"Products" means the products set out in schedule 1 and any other products utilising the Supplier's Group's breath condensate technology from lime to time, packaged loose in bulk and individually labelled.

"Product Limited Warranty" means the warranty as specified in schedule 6 (as may be modified from time to time) made by the manufacturer of the Products and given to end users.

"Representatives" has the meaning given in clause 20.2.

"Specification" means the specification of the Products or Components set out in schedule3.

"Subsequent Term" has the meaning given in clause 3.

"Supplier Intellectual Property" means any and all Intellectual Property Rights owned or controlled from time to time by the Supplier or a member of the Supplier's Group relating to the Products or Components including (without limitation) the Licensed Patents, Licensed Know How and Licensed Trade Marks.

- "Territory" means worldwide excluding the United States, Canada and Mexico.
- "US Military" means any current armed forces personnel of the United States of America.
- "VAT" means value added tax chargeable under the Value Added Tax Act 1994 and any similar replacement or additional tax.
- 1.2 Clause, schedule and paragraph headings shall not affect the interpretation of this Agreement.
- 1.3 A "person" includes a natural person, corporate or unincorporated body (whether or not having separate legal personality) and that person's legal and personal representatives, successors and permitted assigns.
- 1.4 The schedules form part of this Agreement and shall have effect as if set out in full in the body of this Agreement and any reference to this Agreement includes the schedules.
- 1.5 A reference to a "company" shall include any company, corporation or other body corporate, wherever and however incorporated or established.
- 1.6 Unless the context otherwise requires, words in the singular shall include the plural and vice versa.
- 1.7 Unless the context otherwise requires, a reference to one gender shall include a reference to the other gender.
- 1.8 A reference to a statute, statutory provision or any subordinate legislation made under a statute is to such statute, provision or subordinate legislation as amended or reenacted from time to time and, In the case of a statute, includes any subordinate legislation made under that statute from time to time.
- 1.9 A reference to "writing" or "written" includes faxes and email.
- 1.10 A reference to an agreement is a reference to that agreement as varied or novated (in each case, other than in breach of the provisions of this Agreement) at any time.
- 1.11 References to clauses and schedules are to the clauses and schedules of this Agreement; references to paragraphs are to paragraphs of the relevant schedule.
- 1.12 Any phrase introduced by the terms "including", "include", "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

# 2. Termination of Existing Agreements

- 2.1 In partial consideration of the Loans, the Distribution Agreement, the Brand Development and Marketing Agreement and this Agreement, as of the Effective Date:
  - (A) BSI Guernsey, BSIL and the Supplier agree, and the Customer acknowledges, that the Existing Agreements are hereby terminated in their entirety and superseded by this Agreement;

- (B) BSI Guernsey, BSIL and the Supplier hereby release and discharge, any actions, claims, rights, demands and set-offs, in any jurisdiction, whether or not presently known to BSI Guernsey, BSIL, the Supplier, any member of their Groups or to the law, and whether in law or equity, that they or any member of their Groups, may have or hereafter can, shall or may have against BSI Guernsey, BSIL, the Supplier or any member of their Groups arising out of or in connection with the Existing Agreements or the termination thereof; and
- (C) BSI Guernsey, BSIL and the Supplier agree, on behalf of themselves and on behalf of their respective successors, assigns and Groups not to sue, commence, voluntarily aid in any way, prosecute or cause to be commenced or prosecuted against any of BSI Guernsey, BSIL or the Supplier or any member of their Groups, any action, suit or other proceeding in any jurisdiction in connection with the Existing Agreements or the termination thereof.

# 3. Commencement and term

- 3.1 This Agreement comes into force and effect on the Effective Date and shall, subject to the provisions of clause 21, remain in force and effect for an initial period of three (3) years after the Conditions Precedent Notice Date (the period from the Effective Date to the end of such three (3) year period shall be referred to as the "<u>Initial Term</u>") after which time, unless mutually agreed otherwise by the Supplier and Customer in writing, it shall automatically renew on a three (3) year rolling basis (each subsequent three (3) year period comprising a "<u>Subsequent Term</u>").
- 3.2 The Conditions Precedent which must be satisfied (or waived by the Customer) are as follows:
  - (A) a review by the Customer of the Supplier's Licensed Patents with an outcome that is satisfactory to the Customer;
  - (B) freedom to operate searches being conducted by the Customer with an outcome that is satisfactory to the Customer; and
  - (C) NF Approval for the Products being obtained by the Customer or its nominee with support from the Supplier.
- 3.3 The Customer shall inform the Supplier in writing promptly following the satisfaction (or waiver by the Customer) of (A), (B) and (C) in clause 3.2.

# 4. Licence and supply of Products

- 4.1 Subject to the terms and conditions of this Agreement, the Supplier hereby grants to the Customer an exclusive licence (with the right to sub-license) under the Supplier Intellectual Property to import, offer for sale, sell, distribute, use, promote or label the Products for the Field in the Territory during the Initial Term and any Subsequent Term.
- 4.2 During the Initial Term and any Subsequent Term, the Supplier shall exclusively manufacture and supply to the Customer the Products or Components in such quantities as ordered by the Customer for the Field in the Territory in accordance with the terms and conditions of this Agreement.
- 4.3 The Supplier shall not supply, and the Supplier shall procure that those to whom it supplies Products or Components shall not supply, Products or Components directly or indirectly to third parties for sale in the Field in the Territory during the Initial Term or any Subsequent Term.

4.4 Notwithstanding the Customer's right to use the Licensed Trade Mark pursuant to clauses 4 or 5 of this Agreement, nothing in this Agreement shall prevent (a) Customer, its sub licensees or distributors (including the BreathScan International Group) from rebranding or using any other trade mark or name on or in relation to the Products or (b) BreathScan International Group (or its nominee) from obtaining and owning rights in the BREATHSCAN mark or variations thereof in the Territory.

# 5. Right to manufacture Products

- 5.1 Subject to the terms and conditions of this Agreement, and in particular clause 5.2, the Supplier hereby grants to the Customer an exclusive, royalty-free licence (with the right to sub-license) under the Supplier Intellectual Property to make and have made the Products for the Field in the Territory for the Initial Term and any Subsequent Term.
- 5.2 The licence granted pursuant to clause 5.1 shall become effective if the Customer notifies the Supplier in writing that, in the Customer's opinion:
  - (A) the actual or potential demand for any of the Products in any part of the Territory indicates that it is commercially reasonable for the Customer (or its designee) to manufacture the Products; or
  - (B) the Supplier is unable for whatever reason to supply or deliver to the Customer the Products that the Customer forecasts or orders in accordance with clauses 7, 8 or 10
- 5.3 Following notification by the Customer pursuant to clause 5.2:
  - (A) the Supplier shall exclusively supply to the Customer the Components in such quantities as ordered by the Customer for the Field in the Territory for the Initial Term and any Subsequent Term in accordance with the terms and conditions of this Agreement, and references in clauses 6.3, 7, 8, 9, 10, 11, 12, 14, 15, 17, 18, and 22 to Products shall be read as references to Products and Components; and
  - (8) the Supplier shall provide to the Customer, at cost, fully assembled working machines to manufacture and label the Products, together with Licensed Know How, instructions and technical assistance as may be requested by the Customer from time to time in connection with the building, running, servicing and maintaining of any machinery to manufacture and label the Products.
- 5.4 For the avoidance of doubt, the licences granted pursuant to clauses 4.1 and 5.1 and the supply obligations pursuant to clauses 4.2 and 5.3 shall all run concurrently following notification by the Customer pursuant to clause 5.2.

# 6. Minimum Purchase Requirements

- 6.1 The Customer shall during the Initial Term order not less than 4,250,000 (four million two hundred and fifty thousand) units of Products from the Supplier. Thereafter, the Customer shall order an average of 1,000,000 (one million) units of Products per year over each three (3) year rolling period (collectively the "Minimum Purchase Amounts").
- 6.2 In the event that the Minimum Purchase Amounts are not ordered by the Customer, other than to the extent that the shortfall in purchases was caused by the Supplier's default or by Force Majeure Events, then the Supplier shall have the right (but not the obligation) to convert the exclusive licence granted to the Customer under clause 4 to a non-exclusive licence save in countries or regions where the Customer has a fifty per cent (50%) share of the market for products which are the same as or similar to the Products in the Field.

6.3 The Supplier shall maintain accurate and easily accessible records containing all data reasonably required for the verification of the number of sales of units of the Products to the Customer. The Supplier agrees that the Customer (or its appointed representatives) may at anytime during business hours on reasonable notice to the Supplier enter its premises, provided that, in the event of an emergency, the Supplier shall grant the Customer immediate access to its premises, to inspect such records.

# 7. Forecasts

- 7.1 During the Initial Term and any Subsequent Term, the Customer shall give the Supplier not less than five (5) Business Days before the beginning of each Month, a forecast of the Products it expects to purchase during the three (3) Months following that Month.
- 7.2 Forecasts shall be given in writing or, if given orally, shall be confirmed in writing within two (2) Business Days. The Customer shall act in good faith when forecasting its requirements for Products.
- 7.3 Forecasts provided under this clause 7 shall not constitute Orders.
- 7.4 If the Supplier anticipates that it will be unable to meet the Customer's forecasted requirements provided in accordance with this clause 7:
  - (A) the Supplier shall inform the Customer in writing as soon as practicable;
  - (B) without limiting any other right or remedy that the Customer may have, the Customer may at its option (and in addition or as an alternative to exercising its rights pursuant to clause 5) agree alternative delivery dates for the relevant Products; and
  - (C) the Customer may source Products from a third party supplier, or manufacture Products pursuant to clause 5 and such Products shall for the purposes of clause 6 be deemed to have been purchased from the Supplier.

# 8. Orders

- 8.1 Not less than ten (10) Business Days before the beginning of each Month during the Initial Term and any Subsequent Term, the Customer shall give the Supplier its Order for that Month.
- 8.2 The Supplier shall supply Products in accordance with the Customer's Orders, except that, to the extent that an Order exceeds the most recent forecast provided to the Supplier in accordance with clause 7 the Supplier shall supply the Products in forecasts and shall be obliged to use its commercially reasonable endeavours to supply the Products ordered in excess of forecasts (and shall not be under any obligation to supply the Products ordered in excess of forecasts if the Customer's demand exceeds the Supplier's production capacity).
- 8.3 Each Order shall:
  - (A) be given in writing by the Customer or, if given orally, shall be confirmed in writing by the Customer within two (2) Business Days;

- (B) specify the type and quantity of Products ordered; and
- (C) unless the Supplier and Customer agree that the Customer may specify the date after placing the Order, specify the date on which the Order is to be delivered ("Delivery Date"). If the Delivery Date is to be specified after the placing of an Order, the Customer shall give the Supplier reasonable advance notice of the relevant information.
- 8.4 The Supplier shall assign an Order Number to each Order received from the Customer and notify such Order Numbers to the Customer. Each of the Supplier and Customer shall use the relevant Order Number in all subsequent correspondence relating to the Order.
- 8.5 The Customer may at any time prior to despatch of the Products amend or cancel an Order by written notice to the Supplier. If the Customer amends or cancels an Order, its liability to the Supplier shall be limited to payment to the Supplier of all costs reasonably incurred by the Supplier in fulfilling the Order up until the date of receipt of the notice of amendment or cancellation, except that where the amendment or cancellation results from the Supplier's failure to comply with its obligations under this Agreement the Customer shall have no liability to the Supplier in respect of it.
- 8.6 If the Supplier declines an Order for Products in excess of forecasts, the Customer may source Products from a third party supplier or manufacture Products pursuant to clause 5 and such Products shall for the purposes of clause 6 be deemed to have been purchased from the Supplier.

# 9. Manufacture, quality and packing

- 9.1 The Supplier shall at all times maintain sufficient manufacturing capacity, stocks of raw materials and packaging, and stocks of Products to enable it to meet the Customer's forecasted requirements of Products as notified to the Supplier in accordance with clause 7.
- 9.2 The Supplier shall manufacture, pack and supply the Products in accordance all .generally accepted industry standards and practices that are applicable.
- 9.3 The Supplier warrants that the Products supplied to the Customer by the Supplier under this Agreement shall:
  - (A) conform to the Specification;
  - (B) be of satisfactory quality (appearance and finish, safety and durability) and fit for any purpose held out by the Supplier or made known to the Supplier by the Customer;
  - (C) be free from defects in design, material and workmanship and remain so for twenty four (24) Months after Delivery; and
  - (D) so far as it is aware, comply with all applicable statutory and regulatory requirements for the Field in the Territory.
- 9.4 The Supplier shall ensure that the Products are properly packed and secured in such manner as to enable them to reach their destination in good condition.
- 9.5 The Supplier shall obtain and maintain in force for the Initial Term and any Subsequent Terms all licences, permissions, authorisations, consents and permits needed to manufacture and supply the Products in accordance with the terms of this Agreement.

- 9.6 The Supplier shall comply with all applicable laws, enactments, orders, regulations and other instruments relating to the manufacture, packing, packaging, marking, storage, handling and delivery of the Products for the Field in the Territory.
- 9.7 The Customer (or its nominee) shall have the right to enter the Supplier's premises to:
  - (A) inspect the manufacturing facilities and the equipment used by the Supplier in the manufacture of the Products;
  - (B) inspect and take samples of the raw materials, the packaging and the Products; and
  - (C) inspect stock levels of raw materials, packaging or Products.
- 9.8 Inspections carried out pursuant to clause 9.7 shall be carried out during business hours on reasonable notice to the Supplier, provided that, in the event of an emergency, the Supplier shall grant the Customer immediate access to its premises.
- 9.9 If following an inspection the Customer considers that the Products are not or are not likely to be as warranted under clause 9.3, the Customer shall inform the Supplier and the Supplier shall immediately take such action as is necessary to ensure that within thirty (30) days the Products are or will be as warranted under clause 9.3. The Customer shall have the right to re-conduct inspections and take further samples after the Supplier has carried out its remedial actions.
- 9.10 If the Supplier determines that a recall of the Products is necessary, the Supplier shall promptly inform the Customer of the same in writing. The Customer shall take such steps as it considers reasonably necessary to address any such recall of the Products.
- 9.11 The Customer shall keep a written record of any written complaints of which it becomes aware in respect of the Products and shall promptly forward such complaints to the Supplier. The Supplier shall, at its own cost, take all action necessary to promptly address and resolve such complaints.

#### 10. Delivery

- 10.1 The Supplier shall deliver each Order to the Delivery Location on or by the Delivery Date, provided that the Supplier shall not deliver an Order more than live (5) Business Days in advance of the Delivery Date without the prior written consent of the Customer.
- 10.2 Delivery of an Order shall be complete on the completion of unloading of the Order at the Delivery Location.
- 10.3 The Supplier shall not deliver Orders by instalments except with the prior written consent of the Customer. Where Orders are to be delivered by Instalments, they may be invoiced and paid for separately. References in this Agreement to Orders shall, where applicable, be read as references to instalments.
- 10.4 If an Order is not delivered on the specified Delivery Date or within ten (10) days following the specified Delivery Date, then, without limiting any other right or remedy the Customer may have, the Customer may:
  - (A) refuse to take any subsequent attempted delivery of the Order;
  - (B) subject to allowing the Supplier thirty (30) days to deliver the Order, terminate this Agreement with immediate effect;

- (C) obtain substitute products from another supplier or manufacture Products itself and such Products shall be deemed to count towards the Minimum Purchase Amount for the purposes of clause 6;
- (D) claim damages for any other costs, expenses or losses resulting from the Supplier's failure to deliver the Order on the Delivery Date,

provided that the Supplier shall have no liability for any failure or delay in delivering an Order to the extent that such failure or delay is caused by the Customer's failure to comply with its obligations under this Agreement.

- 10.5 If the Customer fails to accept delivery of an Order on the specified Delivery Date, then, except where such failure or delay is caused by the Supplier's failure to comply with its obligations under this Agreement:
  - (A) the Order shall be deemed to have been delivered at 9.00 am on the Delivery Date; and
  - (B) the Supplier shall store the Order until delivery takes place, and charge the Customer for all related costs and expenses (including insurance).
- 10.6 Each Order shall be accompanied by a delivery note from the Supplier showing the Order Number, the date of the Order, the type and quantity of Products included in the Order, including the code numbers of the Products, and, in .the case of an Order being delivered by instalments, the outstanding balance of Products remaining to be delivered.
- 10.7 If the Supplier requires the Customer to return any packaging materials to the Supplier, that fact must be clearly stated on the delivery note accompanying the relevant Order, and any such returns shall be at the Supplier's expense.

## 11. Acceptance and defective products

- 11.1 The Customer shall not be deemed to have accepted any Products until it has had a reasonable time to inspect them following Delivery, provided that the Customer shall be deemed to have accepted Products if it has not rejected them within thirty (30) days of their Delivery, save in the case of a latent defect in the Products where any express or deemed acceptance of Products shall not be effective.
- 11.2 Subject to clause 11.1, if any Products delivered to the Customer do not comply with clause 9.3 or are otherwise not in conformity with the terms of this Agreement, then, without limiting any other right or remedy that the Customer may have, the Customer may reject those Products and:
  - (A) require the Supplier to repair or replace the rejected Products at the Supplier's risk and expense within ten (10) Business Days of being requested to do so;
  - (B) require the Supplier to repay the price of the rejected Products in full (whether or not the Customer has previously required the Supplier to repair or replace the rejected Products); and
  - (C) claim damages for any other costs, expenses or losses resulting from the Supplier's delivery of Products that are not in conformity with the terms of this Agreement.

- 11.3 The Customer's rights and remedies under clause 11 are in addition to the rights and remedies available to it in respect of the statutory conditions relating to description, quality, fitness for purpose and correspondence with sample implied into this Agreement by the Sale of Goods Act 1979.
- 11.4 The terms of this Agreement shall apply to any repaired or replacement Products supplied by the Supplier.
- 11.5 If the Supplier fails to promptly repair or replace rejected Products in accordance with clause 11.2(A), the Customer may, without affecting its rights under clause 11.2(C), obtain substitute products from a third party supplier, or have the rejected Products repaired by a third party, and the Supplier shall reimburse the Customer for the costs it incurs in doing so.
- 11.6 If the Supplier and Customer dispute whether any Products comply with clause 9.3, either of the Supplier and Customer may refer the matter to an Independent Expert for determination in accordance with clause 15.

## 12. Title and risk

- 12.1 The risk in Products delivered to the Customer shall pass to the Customer on Delivery.
- 12.2 The title to Products delivered to the Customer shall pass to the Customer on Delivery.

#### 13. Payments

- 13.1 In consideration of the execution of this Agreement, within 2 (two) Business Days after the Conditions Precedent Notice Date, the Customer shall pay the Supplier an upfront one-off payment of USD\$1,000,000 (one million United States Dollars) by wire transfer to Supplier's bank account: Bank of America ABA 026009593 Swift Code BOFAUS3N ACH 021200339 For credit to Akers Biosciences, Inc. Account 381019483829.
- 13.2 In consideration for the supply of the Products, the Customer shall pay the Supplier:
  - (A) USD\$0.30 (thirty United States cents) per Product unit sold to the Customer during the Initial Term.
  - (8) USD\$0.30 (thirty United States cents), increased annually in line with the Consumer Price Index, per Product unit sold to the Customer during any Subsequent Terms.
- 13.3 In the event that the Customer manufactures (or has manufactured on its behalf) the Products pursuant to clause 5, in consideration for the supply of the Components, the Customer shall pay the Supplier the following amounts:
  - (A) during the Initial Term:
    - (1) USD\$0.1023 (ten point two three United States cents) per Product unit manufactured by the Customer using the Components if the Ampoules are supplied to the Customer pre-filled with Indicator Reagents.
    - (2) A price to be agreed between the Supplier and Customer in USD\$ per Product unit manufactured by the Customer using the Components supplied . separately in bulk to the Customer.

- (B) during any Subsequent Terms:
  - (1) USD\$0.1023 (ten point two three United States cents), increased annually in line with the Consumer Price Index, per Product unit manufactured by the Customer using the Components if the Ampoules are supplied to the Customer pre-filled with Indicator Reagents.
  - (2) A price to be agreed between the Supplier and Customer in USD\$, increased annually in line with the Consumer Price Index, per Product unit manufactured by the Customer using the Components supplied separately in bulk to the Customer.
- 13.4 The above payments in Clauses 13.1, 13.2 and 13.3 are inclusive of all taxes (including VAT) or other charges on the Products or Components, the costs of packaging, insurance and carriage of the Products or Components.
- 13.5 The Supplier shall notify the Customer in writing (supported by appropriate evidence) of the Consumer Price Index applicable to clauses 13.2(B) and 13.3(B) in advance of any increase in price during a Subsequent Term.

#### 14. Terms of payment

- 14.1 The Supplier shall be entitled to invoice the Customer for each Order on or at any time after Delivery. Each invoice shall quote the relevant Order Numbers.
- 14.2 The Customer shall pay invoices in full within ninety (90) days of Delivery to the Customer (or its designee) of Products to which the invoice relate. In the event that the licence in clause 5 is exercised, the Customer shall pay invoices in full within ninety (90) days of shipment to a third party of Products manufactured by the Customer containing the Components to which the invoice relates. Payment shall be made to the bank account nominated in writing by the Supplier.
- 14.3 If either of the Supplier or Customer fails to make any payment due to the other under this Agreement by the due date for payment ("<u>Due Date"</u>), then, without limiting the other's remedies under clause 21.2, the defaulting party shall pay interest on the overdue amount at the rate of 1% per annum above Barclays Bank PLC's base rate from time to time. Such interest shall accrue on a daily basis from the Due Date until the date of actual payment of the overdue amount, whether before or after judgment. The defaulting party shall pay the interest together with the overdue amount. This clause shall not apply to payments that the defaulting party disputes in good faith.
- 14.4 If the Customer disputes any invoice or other statement of monies due, the Customer shall immediately notify the Supplier in writing. The Supplier and Customer shall negotiate in good faith to attempt to resolve the dispute promptly. The Supplier shall provide all such evidence as may be reasonably necessary to verify the disputed invoice or request for payment. If the Supplier and Customer have not resolved the dispute within thirty (30) days of the Customer giving notice to the Supplier, the dispute shall be resolved in accordance with clause 27. Where only part of an invoice is disputed, the undisputed amount shall be paid on the Due Date as set out in clause 14.2. The Supplier's obligations to supply the Products shall not be affected by any payment dispute.
- 14.5 Each of the Supplier and Customer may, without limiting any other rights or remedies it may have, set off any amounts owed to it by the other party under this Agreement against any amounts payable by it to the other party under this Agreement.

14.6 All payments payable to the Supplier or the Customer under this Agreement shall become due immediately on its termination. This clause 14.6 is without prejudice to any right to claim for interest under this Agreement.

#### 15. Expert determination

- 15.1 Where a dispute relating to the Specification, manufacture, quality or condition of the Products is to be referred to an Independent Expert under this Agreement for determination, the Independent Expert shall be selected by the Supplier subject to the approval of the Customer.
- 15.2 The Supplier and Customer are entitled to make submissions to the Independent Expert and will provide (or procure that others provide) the Independent Expert with all such assistance and documents as the Independent Expert may reasonably require for the purpose of reaching a decision. Each of the Supplier and Customer shall with reasonable promptness supply each other with all information and give each other access to all documentation and personnel as the other party reasonably requires to make a submission under this clause.
- 15.3 The Supplier and Customer agree that the Independent Expert may in its reasonable discretion determine such other procedures to assist with the conduct of the determination as it considers appropriate, including (to the extent it considers necessary) instructing professional advisers to assist it in reaching its determination.
- 15.4 The Independent Expert shall act as an expert and not as an arbitrator. The Independent Expert's decision shall be final and binding on the Supplier and Customer in the absence of fraud or manifest error.
- 15.5 Each of the Supplier and Customer shall bear its own costs In relation to the reference to the Independent Expert. The Independent Expert's fees and any costs it properly incurs in arriving at its determination (including any fees and costs of any advisers appointed by the Independent Expert) shall be borne by the Supplier and Customer in equal shares or in such proportions as the Independent Expert shall direct.

#### 16. Insurance

- 16.1 During this Agreement and for a period of one (1) year afterwards the Supplier shall maintain in force the following insurance policies with reputable insurance companies:
  - (A) public liability insurance for not less than USD\$1 (one) million per claim; and
  - (B) product liability insurance for not less than USD\$1 (one) million for claims arising from any single event and not less than USD\$5 (five) million in aggregate for all claims arising in any year.
- 16.2 On taking out and on renewing each policy, on the Customer's written request, the Supplier shall promptly send a copy of the receipt for the premium to the Customer. On the Customer's written request, the Supplier shall provide the Customer with copies of the insurance policy certificates and details of the cover provided.
- 16.3 The Supplier shall ensure that any subcontractors also maintain adequate insurance
- 16.4 The Supplier shall:

- (A) do nothing to invalidate any insurance policy or to prejudice the Customer's entitlement under it; and
- (B) notify the Customer if any policy is (or will be) cancelled or its terms are (or will be) subject to any material change.
- 16.5 The Supplier's liabilities under this Agreement shall not be deemed to be released or limited by the Supplier taking out the insurance policies referred to in clause 16.1.
- 16.6 If the Supplier fails or is unable to maintain insurance in accordance with clause 16.1, or fails to provide evidence that it has paid the current year's premiums in accordance with clause 16.2, the Customer may, so far as it is able, purchase such alternative insurance cover as it deems to be reasonably necessary and shall be entitled to recover all reasonable costs and expenses it incurs in doing so from the Supplier.

#### 17. Warranties

- 17.1 The Supplier hereby represents and warrants that:
  - (A) it has the right, title, interest, power and authority to grant the rights and supply the Products in accordance with the terms of this Agreement;
  - (B) it is the sole legal and beneficial owner of the Supplier Intellectual Property, no claim has been made by any third party that disputes the Supplier's right, title and interest in and to the Supplier Intellectual Property and the Supplier is unaware of any circumstances likely to give rise to such a claim;
  - (C) so far as it is aware, all Supplier Intellectual Property is valid and subsisting and is not subject to, or likely to be subject to, amendment, challenge to validity, removal or surrender, and there is nothing that might prevent any application in the Supplier Intellectual Property proceeding to grant;
  - (D) the exploitation of the Supplier Intellectual Property pursuant to clauses 4 and 5 does not and will not infringe the rights of any third party; and
  - (E) it is unaware of any infringement or likely infringement of any of the Supplier Intellectual Property.
- 17.2 The Customer will in all respects be independent from the Supplier and will not enter into any contracts or make any warranties, guarantees or other commitments in connection with the Products on behalf of or in the name of the Supplier.
- 17.3 The only warranty that shall apply in respect of end users of Products shall be the Product Limited Warranty in effect at the time of each sale to the end user. Supplier and its distributors shall make no warranty regarding the Products other than those contained within the Product Limited Warranty.

#### 18. Indemnity

18.1 The Supplier shall indemnify the Customer against all liabilities, costs, expenses, damages and losses (including any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal and other professional costs and expenses) suffered or incurred by the Customer arising out of or in connection with:

- (A) any claim made against the Customer for actual or alleged infringement of a third party's Intellectual Property Rights arising out of, or in connection with the supply, import, offer for sale, sale, distribution, use, promotion, labelling and/or manufacture of the Products;
- (B) any claim made against the Customer by a third party arising out of, or in connection with, the supply of the Products, to the extent that such claim arises out of the breach, negligent performance or failure in performance of this Agreement by the Supplier, its employees, agents or subcontractors; and
- (C) any claim made against the Customer by a third party for death, personal injury or damage to property arising out of, or in connection with, defective Products, to the extent that the defect in the Products is directly attributable to the acts or omissions of the Supplier, its employees, agents or subcontractors.
- 18.2 In the event that the Supplier disputes whether the Customer has a valid claim under clause 18.1, the matter shall be resolved in accordance with clause 27 and 34.
- 18.3 Nothing in this clause shall restrict or limit the Customer's general obligation at law to mitigate a loss which it may suffer or incur as a result of a matter that may give rise to a claim under this indemnity.

#### 19. Assignment and subcontracting

- 19.1 Neither the Supplier or Customer may subcontract the performance of any of its obligations under this Agreement without the prior written consent of the other party, provided that both the Supplier and Customer may subcontract the performance of their obligations under this Agreement to another member of their respective Groups without the other party's prior written consent.
- 19.2 Subject to the Customer's right to sublicense under this Agreement, neither the Supplier nor the Customer shall assign or transfer any of its rights or benefits under this Agreement without the prior written consent of the other, such consent not to be unreasonably withheld. The Supplier shall not assign or transfer the Supplier Intellectual Property or other assets of its breath condensate technology business to any person without also assigning or transferring this Agreement to that person.

#### 20. Confidentiality

- 20.1 Each party undertakes that it shall not at any time during this Agreement and for a period of five (5) years after termination disclose to any person any confidential information disclosed to it by the other party concerning the business or affairs of the other party or of any member of its Group, including information relating to a party's operations, business, affairs, customers, clients, suppliers, processes, plans, product information, know-how, designs, trade secrets, software and market opportunities ("Confidential Information"), except as permitted by clause 20.2.
- 20.2 Each party may disclose the other party's Confidential Information:
  - (A) to its employees, officers, agents, consultants, subcontractors or investors ("Representatives") who need to know such information for the purposes of carrying out the party's obligations under this Agreement or (in the case of investors) to raise finances, provided that the disclosing party takes all reasonable steps to ensure that its Representatives comply with the confidentiality obligation contained in this clause 20 as though they were a party to this Agreement. The disclosing party shall be responsible for its Representatives' compliance with the confidentiality obligations set out in this clause; and

- (B) as may be required by law, court order or any governmental or regulatory authority.
- 20.3 Each party reserves all rights in its Confidential Information. No rights or obligations in respect of a party's Confidential Information other than those expressly stated in this Agreement are granted to the other party or to be implied from this Agreement.

#### 21. Termination

- 21.1 The Customer may at any time terminate this Agreement in whole or in part by giving the Supplier not less than six (6) Months' notice in writing provided that no such termination shall take effect before expiry of the Initial Term.
- 21.2 Either of the Supplier or Customer shall be entitled to terminate this Agreement with immediate effect by giving notice in writing to the. other party if:
  - (A) the other party fails to pay any undisputed amount due under this Agreement on the due date for payment and remains in default not less than thirty (30) days after being notified in writing to make such payment; or
  - (B) the other party commits a material breach of its obligations under this Agreement and (if such breach is remediable) fails to remedy that breach within a period of thirty (30) days after receipt of notice in writing requiring it to do so; or
  - (C) the other party commits a series of persistent minor breaches which, when taken together, amount to a material breach; or
  - (D) the other party is unable to pay its debts as they fall due within the meaning of Section 123 of the Insolvency Act 1986 or enters into compulsory or voluntary liquidation (other than for the purpose of effecting a reconstruction or amalgamation in such manner that the company resulting from such reconstruction or amalgamation, if a different legal entity, shall agree to be bound by and assume the obligations of such other under the Agreement) and/or a petition is presented or a resolution and/or order is passed for the administration or the winding-up, bankruptcy or dissolution of the other party;
  - (E) the other party compounds with or convenes a meeting of its creditors and/or gives notice to any of its creditors that it has suspended or is about to suspend payment of any of its debts or is commencing negotiations with one or more of its creditors with a view to rescheduling any of its indebtedness or makes an assignment for the benefit of its creditors;
  - (F) the other party has a receiver, manager, administrative receiver or an administrator appointed;
  - (G) the other party dissolves or ceases for any reason to carry on all or substantially the whole of its business;
  - (H) the other party generally takes or suffers any similar action, application or proceeding to those specified in (D) to (G) above in any jurisdiction to which it is subject; and/or
  - (I) any Force Majeure Event prevents the other party from performing its obligations under this Agreement for any continuous period of three (3) Months.

- 21.3 A breach of any of clauses 4, 5, 9.3, 17, 18 and 20 shall be a material breach of obligations for the purposes of this clause.
- 21.4 Termination of this Agreement shall not prejudice any of the parties' rights and remedies which have accrued as at termination.

# 22. Obligations on termination

- 22.1 Each party shall promptly:
  - (A) return to the other party all equipment, materials and property belonging to the other party that the other party had supplied to it or a member of its Group in connection with the supply of the Products under this Agreement;
  - (8) return to the other party all documents and materials (and any copies) containing the other party's Confidential Information;
  - (C) erase all the other party's Confidential Information from its computer systems (lo the extent possible); and
  - (0) on request, certify in writing to the other party that it has complied with the requirements of this clause22.

#### 23. Survival of obligations

On termination of this Agreement clauses 2.1, 16, 17, 18, 20, 22, 23, 27 and 34 shall survive and continue in full force and effect.

# 24. Force majeure

- 24.1 Neither Supplier nor Customer (or any person acting on their behalf) shall have any liability or responsibility for failure to fulfil any obligation under this Agreement so long as, and to the extent to which, the fulfilment of such obligation is prevented, frustrated, hindered or delayed as a consequence of a Force Majeure Event, except as provided in clause 21.
- 24.2 The Supplier or Customer claiming the benefit of this provision shall, as soon as reasonably practicable after the occurrence of a Force Majeure Event:
  - (A) notify the other party of the nature and extent of such Force Majeure Event; and
  - (8) use all reasonable endeavours to remove any such causes and resume performance under this Agreement as soon as feasible.
- 24.3 For the purposes of this clause 24, a "Force Majeure Event" means an event beyond the control of a party (or any person acting on its behalf), which by its nature could not have been foreseen by such party (or such person), or, if ii could have been foreseen, was unavoidable, and includes acts of God, storms, floods, riots, fires, sabotage, civil commotion or civil unrest, interference by civil or military authorities, acts of war (declared or undeclared) or armed hostilities or other national or international calamity or one or more acts of terrorism or failure of energy sources.

#### 25. Costs

Save as otherwise provided in this Agreement, each party shall pay its own costs in connection with the negotiation, preparation, execution and performance of this Agreement, and all documents ancillary to it.

#### 26. Severance

- 26.1 If any provision of this Agreement (or part of a provision) is found by any court or administrative body of competent jurisdiction to be invalid, unenforceable or illegal, the other provisions shall remain in force.
- 26.2 If any invalid, unenforceable or illegal provision would be valid, enforceable or legal if some part of it were deleted, the provision shall apply with the minimum modification necessary to make it legal, valid and enforceable.

#### 27. <u>Dispute resolution procedure</u>

- 27.1 If a dispute arises out of or in connection with this Agreement or the performance, validity or enforceability of it ("Dispute") then, except as expressly provided in this Agreement, the parties shall follow the dispute resolution procedure set out in this clause:
  - (A) either party shall give to the other written notice of the Dispute, setting out its nature and full particulars ("Dispute Notice"), together with relevant supporting documentation. On service of the Dispute Notice the Chief Executive Officer of the Supplier and Chief Executive Officer of the Customer shall attempt in good faith to resolve the Dispute;
  - (B) if the Chief Executive Officer of the Supplier and Chief Executive Officer of the Customer are for any reason unable to resolve the Dispute within thirty (30) days of it being referred to them, the parties will attempt to settle it by mediation in accordance with the CEDR Model Mediation Procedure. Unless otherwise agreed between the parties, the mediator shall be nominated by CEDR Solve. To initiate the mediation, a party must serve notice in writing ("ADR Notice") to the other party requesting a mediation. A copy of the ADR Notice should be sent to CEDR Solve. The mediation will start not later than thirty (30) days after the date of the ADR Notice. Unless otherwise agreed by the parties, the place of mediation shall be nominated by the mediator.
- 27.2 The commencement of a mediation shall not prevent the parties commencing or continuing court proceedings.

#### Further assurance

Each party shall (at its own expense) promptly execute and deliver all such documents, and do all such things, or procure the execution and delivery of all documents and doing of all such things as are required to give full effect to this Agreement and the transactions contemplated by it, including the registration of the licences granted to the Customer under this Agreement.

#### 29. Variation and waiver

29.1 Any variation of this Agreement shall be in writing and signed by or on behalf of the parties.

- 29.2 Any waiver of any right under this Agreement is only effective if it is in writing and it applies only to the party to whom the waiver is addressed and to the circumstances for which it is given.
- 29.3 No failure to exercise or delay in exercising any right or remedy provided under this Agreement or by law constitutes a waiver of such right or remedy, nor shall it prevent or restrict any future exercise or enforcement of such right or remedy.
- 29.4 No single or partial exercise of any right or remedy under this Agreement shall prevent or restrict the further exercise of that or any other right or remedy.

#### 30. Notices

- 30.1 A notice served under this Agreement:
  - (A) shall be in writing in the English language;
  - (8) shall be signed by or on behalf of the party giving it;
  - (C) shall be sent for the attention of the person, and to the address, fax number or email address, given in this clause 30 (or such other address, fax number, email address or person as the relevant party may notify to the other parties in accordance with the provisions of this clause 30); and
  - (D) shall be delivered personally, sent by fax, sent by email, sent by commercial courier, sent by pre-paid first-class post or recorded delivery, or (if the notice is to be served by post outside the country from which it is sent) sent by airmail requiring signature on delivery.
- 30.2 The addresses for service of notice are:
  - (A) Akers Biosciences, Inc.

Address: 201 Grove Road, Thorofare, New Jersey 08086 USA

For the attention of: Thomas A. Nicolette

Fax number: +1.856.848.0269

Email:tan@akersbiosciences.com

(B) Sono International Limited

Address: 2nd Floor, 37 lxworth Place, London, United Kingdom, SW3 3QH

For the attention of: Darren Jenkins Fax number: +44 (0) 20 7225 6429

Email: darren.jenkins@sonointernational ..com

(C) BreathScan International (Guernsey) Limited

Address: 18

- 20 Le Pollet, St Peter Port, Guernsey, GY1 1WH

For the attention of: Mark Chasey or Sharon King

Fax number: +44 (0)1481 727 561

Email: mchasey@oaktrust.co.uk; sking@oaktrust.co.uk

(D) BreathScan International Limited

Address: Richmond Terrace, 49 London Road, Tunbridge Wells, United Kingdom,

TN1 1DT

For the attention of: Kevin Wright

Fax number: +44(0) 1892 526 488

Email: kevin.wright@breathscan.com

- 30.3 A notice or any other communication given in connection with this Agreement is deemed to have been received:
  - (A) if delivered personally, at the time of delivery; or
  - (B) in the case of fax, at the time of transmission; or
  - (C) in the case of email, at the time the email left the e-mail gateway of the server of the notice; or
  - (D) if sent by commercial courier, at the time of signature of the courier's delivery receipt; or
  - (E) in the case of pre-paid first class post or recorded delivery, 9.00 am on the second Business Day after posting; or
  - (F) in the case of airmail, 9.00 am on the fifth Business Day after posting.
- 30.4 For the purposes of this clause:
  - (A) all times are to be read as local time in the place of deemed receipt; and
  - (B) if deemed receipt under this clause is not within business hours (meaning 9.00 am to 5.30 pm Monday to Friday on any Business Day), the notice shall be deemed to have been received at the opening of business on the next Business Day in the place of receipt.
- 30.5 To prove delivery, it is sufficient to prove that the notice was transmitted by fax to the fax number of the party or, in the case of email, that the email containing the notice was properly addressed and left the e-mail gateway of the server of the notice or, in the case of post, that the envelope containing the notice was properly addressed and posted.
- 31. Entire agreement
- 31.1 This Agreement constitutes the whole agreement and understanding of the parties and supersedes any previous arrangement, understanding or agreement between them relating to the subject matter of this Agreement.

- 31.2 Each party acknowledges that, in entering into this Agreement, it has not relied on any statement, representation, assurance or warranty (whether made negligently or innocently) other than those expressly set out in this Agreement.
- 31.3 Each party agrees that all liability for and remedies in respect of any representations are excluded except as expressly provided in this Agreement.
- 31.4 Nothing in this clause shall limit or exclude any liability for fraud.

#### 32. Rights of third parties

No term of this Agreement shall be enforceable under the Contracts (Rights of Third Parties) Act 1999 by a person who is not a party to this Agreement, but this does not affect any right or remedy of a third party which exists or is available apart from under that Act.

## 33. Counterparts

This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original of this Agreement, but all the counterparts shall together constitute the same agreement.

#### 34. Governing law and iurisdiction

- 34.1 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.
- 34.2 The parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).

This Agreement has been entered into on the date stated at the beginning of it.

SIGNED by Thomas A Nicolette

duly authorised for and on behalf of **AKERS BIOSCIENCES, INC.** 

/s/ Thomas A. Nicolette 19 June 2012 Signature

Name

SIGNED by Darren Jenkins duly authorised for and on behalf of

SONO INTERNATIONAL LIMITED

Nicoletto

Signature

Name

SIGNED by a Director duly authorised for and on behalf of BREATHSCAN INTERNATIONAL (GUERNSEY) LIMITED

Signature

Name

SIGNED by Kevin Wright duly authorised for and on behalf of BREATHSCAN INTERNATIONAL LIMITED

Signature

Name

# SCHEDULE 1: PRODUCTS

Akers Biosciences, Inc. owns, manufactures and distributes hand-held disposable breath alcohol detection devices ("Devices") which are class 1 medical devices	es regulated and
cleared for marketing by the United States Food and Drug Administration (FDA) 510(k) process. "Devices" shall mean those products used for mobile testing	of human breath
for the presence of alcohol.	

Breathscan tube 0.02% cut off
Breathscan tube 0.04% cut off

Breathscan tube 0.05% cut off

Breathscan tube 0.08% cut off

1 litre blow bag

BreathScan Pro System

#### SCHEDULE 2:COMPONENTS

The BreathScan® Detectors are based on indicator chemistry that changes colour in the presence of breath that contains alcohol. The Detector contains chemicals that change colour in the presence of alcohol vapours utilizing patented technology. The Detectors consist of two parts. One part is a glass ampoule containing an indicator reagent of light yellow crystals. The other part is a plugged, plastic tube with an opening to blow into while running the test. If alcohol is present, the crystals will change from yellow to light green/blue. The amount of alcohol in the breath determines the strength of the chemical reaction; hence the degree of colour change.

#### Part I- Filter Plugs

These filters are used to protect the indicator ampoule in the tube, permitting breath flow into the indicator during use. The filters are moulded from porous polyethylene, and have critical specifications in airflow, length and width at the widest end.

# Part II- Indicator Reagents

The BreathScan® Detector contains indicator chemistry that will undergo a colour change in the presence of alcohol contained in the breath of the subject. Indicator chemistry is based on the reactivity of alcohol vapour with a coating on the surface of crystals which provide a porous surface area to breath flow. The hue and intensity of the colour change depends upon the amount of alcohol present in the breath being tested. A change in colour from yellow to blue green signifies that alcohol is present breath sample.

#### Part Ill -Ampoules

The indicator crystals are layered with inert gas and hermetically sealed in an onionskin glass ampoule until use. The glass is of a borosilicate, onionskin type. Ampoule specifications control the diameter, length, and wall thickness of the glass as well as the quantity of crystals filled into each ampoule.

#### SCHEDULE 3: SPECIFICATIONS

#### Part I- Products

Akers Biosciences, Inc. owns, manufactures and distributes hand-held disposable breath alcohol detection devices {"Devices") which are class 1 medical devices regulated and cleared for marketing by the united states food and drug administration {fda} 510{k} process. "Devices" shall mean those products used for mobile testing of human breath for the presence of alcohol.

The hand-held, disposable device detects the presence of alcohol in the breath condensate sample ("breath") of one individual. The device is comprised of a cylindrical housing ("housing") with a first porous filter positioned within said housing. A hermetically sealed glass ampoule contains indicator reagent and is positioned after the first porous filter. A second porous filter is inserted from the end of the housing that does not contain the first porous filter; the second porous filter, positioned after the ampoule, is longitudinally spaced in relation to the first porous filter (EXHIBIT A).

#### Ptg28

The housing forms a test chamber for the interaction of the indicator reagent with the individual's breath. The presence of a specific level of alcohol in the breath causes the indicator reagent to undergo a visually ascertainable change. A label is often adhered to the housing with a cut-out forming a "window" that enables the user to observe the colour of the indicator reagent after the test procedure is completed.

#### BreathScan Tube Configuration

Indicator Reagent Chromatographic Media Grade 20150 Silica coated with potassium dichromate and sulfuric acid

Fill Requirements 0.20g with accuracy of ± .02g Filled in Borosilicate Glass ampoules.

Tube: (Polyester) Length:  $2.75" \pm 0.031"$ 

Wall Thickness:  $0.016" \pm 0.002"$ Inner Diameter:  $0.337" \pm 0.003"$ Outer Diameter:  $0.369" \pm 0.007"$ 

Filter Plugs Length: between 0.355" and 0.405"

Width: between 0.345" and 0.360"

Located on each end of the tube. Bottom Plug insertion depth is  $0.059" \pm 0.20"$ 

Packaging Each individual tube labelled with Lot # and Expiration date: Tubes

with 1 ampoule are packaged in containers of 100			
Part II - Components			
(See table in Part I of schedule 3)			
26			

# SCHEDULE 4: LICENSED PATENTS AND LICENSED TRADE MARKS

#### Part I- Licensed Patents

- 1. US PATENT 7,285,246 81 Issued October 23, 2007 "Hand-Held Fluid Analyzer"
- 2. US PATENT 7,837,936 Issued November 23, 2010 "Hand-Held Fluid Analyzer"
- 3. US PATENT PENDING Application No. 12951345; Application File Date December 3, 2010 "Hand Held Fluid Analyzer"

and in each case, any conversion, continuation, division, or substitution thereof, and any patents issuing thereon, any reissues, reexaminations or extensions of such patents and any foreign counterparts of such patent applications and patents in any country of the Territory.

#### Part II- Licensed Trade Marks

BREATHSCAN

Territory: USA

Serial Number: 78700748

Registration Number: 3200905

Registration Date: 23 January 2007

Goods and Services: Alcohol breath testing tubes containing a disposable chemical.



# **SCHEDULE 5: EXISTING AGREEMENTS**

- 1. An Authorized Distributor Agreement dated 21 December 2010 between the Supplier and BSI Guernsey relating to the exclusive worldwide (excluding the United Kingdom, United States of America, Canada and Mexico) distribution of certain products.
- 2. An Addendum 1 Supply Agreement dated 21 December 2010 between the Supplier and BSI Guernsey relating to the exclusive worldwide (excluding the United Kingdom, United States of America, Canada and Mexico) distribution of certain products.
- 3. An Authorized Distributor Agreement dated 15 March 2010 between the Supplier and BSIL relating to the exclusive distribution of certain products in the United Kingdom and Ireland.
- 4. An International Distributor Shipping Agreement for Export Products dated 20 March 2012 between the Supplier and BSIL relating to the shipping of certain products.

# SCHEDULE 6: PRODUCT LIMITED WARRANTY

THIS PRODUCT SHOULD BE USED ONLY AS A SCREENING DEVICE AND IS ONLY AN INDICATION OF THE POSSIBLE PRESENCE OF ALCOHOL IN THE BLOOD OF THE TEST SUBJECT. CORRELATION BETWEEN BREATH ALCOHOL CONTENT AND BLOOD ALCOHOL CONTENT DEPENDS ON MANY VARIABLES, INCLUDING ALTITUDE. THE EXACT CONCENTRATI ON OF ALCOHOL IN THE BLOOD OF THE TEST SUBJECT CANNOT BE ACCURATELY DETERMINED USING THIS DEVICE.

THIS DEVICE IS NOT INTENDED TO LEGALLY DETERMINE BLOOD ALCOHOL PRESENCE OR LEVEL NO INFERENCE OF INTOXICATION IS TO BE MADE FROM A POSITIVE INDICATION. BREATHSCAN® DEVICES AND SIMILAR PRODUCTS PRODUCED BY AKERS BIOSCIENCES INC AND SOLD UNDER DIFFERENT TRADE NAMES ARE GUARANTEED TO BE FREE FROM MANUFACTURE DEFECTS. THIS WARRANTY IS EXPRESSLY MADE IN LIEU OF ANY AND ALL OTHER WARRANTI ES, EXPRESSED OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABI LITY AND FITNESS FOR A PARTICULAR PURPOSE OR USE. THERE ARE NO WARRANTI ES EXPRESSED OR IMPLIED WHICH EXTEND BEYOND THE DESCRIPTION OF THE PRODUCT CONTAINED ON THE PRODUCT PACKAGE. THE WARRANTY EXPRESSLY DISCLAIMS LIABILITY FOR INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY NATURE.

THE SINGLE-USE, BREATH ALCOHOL DETECTORS MUST BE USED IMMEDIATELY AFTER BREAKING THE GLASS VESSEL THE PRODUCT SHOULD NOT BE USED IF GLASS VESSEL CONTAINING CRYSTALS IS RUPTURED PREMATURELY OR IF CRYSTALS ARE NOT YELLOW.

- 31.2 Each party acknowledges that, in entering into this Agreement, it has not relied on any statement, representation, assurance or warranty (whether made negligently or innocently) other than those expressly set out in this Agreement.
- 31.3 Each party agrees that all liability for and remedies in respect of any representations are excluded except as expressly provided in this Agreement.
- 31.4 Nothing in this clause shall limit or exclude any liability for fraud.

# 32. Rights of third parties

No term of this Agreement shall be enforceable under the Contracts (Rights of Third Parties) Act 1999 by a person who is not a party to this Agreement, but this does not affect any right or remedy of a third party which exists or is available apart from under that Act.

#### 33. Counterparts

This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original of this Agreement, but all the counterparts shall together constitute the same agreement.

#### 34. Governing law and iurisdiction

- 34.1 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.
- 34.2 The parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).

This Agreement has been entered into on the date stated at the beginning of it.

SIGNED by Thomas A. Nicollette

duly authorised for and on behalf of **AKERS BIOSCIENCES, INC.** 

Signature

Name

SIGNED by Darren Jenkins duly authorised for and on behalf of SONO INTERNATIONAL LIMITED

Signature

Name

SIGNED by a Director duly authorised for and on behalf BREATHSCAN INTERNATIONAL (GUERNSEY LIMITED)

SIGNED by Kevin Wright duly authorised for and on behalf of BREATHSCAN INTERNATIONAL (GUERNSEY) LIMITED

Signature

Name

SIGNED by a Director duly authorised for and on behalf BREATHSCAN IINTERNATIONAL (GUERNSEY) LIMITED

Signature

Name

SIGNED by Kevin Wright duty authorised for and on behalf of BREATHSCAN INTERNATIONAL LIMITED

# SONO INTERNATIONAL

Akers Biosciences, Inc. 201 Grove Road Thorofare, New Jersey 08086 USA

Attention: Thomas A. Nicolette, President and

CEO

Cc: Mark Chasey, BreathScan International (Guernsey) Limited Kevin Wright, BreathSan International

Limited

19 JUNE 2012

#### Dear Thomas

Licence and Supply Agreement between Akers Biosciences, Inc. ("ABI"), Sono International Limited ("SIL"), BreathScan International (Guernsey) Limited and BreathScan International Limited, dated 19 June 2012 ("Agreement")

I refer to the amount of USO\$ 1,000,000 (one million United States Dollars) which shall become payable by SIL to ABI pursuant to clause 13.1 of the Agreement within two (2) Business Days after the Conditions Precedent Notice Date ("Upfront Fee").

In accordance with clause 3 of the Agreement, the Conditions Precedent Notice Date shall occur only once SIL has notified AB! in writing that all Conditions Precedent have been satisfied or waived by SIL.

Notwithstanding that all Conditions Precedent have not been satisfied or waived, and the Conditions Precedent Notice Date has not occurred, ABI has requested SIL to pay an amount of USD\$100,000 (one hundred thousand United States Dollars) on or before 21 JUNE 2012 ("Advance Payment"), and SIL agrees to make such Advance Payment, on the understanding that the Advance Payment shall be deducted from the Upfront Fee, such that USO\$ 900,000 (nine hundred thousand United States Dollars) only shall become payable pursuant to clause 13.1 of the Agreement within two (2) Business Days after the Conditions Precedent Notice Date. For the avoidance of doubt, no satisfaction or waiver of the Conditions Precedent, or occurrence of the Conditions Precedent Notice Date, shall be inferred from the Advance Payment.

Capitalized terms used in this letter shall have, the meaning given to them in the Agreement unless defined in this letter. This letter shall be governed by and construed in accordance with the laws of England and Wales.

Please indicate your agreement to these terms by signing and returning the enclosed copy of this letter.

Yours Sincerely

/s/ Darren Jenkins Darren Jenkins For and on behalf of Sona International Limited

Accepted and agreed:

Thomas A. Nicolette, President and CEO For and on behalf of Akers Biosciences, Inc.



37 Ixworlb Place, London SWJ 3QH
Registered ill England & Wales No 7121719
Registered office: 37 Ixworth Place, London SW3 3QH
VAT No: 08991 392093

# **CHUBEWORKX**

12 June 2013

Akers Biosciences, Inc. 20 1 Grove Road Thorofare, New Jersey 08086 USA

Attention: Thomas A. Nicolette, President and CEO

Cc: Mark Chasey, (EN) 10 (Guernsey) Limited Darren Jenkins, (EN) 10 Limited

By Email and Post

Dear Thomas

Licence and Supply Agreement between Akers Biosciences , Inc. ("ABI"), Chubeworkx Guernsey Limited (as successor to Sono International Limited), (EN)10 (Guernsey) Limited (formerly BreathScan International Limited) dated 19 June 2012 (the "Agreement")

We refer to our recent discussions regarding the expansion of the scope of the Agreement to wor ldwide coverage subject to ongoing supply agreements which ABI has entered into with third party customers. Accordingly, the Agreement shall be amended as follows:

- 1. The definition of "Territory" shall be deleted and replaced with the following:
  - "" Territory" means worldwide ."
- 2. The definition of "Field" shall be deleted and replaced with the following:
  - ""Field" means any use, including relating to the operation of vehicles, employer screening programmes and the armed forces."
- 3. The definition of "US Military" shall be deleted.
- A new definition of "Existing Customers" shall be inserted into clause 1.1 as follows:
  - "Existing Customers" means those parties listed in Schedule 7."
- 5. A new definition of "Amendment Date" shall be inserted into clause 1.1 as follows

"Amendment Date" shall have the meaning accorded to it in the Letter of Amendment between the Parties which amends this Agreement and is dated 12 June 2013."

6. A new clause 4 .5 shall be inserted into the Agreement and read as follows

1

# CHUBEWORKX

- " The exclusivity of the rights granted to the Customer by the Supplier under clauses 4. 1, 4.2 and 4.3 of this Agreement shall be subject only to the supply rights of the Existing Customers in the United States of America, Canada and/or Mexico as at the Amendment Date."
- A new clause 4.6 shall be inserted into the Agreement and read as follows:
  - "4.6 The Supplier agrees that on and from the Amendment Date it shall not:
  - (A) enter into any new arrangements or new agreements (whether formal or informal) with any third party regarding the supply of any of the Products in the Territory without the Customer's prior written consent;
  - (8) amend or extend any existing agreements with any of its Existing Customers who resell any of the Products supplied to them by the Supplier, in any manner which increases the sale or supply to each such Existing Customer to more than 500,000 units of Products per year, without the Customer's prior written consent; and
  - (C) supply the Existing Customers or any other party with any Products bearing: (i) the trade mark CHUBE or any trade mark confusingly similar thereto; or (ii) any get-up used in connection with CHUBE branded Products or any get-up confusingly similar thereto, whether for the recipients own use or for resale.
- 8. The Supplier hereby restates the warranties set out in clause 17 of the Agreeme nt as at the Amendment
- 9. New clauses 17.1 (F) (G) shall be inserted into the Agreeme nt and read as follows:
  - "(F) the list of Existing Customers in Schedule 7 of this Agreement is a full and complete list of all other parties with any rights in, or rights to the supply of, any of the Products in the Territory as at the Amendment Date;
  - (G) no Products are supplied to, used by and/or resold by, the Existing Customers or otherwise bearing: (i) the trade mark CHUBE or any trade mark confusingly similar thereto; or (ii) any get-up used in connection with CHUBE branded Products or any get-up confusingly similar thereto."
- 10. The Annex to this letter shall be inserted into the Agreemen t as Schedule 7.

These amendments shall take effect on and from 12 June 20 13 (the "Amendment Date").

Completion of the subsc ription of shares and share sale described in the Memorandum of Understanding between Akers Biosciences, Inc., Chubeworkx Guernsey Limited and (EN)10 (Guernsey) Limited dated 29 April 2013, shall be subject to the prior execution of this letter by all parties.

Capita lised terms used in this letter shall have the meaning given to them in the Agreement unless defined in this letter. Save as express ly agreed herein, or the Letter dated 19 June 2012 from Sono International Limited to ABI, the Ag reement remains in full force and effect. This letter shall be governed by and construed in accordance with the laws of England.

# **CHUBEWORKX**

Please confirm your acceptance of these amendments by signing and returning the enclosed copy of this letter.

Yours sincerely

Mark Chasey for and on behalf of Chubeworkx Guernsey Limited

Accepted and agreed:

/s/ Thomas A. Nicolette Thomas A. Nicolette for and on behalf of Akers Biosciences, Inc

APPROVED

Akers Biosciences, Inc. Thomas A. Nicolette Chief Executive Officer

Accepted and agreed:

Mark Chasey for and on behalf of (EN)10 (Guernsey) Limited

Accepted and agreed:

Darren Jenkins for and on behalf of (EN)10 Limited

# ANNEX

# SCHEDULE 7: EXISTING CUSTOMERS

Brand Name of Products supplied to Existing Customers	Name of Existing Customers	Address of Existing Customers	
A lcohol "Check"	Akers Biosciences, Inc.	Thorofare, New Jersey USA	
BreathScan	Akers Biosciences, Inc.	Thorofare, New Jersey USA	
BreathScan PRO	Akers Biosciences, Inc.	Thorofare, New Jersey USA	
Breath A lcohol "Check"	Akers Biosciences, Inc.	Thorofare, New Jersey USA	
Breath Alcohol "Check" .02 Detection System	Akers Biosciences, Inc.	Thorofare, New Jersey USA	
Breath Pulmo Health Check - Asthma	Akers Biosciences, Inc.	Thorofare, New Jersey USA	
Breath Pulmo Health Check - COPD	Akers Biosciences, Inc.	Thorofare, New Jersey USA	
Breath Pulmo Health Check - Lung Cancer	Akers Biosciences, Inc.	Thorofare, New Jersey USA	
BreathScan Legal Limit	Akers Biosciences, Inc.	Thorofare, New Jersey USA	
Breath Ketone "Check"	Akers Biosciences, Inc.	Thorofare, New Jersey USA	
Metron	Akers Biosciences, Inc.	Thorofare, New Jersey USA	
VIVO	Akers Biosciences, Inc.	Thorofare, New Jersey USA	
BreathScan	One Stop / Diinsel, SA de CV	Monterrey, NL Mexico Hidalgo, TX USA	
BreathScan	Lifeloc	Wheat Ridge, CO USA	
BreathScan	Micro Distributing II, Ltd	Belton, TX USA	
BreathScan	Alere Toxicoloay	Norfolk, VA USA	
BreathScan	Quest Diagnostics	Collegeville, PA USA	
BreathScan	NPACT America	Jacksonville, FL USA	
BreathScan	GE Oil & Gas	Oklahoma City, OK USA	
BreathScan	Test Medical Symptoms at Home	Maria Stein, OH USA	
BreathScan	VShips	Miami, FL USA	
BreathScan	CUA-Waived Inc.	San Dieao, CA USA	
BreathScan	Everglades Direct	Sunrise, FL USA	
BreathScan	American Bio Medica Corporation	Kinderhook, NY USA	
BreathScan	Bob Barker Company	Fuquay-Varina, NC USA	
BreathScan	Capital Medical & Suraical	Tallahassee, FL USA	
BreathScan	Cardinal Health	Waukega n, IL USA	
BreathScan	Fisher Healthcare	Houston, TX USA	
BreathScan	Conney Safety Products	Madison, WI USA	
BreathScan	Farahi Medical Inc.	Toronto, Canada	
BreathScan	Corporate Wellness, Inc.	Stamford, CT USA	
BreathScan	JJ Keller & Associates, Inc	Neenah, WI USA	
BreathScan Legal Limit US Navy -	US Government GSA	Washington, DC USA	
"Shipmates Take Care of Shipmates"	Contract		

Brand Name of Products supplied to Existing Customers	Name of Existing Customers	Address of Existing Customers	
BreathScan Legal Limit US Air Force	US Government GSA	Washington, DC USA	
- "Protect Your Winoman"	Contract	<i>5</i> /	
BreathScan Legal Limit USMC -	US Government GSA	Washington, DC USA	
"Marines Save Lives"	Contract	<i>5</i> /	
BreathScan Legal Limit US Army -	US Government GSA	Washington, DC USA	
"Soldiers Savino Lives"	Contract	<b>5</b> ,	
BreathScan Legal Limit US SOCOM	US Government GSA	Washington, DC USA	
Quiet Professionals - "Safety Begins	Contract	<b>5</b> ,	
With Me"			
BreathScan Legal Limit USCG	US Government GSA	Washington, DC USA	
Semper Paratus - "Are You Ready to	Contract	-	
Save a Life?"			
Breath Scan Legal Limit US Army	US Government GSA	Washington, DC USA	
Medical Command - Don't drive &	Contract	<b>5</b> ,	
drive!			
BreathScan Legal Limit Fort Benning	US Government GSA	Washington, DC USA	
ASAP "Power of Choice" - Fort	Contract	<b>5</b> ,	
Benning Soldiers Don't Drink & Drive			
BreathScan Legal Limit US Army	US Government GSA	Washington, DC USA	
Combat Readiness Center -	Contract	<i>5</i> /	
"Soldiers Savings Lives"			
BreathScan Legal Limit US Armed Forces Command Safety	US Government GSA	Washington, DC USA	
Program -	Contract	<i>5</i> /	
"Protecting Freedom's Guardians			
BreathScan Legal Limit US Army	US Government GSA	Washington, DC USA	
Corps of Engineers - "Be Safe Share	Contract	<i>5</i> /	
The Ways"			
BreathScan Legal Limit Marine Corps	US Government GSA	Washington, DC USA	
Logistics Base Albany - "Marines	Contract	<b>5</b> ,	
Take Care of Marines" Semper			
Fidelis			
BreathScan Legal Limit US Army -	US Government GSA	Washington, DC USA	
Arm yourself against drunk driving	Contract	-	
BreathScan Legal Limit US Army	US Government GSA	Washington, DC USA	
Safety Center - "Make It Home Be	Contract	-	
Safe!"			
BreathScan POV Safety Program	US Government GSA	Washington, DC USA	
	Contract	-	
Alcolimit - Private Label BAC	Silmarc Pharma S.r.I.	Lucca, Italy	
BacTrack - Private Label BAG	KHN Solutions	San Francisco, CA USA	
DUI Alert - Private Label BAC	Martini Promotions	Saint-Laurent, Quebec	
		CANADA	
El-Screen - Private Label BAC	MEDTOX Scientific Inc.	St. Paul, MN USA	
FamilySafe - Private Label BAC	Comvate, LLC	Eagle Pass, TX USA	
PartySafe - Private Label BAC		- · · · · · · · · · · · · · · · · · · ·	
GM Safe Driving Program - "Friends	General Motors Co.	New York, NY USA	
Don't Let Friends Drive Drunk"			
RediTest Private Label BAG	Redwood Biotech	Santa Rosa, CA USA	
TESTorARREST - Private Label	CTAS, Inc.	Liberty Twp., OH USA	
BAG		• •	

Brand Name of Products supplied to Existing Customers	Name of Existing Customers	Address of Existing Customers
V IVO	LifeVantage	Sandy, UT USA
VIVO	lsagenix	Chandler, AZ USA
VIVO	Summa Health	Portland, OR USA
Metron	Summa Health	Portland, OR USA
Metron	lsagenix	Chandler, AZ USA
	6	



Akers Bioscience,Inc. 201 Grove Road Thorofare, New Jersey 08086 USA

Attention: Thomas A. Nicolette, President and CEO

Cc Mark Chasey, (EN)10 (Guernsey) Limited

kevin Wright, (EN)10 International Limited

5th December 2012

#### Dear Thomas

Licence and Supply Agreement between Akers Bioscience, Inc. ("ABI"), Sono International Limited ("SIL"), (EN)10 (Guernsey) Limited and (EN)10 International Limited, dated 19<sup>th</sup> June 2012 ("Agreement").

In accordance with clause 19 (Assignment and subcontracting) of the Agreement, SIL wish to assign the rights, benefits and obligations under the Agreement to Chubeworkx Guernsey Limited, and hereby requests consent of Akers Bioscience, Inc.

Chubeworkx Guernsey Limited has been established as a special purposed vehicle (SPV) in order to hold the beneficial interest and manage the operations of the Agreement . This SPV is the entity that was envisaged to be set up when we signed the Agreement .

Please find attached a copy of the proposed Assignment Agreement.

Please evidence the consent of Akers Bioscience, Inc. by signing and returning a copy of this letter.

Yours sincerely,

/s/ Darren Jenkins Darren Jenkins Director, Sono International Limited

Accepted and agreed:

/s/ Thomas A Nicolette Thomas A Nicolette, President and CEO For and on behalf of Akers Bioscience, Inc.

37 Ixworth Place, London SW3 3QH

Registered in England & Wales No 7121719 Registered Office: 5 North End Rd, London NW 11 7RJ

# FISHER HEALTHCARE, A DIVISION OF FISHER SCIENTIFIC COMPANY L.L.C. ("FISHER") DISTRIBUTION AGREEMENT

(June 15, 2010 through May 31, 2012) (the "Initial Term")

Supplier In	formation		Supplier	#:	
Supplier Legal Name: Akers Biosciences, Inc.  EIN #: 22-2983783  State of Organization New Jersey Corporation		22-2983783			
Address:	201 Grove Road		Contact:	Name:	Thomas A. Nicolette
	Thorofare,	New Jersey 08086 USA		Title:	President and Chief Executive Officer
	<u>,                                      </u>			E- Mail:	tan@akersbiosciences.com
	<u>,                                      </u>			Phone:	856.848.2116
	<u>,                                      </u>			Fax:	856.848.0269

#### 1. PRODUCTS, INVENTORY AND WARRANTY

- 1.1 This Agreement will cover all products sold by Supplier to Fisher (the "Products"). If Supplier develops similar or replacement products Supplier will make those products available to Fisher under the terms set forth in this Agreement, (except for price which will be agreed upon by Supplier and Fisher).
  - 1.2 Fisher will have the non-exclusive right to distribute the Products in the United States.
- 1.3 Fisher will order Products by placing purchase orders and Supplier will fill those orders as set forth in this Agreement. Fisher and Supplier acknowledge and agree that Supplier shall be required to fill any orders placed by Fisher pursuant to this Agreement and that Supplier shall not have the right to decline such orders.
  - 1.4 In ordering and invoicing, Supplier agrees to use an electronic (EDI) system reasonably acceptable to Fisher.
- 1.5 If Fisher agrees to stock the Products, Supplier agrees to accept returns or exchanges of saleable new Product inventory at full acquisition cost with no restocking or handling fees if Fisher reasonably determines that sales are not sufficient to justify inventory levels. SUPPLIER will accept returns of product in unopened, saleable, case quantities on a quarterly basis. In the event of a return or exchange, Supplier agrees to pay all associated shipping costs, F.O.B. shipping point. Additionally, Supplier agrees to repurchase from Fisher at full acquisition cost with no restocking or handling fees any saleable new Product inventory at the time of termination or expiration of this Agreement, subject to Fisher's post-termination needs set forth in Section 6.3 below. SUPPLIER will accept returns of product in unopened, saleable, full case quantities on a quarterly basis. Supplier agrees to pay all associated shipping costs for returns and exchanges, F.O.B. shipping point. In addition, any Products owned by Fisher and rendered unusable due to: (i) a change in any Product specification by Supplier or FDA, (ii) discontinuation or elimination or recall by Supplier of any Product from its product offering, (iii) release by Supplier of any improved or updated version of any Product or (iv) other cause listed in Attachment A, shall be repurchased from Fisher by Supplier within thirty (30) days following Fisher's written request at full acquisition cost by Fisher. Supplier agrees to pay all associated shipping costs for returns and exchanges, F.O.B. shipping point.

#### FISHER SCIENTIFIC COMPANY L.L.C. DISTRIBUTION AGREEMENT

- 1.7 Supplier will provide to Fisher and its customer (as requested) current MSDS for all hazardous Products and product information as requested by Fisher for proper regulatory classification. Supplier agrees to work in good faith with Fisher to provide the MSDS to Fisher prior to the initial shipment of product to Fisher or its customers to which Supplier drop-ships. Current copies of product MSDS are immediately available in the pertinent Product's section of Supplier's website under Literature.
  - 1.8 Supplier agrees to extend to Fisher and its customers no less than its standard warranty and product return policies.
- 1.9 In the event of breach of any applicable warranty, Supplier will at Fisher's discretion, (i) repair or replace the Product at Supplier's expense, or (ii) refund the purchase price, including any applicable shipping charges.

#### 2. PRICING, PAYMENT AND REBATES

The purchase prices to be charged will be the net purchase price for the Products. These prices are outlined on Attachment A. The quoted prices include all hazardous materials, refrigeration or other fees, charges or surcharges unless otherwise noted on the attachment.

- 2.2 The Attachment A pricing will remain fixed through December 31, 2011. After the expiration of the Firm Price Period, prices may be increased no more than once in any contract year to be effective January 1 of the following calendar year. Supplier will provide written notice of any proposed price increase at least 120 days prior to the effective date. Price increases will not exceed the lesser of two percent (2%) per year or the annualized percentage change in Consumer Price Index (CPI) for all Urban Consumers (Current Series) U.S. All items Less Food and Energy Series I.D.: CUUR0000SA0L1E at http://data.bls.gov/cgi-bin/surveymost?cu for the previous 12 month period. New prices, once agreed upon, shall be firm and remain in effect until the next December 31, unless otherwise agreed to. Shipments shall be billed at the price in effect at time of order placement. Notwithstanding the foregoing, to the extent that Fisher cannot pass onto its contracted customers all or a portion of the price increase provided for in this Section 2.2, Supplier and Fisher shall execute a cost recovery rebate agreement (substantially in the form attached hereto at Exhibit C) providing a rebate to Fisher of any amounts that cannot be passed on to customer.
- 2.3 Shipments will be billed at the price in effect at time of order placement. In the event of a price decrease, Supplier will provide Fisher with a credit for the price reduction with respect to any on-hand inventory or in-transit inventory.
  - 2.4 Supplier agrees to negotiate in good faith with Fisher to provide special pricing on large quantities or where required in order for Fisher to meet competition.
- 2.5 Payment terms will be Net 45 days from the date of receipt of an accurate invoice. Notwithstanding the foregoing, Fisher will not be in default if payments are paid within five (5) days of due date.
- 2.6 Supplier agrees to pay to Fisher the Rebate/Growth Incentive described on Attachment A. Annual rebates will be paid to Fisher by March 31 of the following year. If Supplier does not make its rebate payment in a timely manner, Fisher will be permitted to auto-debit Supplier's account.

#### 3. DELIVERY AND TRANSPORTATION

- 3.1 Supplier will ship the Products F.O.B. Destination point as designated by Fisher or its customer freight to be prepaid and absorbed by Supplier. Unless otherwise stated on Attachment A, Supplier will not apply any additional fees or charges to Fisher for the shipment of goods.
- 3.2 Supplier will drop ship products that are utilized for user training and/or require packaging in dry ice directly to Fisher's customers, in accordance with the terms outlined in Attachment A.

#### FISHER SCIENTIFIC COMPANY L.L.C. DISTRIBUTION AGREEMENT

- 3.3 Supplier will take all necessary measures to ensure that PIFA Heparin/PF4 Rapid Assay devices are received by Fisher (or its customers) with at least six (6) months of the remaining shelf-life. Supplier will take all necessary measures to ensure that Heparin/PF4 Antibody Serum Panels are received by Fisher (or its customers) with at least twelve (12) months of the remaining shelf-life. Supplier will take all necessary measures to ensure that BreathScan products are received by Fisher (or its customers) with at least eighteen (18) months of the remaining shelf-life. Products that do not conform with this requirement will be considered to be defective.
- 3.4 Supplier will ship to Fisher all Products ordered by Fisher within five (5) days of receipt of the purchase order so long as the order size is consistent with historical levels provided by Fisher to Supplier. If the order size exceeds historical, Fisher and Supplier will mutually agree on an acceptable delivery date.

#### 4. SALES, MARKETING AND TECHNICAL SUPPORT

- 4.1 Supplier will engage in sales and marketing support as noted in Attachment C, Rules of Engagement.
- 4.2 Supplier will provide to Fisher's customers and sales personnel all reasonable technical support. If there are any spare parts necessary for the operation and repair of the Products, Supplier will make those spare parts available to Fisher or its customers for a reasonable period after delivery of the Products.
- 4.3 Supplier will provide Fisher with electronic and hard copies of sales and marketing literature for reproduction or electronic distribution by Fisher in the marketing, sale and distribution of the Products.
  - 4.4 Supplier will make demonstration materials available to Fisher's customers for purchase from Fisher to assist Fisher with marketing and sales of the Products.

#### 6. MISCELLANEOUS PROVISIONS

- 6.1 This Agreement will be effective for the Initial Term stated in the heading of the Agreement. This Agreement will automatically renew for successive twelve (12) month periods at Fisher's option in its sole discretion provided Fisher hits certain targets, as set forth on Attachment 1.3. In the event that Fisher does not hit such Targets, either party may give written notice of its intent not to renew at least ninety (90) days prior to the expiration of the Initial Term and any renewal term. The Initial Term and any renewal terms shall be collectively referred to as the "Term."
- 6.2 Either party may terminate this Agreement in the event of a material breach of by the other party. In such event, the non-breaching party will provide thirty (30) days written notice of the breach and will provide an opportunity for the breaching party to cure the breach during the notice period. Notwithstanding the foregoing, Fisher may terminate this Agreement immediately and without penalty if Supplier has breached the provisions set forth in paragraph 20 (Compliance with Laws) of Attachment B hereto.
- 6.3 In the event of termination or expiration of this Agreement, in the absence of contracts or other obligations between Fisher and its customers that survive termination, Supplier agrees to continue to sell the Products to Fisher for a period of sixty (60) days following termination of the Agreement. In the event that Fisher has customer commitments that survive beyond the termination date of this agreement, Supplier will honor orders for Products necessary to fulfill the customer commitments on the terms and condition applicable at the time of termination until the termination date of the customer commitments.
- 6.4 Any term of this Agreement that contemplates survival beyond the term of this Agreement will remain enforceable in accordance with its terms notwithstanding the termination or expiration of this Agreement.
- 6.5 Supplier agrees that it will not use Fisher's name, logo, or trademarks in any manner (including marketing materials, public announcements, press releases, or similar communications) without the express written consent from Fisher.

# FISHER SCIENTIFIC COMPANY L.L.C. DISTRIBUTION AGREEMENT

6.6 This Agreement specifically incorporates by reference the Procurement Terms and Conditions attached hereto as Attachment B as though they were included in their entirety in this Agreement. This Agreement (including Attachment A) and the Procurement Terms and Conditions comprise the entire agreement between the parties. In ordering and delivery of the Products, Fisher and Supplier may use their standard forms, but nothing in those forms will in any way modify or amend the terms of this Agreement or the Procurement Terms and Conditions.

Supplier Signatur	e:		Accepted by:	Fisher Healthcare, a division of Fisher Scientific Company L.L.C.
Printed Name:	Thomas A. Nicolette		Signature:	
Title:	President & Chief Executive Officer, Akers Biosciences, Inc.		Printed Name:	Joe Bernardo, President
Date:	11 JUNE 2010		Date:	11 JUNE 2010
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# FISHER SCIENTIFIC COMPANY L.L.C. DISTRIBUTION AGREEMENT ATTACHMENT 1.3 – TARGET ORDERS

Target Orders. The Target Orders, for purposes of renewing the contract beyond the Initial Term, are set forth below represent the number of cases of PIFA Heparin/PF4 Rapid Assay delivered to Fisher subsequent to Supplier's receipt of Purchase Orders by December 31 of the corresponding Calendar Year (2012, for the Initial Term and then each calendar year thereafter):

30 Cases

# FISHER SCIENTIFIC COMPANY L.L.C. DISTRIBUTION AGREEMENT

ATTACHMENT "A"

Product an	d Discount Information						
Supplier							
Item			Purchasing	Acqu	istion	Min.	
Number	Material Description	Material Desc 2	Order Unit	cost		Purchase	
					<u>.</u>		
4036025	PIFA HEPARIN/PF4 Rapid Assay	Box = 6 PIFA HPF4 devices	Box	\$	180.00		48
	Heparin/PF4 Antibody Serum Panel - 2 MEMBER						
4036027	1POS/1NEG	DROP SHIP ONLY 2EA/BX	Box	\$	39.00		1
	Heparin/PF4 Antibody Serum Panel - 6 MEMBER 5						
4036028	POS/1 NEG	DROP SHIP ONLY 6EA/BX	Box	\$	117.00		1
	Training KIT: 3-Device PIFA HEPARIN/PF4 Rapid						
3330047	Assay	DROP SHIP ONLY 3EA/BX	Box	\$	90.00		1
4000122	BREATHSCAN .02% Breath Alcohol DETECTOR	Box = 100 lab packs	Box	\$	200.00		4
4000124	BREATHSCAN .05% Breath Alcohol DETECTOR	Box = 100 lab packs	Box	\$	200.00		4
4000125	BREATHSCAN .08% Breath Alcohol DETECTOR	Box = 100 lab packs	Box	\$	200.00		4

All Drop Shipments to DISTRIBUTOR's customers by SUPPLIER will be made using DISTRIBUTOR's UPS Freight Account Number.. SUPPLIER will not charge any additional material or handling fees on DISTRIBUTOR invoices and DISTRIBUTOR will not request that SUPPLIER provide any reimbursement for freight charges related to Drop Shipments.

# Rebate /Growth Incentives

#### **Growth Rebate YOY:**

Fisher will be entitled to the growth rebate as set forth below ("Rebate").

Fisher will measure its SAC for each calendar year of the term of this Agreement and will compare the current year's Sales at Cost (the "Current SAC") against the previous calendar year's SAC (the "Previous SAC"). In the event that Fisher's Current SAC meets or exceeds the Previous SAC, Fisher will be entitled to a Growth Rebate calculated by multiplying the entire Current SAC by the applicable percentage set forth in the following table:

Current SAC	Applicable Growth Rebate Percentage
>.2M	1.0%
0.2-1.0M	3.0%
\$1.0M-2.0M	5.0%
2.0-2.5M	6.0%
>2.5M	7.0%

By February 28 of each calendar year, Fisher will invoice SUPPLIER for the Rebate.

#### PROCUREMENT TERMS AND CONDITIONS

ALL GOODS AND SERVICES PROCURED BY FISHER HEALTHCARE, A DIVISION OF FISHER SCIENTIFIC COMPANY L.L.C, ITS AFFILIATES OR SUBSIDIARIES, (THE "BUYER") FROM AKERS BIOSCIENCES, INC. ("SELLER") SHALL BE IN ACCORDANCE WITH THE FOLLOWING TERMS AND CONDITIONS

#### ATTACHMENT "B"

- 1. ACCEPTANCE. This Order is Buyer's offer to Seller (which term shall include subcontractors, independent contractors, and all other classes of persons performing work hereunder) and shall become a binding contract on the terms and conditions set forth herein upon the earlier of (i) Seller's acknowledgement or (ii) by Seller's full or partial performance hereunder. This Order does not constitute an acceptance by Buyer of any prior proposal, quote or offer to sell, and any reference to such is solely for the purpose of incorporating the description and/or specifications of the goods and services contained therein, but only to the extent that such description or specification does not conflict with the description and specifications on the face of the Order.
- 2. COMPLETE AGREEMENT. This Order and any underlying agreement between the parties on which this Order is based (the "Underlying Agreement") and the terms and conditions herein constitute the complete agreement between the parties and may not be altered or modified except in writing duly executed by each party. Any additional terms or conditions contained in Seller's order acknowledgment, or in any other Seller document, shall be deemed objected to by Buyer without the need for further notice of objection, and shall be of no effect, nor shall they be binding upon Buyer under any circumstances unless expressly accepted by Buyer in writing. Buyer's acceptance or rejection of one or more additional terms or conditions shall not constitute an acceptance of any other additional term or condition. Trade custom, trade usage, course of dealing, and past performance are superseded by this Order and shall not be used to interpret this Order.
- 3. CHANGES. Buyer shall have the right to make changes to its order prior to receiving a Purchase Order Acknowledgement (EDI code 855) from Seller, including without limitation, in the quantities, specifications, drawings, instructions, or delivery schedule. Any such change that has a significant impact on Seller's time or cost of performance shall entitle either Seller or Buyer to an equitable adjustment. However, no additional charge will be allowed unless asserted by the Seller within five (5) business days after the change is ordered and authorized by Buyer in writing. Information, such as technical direction or guidance provided to Seller by Buyer's representatives in connection with Seller's performance hereunder, shall not be construed either as a change within the meaning of this provision or as direction to proceed outside the scope of this Agreement.
- **4. CANCELLATION**. Buyer may cancel this Order in whole or in part upon notice to Seller in writing or via EDI, within one (1) business day of Buyer's receipt of Purchase Order Acknowledgment, without liability to Buyer.
- 5. NO PUBLICITY. Seller shall not issue or cause to be issued any press release, public announcement or disclosure of any kind or nature whatsoever or otherwise disclose the existence of the transactions contemplated hereby except as and to the extent that both parties jointly agree to such press release, public announcement or disclosure previously and in writing.
- 6. DELIVERY. TIME IS OF THE ESSENCE for delivery to Buyer hereunder. Seller shall promptly provide written notification to Buyer of any possible or actual delay in performance hereunder and shall provide all relevant information concerning the cause for such delay. In no event, however, shall such notice relieve Seller of its obligations under this Order. If delivery is not made within the time specified, Buyer may purchase elsewhere and charge Seller any difference in price and/or Buyer may cancel the entire order or any undelivered portion thereof. Payments due to Seller may be offset against sums owed to Buyer by Seller. Deliveries shall be strictly in accordance with the schedule set out or referred to in the Order and in the exact quantities ordered. In no event shall Buyer be liable for any excess goods shipped by Seller. Buyer reserves the right at Seller's expense to return goods shipped not in accordance with Buyer's order set forth on the face hereof. Notwithstanding anything to the contrary set forth in the Agreement or in this Attachment, Seller hereby agrees that it shall not have the right to decline to fill any order submitted by Fisher in accordance with this Agreement.
- 7. WARRANTY. Seller warrants and guarantees that its goods and services (collectively "Products"): (a) will comply with all relevant specifications and requirements; (b) will be of merchantable quality, free from any latent or patent defects; (c) will be safe and fit for their intended use; (d) shall reference true weights, measures, sizes, legends or descriptions indicated; (e) will be of comparable quality as all samples delivered to Buyer, if any; and (f) shall comply with all applicable laws, rules, regulations, licenses, permits, ordinances, codes and or standards. This warranty and guaranty shall be in addition to any statutory or implied warranties, and warranties of broader scope and service warranties and guarantees given to Buyer by the Seller, and shall survive inspection, test, acceptance, and payment, and shall run to Buyer, its successors, assigns, and customers.
- 8. NONCONFORMANCE. Buyer will immediately notify the Seller's Quality Control (QC) Department, in writing, upon discovery thereof, of any products that in the Buyer's opinion do not conform to the requirements of this Order. All nonconformance inquiries that originate from Buyer's customers will be handled by Buyer's customer service organization in accordance with Buyer's Returned Goods Policy. Once contacted by Buyer, Seller's QC Department will provide Buyer with a Return Goods Authorization Number ("RGA Number"). This number must be referenced on return shipping documents. Seller will arrange to have said Product shipped to Seller, at the Seller's expense, for further analysis by the Seller's QC Department.. All costs with respect to the repair, replacement or refund of the Products that are confirmed to be nonconforming by Seller, including packing, packaging and freight charges, shall be at the Seller's expense. In the event of a dispute between Seller and Buyer as to the conformity of the Product, the Parties shall engage an independent third party laboratory to resolve same within 30 days of the initial nonconformance inquiry and such third party's decision shall be final and binding on the Parties.
- 9. PROPRIETARY RIGHTS. Seller hereby acknowledges that Buyer is the owner of the trademarks and trade names connoting Buyer or Buyer products which it may elect to use in the distribution and sale of the Products, and that Seller has no right or interest in such trademarks and trade names. Seller agrees that it will not use Buyer's name, trade name or trademark in any way without the prior express written consent of Buyer. Seller hereby grants to Buyer the royalty-free license to use Seller's trademarks on the Products, it being expressly understood that if Buyer elects to use Seller's trademarks during the term of the Agreement, Buyer shall properly do so by acknowledging Seller as the owner of such trade names or trademarks and shall discontinue the use of such trademarks in any new material published after the termination hereof. Following the termination of this Agreement, Seller grants to Buyer the right to continue to use Seller's trademarks as necessary in connection with the sale or service of Products purchased by Buyer during the term of this Agreement. Seller represents and warrants that it maintains all rights of ownership or use in any trademark, patent, copyright or any other Intellectual Property necessary to sell the Products to Buyer pursuant to this Agreement ("Intellectual Property"), and that the use by Buyer of any Intellectual Property pursuant to this Agreement will not conflict with or infringe upon the rights of any third party.
- 10. EQUIPMENT & SPECIAL TOOLING. Buyer shall not be obligated to reimburse Seller for the cost of any equipment or tooling unless specifically agreed to in writing by Buyer. Any equipment, tools, jigs, dies, fixtures, templates, patterns, or drawings (hereinafter collectively called "tools") furnished by Buyer to Seller and any tools made or acquired by Seller for the performance of Buyer's order, the cost of which is separately quoted or advertised in the unit price, shall remain or become the property of Buyer. All such tools shall be used exclusively for production under Buyer's orders. Reproducible drawings for tools to be made or acquired by Seller for performance of Buyer's orders shall be submitted to Buyer for approval or to the manufacturer for acquisition of such tools. Seller will maintain the tools in first-class condition and will make replacements when necessary. Seller will not make any alterations to such tools without Buyer's specific written authorization. Seller will be responsible for all loss or damage to such tools while in Seller's possession. Upon completion or cancellation of this order, such tools shall be disposed of as Buyer shall direct.
- 11. WORK ON BUYER'S PREMISES. Where Seller is required to enter premises occupied by Buyer or under Buyer's control to perform services or otherwise, Seller will inspect the premises involved, will provide all necessary safeguards for persons it brings on to the premises, will defend, protect, indemnify and hold Buyer and its successors, assigns and employees harmless from and against all claims, losses, expenses, damages and liabilities, direct, incidental or consequential arising from damage to or loss of property by Seller, its employees or others, or from personal injuries to or death of Seller, Seller's employees or others resulting from or incidental to the presence of such persons on the premises involved WHETHER THE SAME RESULTS IN WHOLE OR IN PART FROM BUYER'S NEGLIGENCE OR OTHER FAULT BY ACT OR OMISSION, OR THAT OF BUYER'S EMPLOYEES OR OTHERWISE, IT BEING THE INTENT OF THIS PROVISION TO ABSOLVE AND PROTECT BUYER AND ITS SUCCESSORS, ASSIGNS AND EMPLOYEES FROM ANY AND ALL LOSS BY REASON OF SELLER'S PERFORMANCE OF WORK ON BUYER'S PREMISES,

and will maintain workmen's compensation insurance covering all employees performing services related to this order on premises occupied by Buyer or under Buyer's control. Seller expressly agrees to waive any provisions of the applicable workers compensation law, whereby Seller could preclude its joinder as an additional defendant or avoid liability for damages, contribution or indemnity.

12. RIGHT-OF-ACCESS. Buyer reserves the right, during normal business hours, and with a two (2) business day notice, to verify purchased Products at Seller's premises and to inspect Seller's work hereunder to ensure that all relevant standards and specifications are met. Any such inspection by Buyer does not absolve Seller of the responsibility for the quality of Products, nor shall it preclude subsequent rejection by Buyer.

- 13. PACKING & SHIPPING. No charge shall be allowed for handling, packing, crating, drayage or storage without written permission of Buyer and/or as outlined in Attachment A of this Agreement. Goods shall be packaged in a method to preserve and protect from damage and/or degradation, and shall be suitably prepared for shipment by Seller in accordance with acceptable commercial practices and in compliance with all applicable laws. Seller shall cause the goods to be labeled and marked to conform to all requirements of all applicable federal, state and local laws, including but not limited to CE markings. Seller shall identify Buyer's purchase order number on Seller's invoice, packing list, bill of lading or on any packages. Seller shall attach an invoice to all shipments, in addition to forwarding a copy of such invoice to Buyer.
- 14. PRICING. This Order must not be filled at prices higher than last quoted by Seller or as set forth in the Underlying Agreement unless Buyer consents in writing. Seller represents that the prices to be paid or otherwise charged to Buyer are not any higher than the lowest price for such goods or services offered by Seller to any other of its customers, excluding United States government entities. Seller shall be responsible for and pay all federal, state, and local sales, use, income, excise, property, employment, and other taxes similar to, or differing from, any of the foregoing, incurred or levied on or in connection with the manufacture of goods, provision of services, or relating to Seller's own property. Buyer shall be responsible only for taxes arising from its ownership of the Products. Seller agrees to indemnify Buyer against any loss, liability or expense (including reasonable attorneys fees) resulting from Seller's failure to pay such taxes, fees, duties, assessments, charges or conditions.
- 15. TITLE. Seller warrants full, unrestricted title to all goods and services furnished hereunder, free and clear of all liens, security interests and encumbrances. Care, custody and control of, and title to all Products remain with Seller until such time as Buyer takes physical possession or otherwise agrees in writing. Seller shall carry on its work and manufacture of Products at its own risk until the Products are completed and accepted by the Buyer. In the case of accident, destruction or injury to the Products before the Buyer's final completion and acceptance, Seller shall repair or replace such Products at its own expense and to the Buyer's satisfaction.
- 16. HAZARDOUS MATERIALS. Seller will notify Buyer in writing upon acceptance of this Order if Products furnished are subject to laws or regulations relating to hazardous or toxic substances, whether for shipment or use, or when disposed of, to regulations governing hazardous wastes, or any other applicable environmental, health, or safety laws or regulations. Instructions for shipping, handling, warnings, and material safety data sheets shall be provided with each shipment. Seller shall submit to Buyer, prior to the initiation of shipments to Buyer or Buyer's customer to which Seller drop ships, a copy of all relevant MSDS sheets. Seller agrees to and shall accept, at its facility, all of Buyer's unsold or expired Products containing hazardous chemicals, materials or substances for disposal, recycling or use. Buyer shall be responsible for packing and transportation costs to Seller. Seller shall be responsible for all other costs, including, without limitation, any costs associated with Seller's disposal, recycling or use.
- 17. PATENTS. Seller warrants that the manufacture, use and sale of the Products do not infringe any claims of any patent, trademark, trade name, copyright or any other third-party property right. Seller agrees to defend, indemnify and hold Buyer (and its agents, representatives, employees, officers, directors, affiliates, successors, assigns, and customers) harmless from any and all claims, demands, actions, damages and liabilities (including legal fees) involving the infringement of any third-party patent, trademark, copyright or other intellectual property right, or the misappropriation of any trade secret, by reason of the manufacture, use, or sale of said Products by Buyer. Without limiting the foregoing, if any of the Products becomes, or in Buyer's opinion, may become the subject of any claim, suit or proceeding for infringement of any patent, Seller will, at Buyer's opion and at Seller's sole expense, (i) obtain for Buyer the right to use, lease or sell the Product, (ii) replace the Product, (iii) modify the Product, or (iv) remove the Product and refund the full purchase price paid by Buyer
- 18. INDEMNITY & INSURANCE. Seller agrees to defend, indemnify and hold Buyer (and its agents, representatives, employees, officers, directors, affiliates, successors and assigns, customers, and all subsequent users of the Products) harmless from all claims, demands, actions, damages, and liabilities (including reasonable attorney's fees) in any way connected with the goods or services provided to Buyer hereunder, the breach of any of the terms and conditions contained herein, or any act or omission of Seller, its agents, employees, or subcontractors. Should Seller deem that a recall be necessitated due to a defect or non-conformance of the Products, Seller shall bear all pre-approved costs and expenses of such recall, detailed in writing by Seller, including without limitation, costs of notifying customers, returning Products, customer refunds, lost profits, and any expenses incurred to meet obligations to third parties. Buyer agrees to assist Seller in conducting the recall in a timely manner in accordance with the Guidelines set forth in Title 21 C.F.R. (Food & Drugs). Seller agrees to procure and maintain on an occurrence form basis product liability insurance with respect to the Products and contractual liability coverage relating to the Underlying Agreement, if any, with insurer(s) having Best's rating(s) of A- or better, naming Buyer as an additional insured (Broad Form Vendors Endorsement), with minimum limits in each case of \$2,000,000. Seller shall promptly furnish to Buyer a certificate of insurance and renewal certificates of insurance evidencing the foregoing coverages and limits. The insurance shall not be canceled, reduced or otherwise changed without providing Buyer with at least thirty (30) days prior written notice.
- 19. LIMITATION OF LIABILITY. IN NO EVENT SHALL BUYER BE HELD LIABLE FOR PUNITIVE, EXEMPLARY, SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, UNLESS DAMAGES WERE LEGALLY DETERMINED TO BE CAUSED BY THE FAULT OR NEGLIGENCE OF BUYER. Buyer's liability on any claim of any kind for any loss or damage arising out of or in connection with this Order or from the performance or breach thereof shall in no case exceed the price allocable to the Products ordered and delivered hereunder. Any action resulting from any alleged breach by Buyer must be commenced within one year after the cause of action has accrued, or Seller shall be deemed to have waived any such claims.

# 20. COMPLIANCE WITH LAWS.

- (a) Seller shall comply with all applicable international, federal, state, county, and municipal statutes, laws, regulations, codes, standards, ordinances and orders in its performance hereunder and shall be responsible for all fees associated with such compliance, licenses, permits, certifications, bonds, taxes, duties, tariffs and other applicable fees. Without limiting the foregoing, Seller will comply with all applicable customs laws and requirements of the U.S. (including specifically the U.S. Export Administration Act) and of each country in which the Products are made or likely to transit with respect to (a) the labeling of the Products and their packaging, (b) the export and import of the Products and the subsequent distribution of the Products to Buyer and/or directly to the Buyer's customers, including the completion and submission of all required documentation, and the payment of all taxes, duties, tariffs and similar expenses. In addition, Seller hereby acknowledges, represents and warrants (i) that Seller WILL NOT provide any Products that in whole or in part have been transferred, exported or imported, directly or indirectly, from a country or nation thereof, subject to restrictions under applicable laws and regulations, including but not limited to inclusion on the Export Administration Regulations' Denied Party List or any similar list published by a United States or foreign agency; (ii) Seller is not located in, under the control of, or a national resident of any such restricted country; (iii) the Products have not been produced, in whole or in part, by prison labor, sweatshop labor, abusive forms of child labor, slave labor, or by other labor practices in violation of applicable laws, and (iv) unless otherwise agreed to in writing by Buyer and Seller, Seller shall serve as the Importer of Record for the Products and shall comply with all applicable laws, be responsible for all applicable fees, and assume all obligations incurred as the Importer of Record.
- (b) <u>U.S. Food & Drug Administration (FDA) Compliance:</u> Seller shall comply with all aspects of the FDA Regulations as detailed in Title 21 C.F.R. (Food & Drugs) § 1-1499. Without limiting the foregoing, Seller specifically agrees to the following:
- (i) Seller shall ensure proper registration of all establishments and products involved in the development, manufacture and distribution cycles of the Products and shall comply in all respects with any laws relating thereto.
- (ii) Seller shall register and remain registered with FDA as the Specification Developer and the Manufacturer of the products and will serve as the Importer of Record under U.S. Customs and Border Protection laws.
- (iii) Seller shall register with FDA all Foreign Establishments manufacturing FDA-regulated Products according to the applicable laws and regulations and hereby agrees to perform routine audits of such Foreign Establishments during the term of this Agreement. Seller shall ensure that all Medical Devices produced in their establishment(s) are listed with the FDA and conform to regulations pursuant to FDA Federal Code of Regulations (C.F.R.) Title 21, Subpart H, Part 807.
- (iv) All Products quality issues, Medical Device Reporting, reports of corrections and removals and Medical Device Tracking must be performed in a timely manner by Seller and as required by federal laws and regulations with appropriate notice provided to Buyer. Without limiting the foregoing, Seller shall promptly acknowledge receipt of all Product Improvement Reports submitted by Buyer and shall take all necessary and appropriate corrective action deemed appropriate by Seller's QC Department.

(v) Seller must assure that any Products requiring sterilization comply with all applicable law and Good Manufacturing Practices, as defined by FDA regulations.

(vi) Seller will maintain all required documentation as mandated by FDA regulations and as required pursuant to Seller's Quality System. Additionally, Seller will comply with and will maintain a process to document such compliance in accordance with the Quality System Regulations (21 C.F.R. § 820). Seller will make any and all such documentation available for review by Buyer (or its designee) pursuant to the terms of this Agreement.

#### FISHER SCIENTIFIC COMPANY L.L.C. DISTRIBUTION AGREEMENT

- (vii) Seller will cooperate with Buyer to allow Buyer (or its designee) to audit Seller or any of Seller's manufacturers in the supply chain as needed and upon request in compliance with this Agreement given five (5) business days notice.
- (viii) With respect to any labels and packaging (including specifically any Instructions for Use and packaging inserts), Seller verifies that all such labels and packaging if required by law, is approved in advance by the FDA.
- (ix) With respect to process changes, Seller will communicate to Buyer, in a timely manner, any raw material, formulation or process change that significantly alters the product design or function.
- (x) Seller shall be responsible for distributing any customer notifications required by law. Seller shall coordinate such distribution with Buyer's Quality and Regulatory Departments. Examples of such required communication would be: (i) quality issues, (ii) process changes, (iii) recalls, (iv) Medical Device Reporting, (v) reports of corrections and removals, and (vi) Medical Device Trading.
  - (xi) Seller, as the Specification Developer and Manufacturer will be responsible for notifications, as required, to FDA pursuant to 21 C.F.R. § 1-1499.
- (xii) Notwithstanding the foregoing, in the event that the Products are manufactured or transported by Seller in such a way that another country's equivalent of the U.S. FDA may have jurisdiction, Seller agrees that it will comply with any such laws and regulations which relate in any way to the marketing, manufacture, distribution or transportation of the Products.
- 21. ASSIGNMENT. Seller shall not assign this Agreement or any rights or work performed hereunder without the prior written consent of Buyer. Any attempted assignment without such consent shall render this Agreement null and void.
- 22. WAIVER. No failure to exercise, and no delay in exercising, on the part of Buyer any right, power or privilege hereunder will operate as a waiver, nor will any single or partial exercise of any right, power or privilege preclude further exercise of the same right, power or privilege.
- 23. VALIDITY OF PROVISIONS. In the event that any provision or any part or portion of any provision of this Order shall be held to be invalid, void or otherwise unenforceable, such holding shall not affect the remaining parts or provisions hereof.
- 24. GOVERNING LAW & VENUE. This Agreement shall be governed in accordance with the laws of the State of Pennsylvania, without reference to any conflict of law provisions; provided, however, that Seller's liability for any harm caused by the Products shall be governed by Chapter 82 of the Texas Civil Practice & Remedies Code (the "Texas Code"). Unless the parties agree otherwise in writing, the state and federal courts located in Alleghany County, Pennsylvania shall have exclusive jurisdiction over all disputes hereunder, and the parties hereby consent to such jurisdiction, agree to accept service process by mail, and hereby waive any jurisdiction or venue defenses otherwise available. The parties agree the UN Convention on Contracts for the International Sale of Goods shall not apply to the sale of goods hereunder.
- 25. CONFIDENTIALITY. Seller expressly agrees to hold as confidential any information which is provided by Buyer ("Confidential Information"). Seller expressly acknowledges and agrees that Buyer's customer names, addresses, key contacts, customer purchase history, documents and information in any way related to the marketing, sale, pricing or distribution of any products are and shall be the Confidential Information of Buyer, regardless of whether such information is expressly marked as "confidential" by Buyer. Additionally, Seller hereto acknowledges and agrees that the existence and nature of this Agreement shall constitute Confidential Information. Seller agrees that it will limit the Confidential Information that it provides to Buyer to information concerning sources, new products development and financial information unless Buyer consents to the disclosure of additional information. In the event Confidential Information is exchanged according to these guidelines, such information will be retained by the Seller in confidence during the term of this Agreement and for a period of five (5) years following the termination of this Agreement. The transmittal of such information is and shall be upon the express condition that the information is to be used solely to effectuate this Agreement; and the Seller shall not use, publish, or disclose said information, in whole or in part, for any purpose other than that stated herein. Notwithstanding the foregoing, the above restrictions on disclosure and use shall not apply to any information which the Seller can show by written evidence, was known to it at the time of receipt, or which may be obtained from third parties who are not, to the Seller's knowledge, bound by a confidentiality agreement to the Buyer, or which is in the public domain, or which may be independently developed without use of the Confidential Information.
- 26. GRATUITIES. Neither the Seller, nor anyone in privity with the Seller, shall have accepted or accept, or give or agree to give, any gratuity from any person, including but not limited to the Buyer, in connection with the purchase of Products.
- 27. NON-SOLICITATION. During the term of any Underlying Agreement and for one (1) year after termination of the Underlying Agreement or after placement of the Order (as applicable) (the "Restricted Period"), Seller, whether for its own account or the account of any other person or entity at any time, shall not, directly or indirectly, solicit for employment, any person who is (or was during the Restricted Period) an employee or agent of Buyer, or in any manner, directly or indirectly, induce or attempt to induce any employee of Buyer to terminate his or her employment with Buyer.
- 28. AUDIT RIGHTS. During the term of the Underlying Agreement or for a reasonable period after placement of the Order or termination of the Underlying Agreement, Buyer shall have the right upon reasonable notice and during normal business hours, with five (5) business days notice, to audit the facilities and records of Seller as reasonably necessary and as subject to any existing confidentiality agreements in order to ensure compliance with the terms of the Underlying Agreement and these Terms and Conditions; provided that Buyer will use commercially reasonable efforts to minimize any inconvenience to Seller as a result of such audit.

If the end user of the Products or Services will be a federal, state or local government or municipality or similar party, the following provisions will apply:

29. GOVERNMENT PROCUREMENT PROVISIONS. If the Products to be furnished by Seller are to be used in the performance of a U.S. government contract or subcontract, those clauses of the applicable U.S. Government procurement regulation which are required and mandated by Federal Statute to be included in U.S. Government subcontracts shall be incorporated herein by reference including, without limitation, the Fair Labor Standards Act of 1938, as amended, and the provisions of Executive Orders Nos. 11246, 11701 and 11758, the Rehabilitation Act of 1973, the Vietnam Era Veterans Readjustment Assistance Act of 1974, and all applicable amendments thereto and rules and regulations issued hereunder. Upon Buyer's request, Seller will promptly provide certification to evidence the country of origin of such materials purchased hereunder. Seller shall indemnify Buyer for any loss, liability, or expense resulting from Seller's failure to properly comply with Seller's requirements or applicable laws or regulations regarding country of origin, including but not limited to the Berry Amendment, where applicable.

If the end user of the Products or Services will in any way relate to the federal healthcare programs, the following provision will apply:

30. HEALTHCARE REPRESENTATIONS. The Office of Inspector General ("OIG") Special Advisory Bulletin on the Effect of Exclusions on Participation in Federal Health Care Programs clarifies the OIG's sanction authority to impose civil money penalties and deny reimbursement under federal health care programs of any and all products or services if products or services are provided by an excluded entity. (Federal Register, September 30, 1999, Vol. 64, No. 189, pp. 52791-52794.) The OIG Special Advisory Bulletin specifically provides that "items or equipment sold by an excluded manufacturer or distributor, used in the treatment of beneficiaries and reimbursed, directly or indirectly, by a federal health care program violate the OIG's exclusion." Seller represents and warrants that neither it, any of its subsidiaries or affiliated businesses, nor any officers, directors, or other key personnel of same, have been (a) convicted or threatened with conviction of any health care related offense, whether state or federal, or (b) been or threatened with being debarred, excluded, or otherwise listed or rendered ineligible for participation in any federal or state healthcare program, as that term is defined by 42 USC §1320a-7b(f) by any state or federal agency (collectively referred to herein as being "Excluded"). If Seller, any of its subsidiaries or affiliated businesses, or any officers, directors, or other key personnel of same, are Excluded or otherwise receive from authorities a notice of intent to Exclude from federal or state healthcare program participation, Seller shall immediately notify Buyer of the same in writing within forty-eight (48) hours. Upon notice of same, Buyer shall have the right to immediately terminate this Order or the Underlying Agreement in its sole discretion without cost or penalty. In the event Seller breaches or otherwise fails to comply with any provision of this Paragraph, Seller

hereby agrees to defend, indemnify and hold Buyer harmless from and against any loss, claim, suit, expense or obligation arising out of or resulting from any such breach or noncompliance, including, but not limited to, sanctions, penalties, or fines incurred under the federal Civil Monetary Penalty Law (Section 1128A of the Social Security Act), the Health Insurance Portability and Accountability Act of 1996 or the Balanced Budget Act of 1997.

# AMENDMENT TO DISTRIBUTION AGREEMENT BETWEEN AKERS BIOSCIENCES, INC. AND FISHER HEALTHCARE

THIS AMENDMENT TO THE DISTRIBUTION AGREEMENT ("Amendment") is made and entered into effective as of <u>May 1, 2012</u> (Effective Date"), by and between Akers Biosciences, Inc. ("Supplier") and Fisher HealthCare, an unincorporated division of Fisher Scientific Company, L.L.C. ("Fisher HealthCare"). Supplier and Fisher HealthCare are each sometimes referred to herein individually as "Party" and collectively as the "Parties".

#### **RECITALS:**

WHEREAS, the Parties executed a Distribution Agreement effective June 15, 2010 (the"Agreement");

WHEREAS, Supplier per letter dated April 12, 2012 desires to rescind Supplier's letter dated February 22, 2012 terminating the Agreement; and

WHEREAS, Supplier and Fisher HealthCare each desire to amend the Agreement upon the terms and conditions agreed to herein.

NOW, THEREFORE, for the consideration described herein, the Parties agree to amend the Agreement as follows:

1. Supplier's letter dated April 12, 2012 is hereby rescinded and of no force and effect and the Initial Term shall be amended as follows:

The Initial Term set forth at the top of the first page of the Agreement shall be extended to May 31, 2014. The Initial Term shall automatically renew for successive twelve (12) month periods as set forth in Section 6.1 of the Agreement.

2. <u>Attachment A to Distribution Agreement</u>. Attachment A shall be amended to reflect the pricing for the Products set forth below:

ABI Item # 4036025 Price \$208 ABI Item #4036027 Price \$45 ABI Item #4036028 Price \$135

- 3. <u>Defined Terms and References.</u> All capitalized terms used herein that are not defined herein shall have the same respective meanings ascribed to such terms in the Agreement. All references to Articles, Sections, Paragraphs and Exhibits are to corresponding Articles, Sections, Paragraphs and Exhibits of the Agreement.
- 4. <u>Amendment.</u> This Amendment may be amended or supplemented only by an instrument in writing executed by the parties hereto. Except as specifically amended hereby, the Agreement shall continue in full force and effect and is hereby ratified by all parties thereto.
- 5. Parties Bound. This Amendment shall be binding upon and inure to the benefit of the parties hereto and their respective successors and legal representatives. Each Party represents and warrants that it has the authority to sign in their respective capacity as contemplated hereby.

- 6. <u>Conflicts.</u> In the event that any conflict is determined to exist between a term or provision of this Amendment and a term or provision set forth in the Agreement or in any other document, it is understood and agreed that this Amendment shall control and govern the construction and interpretation of such term or provision.
- Facsimile/Countemarts. This Amendment may be executed in counterparts and by facsimile signatures and such counterparts shall together constitute one enforceable document.
- 8. No Oral Agreements. THE AGREEMENT, AS MODIFIED BY THIS AMENDMENT, REPRESENTS THE FINAL AGREEMENT BETWEEN THE PARTIES AND MAY NOT BE CONTRADICTED BY EVIDENCE OF PRIOR, CONTEMPORANEOUS, OR SUBSEQUENT ORAL AGREEMENTS OF THE PARTIES.

IN WITNESS WHEREOF, this Amendment has been executed as of the Effective Date.

FISHER HEAL	THCARE, an	AKERS	BIOSCIENCES, INC.	
unincorporated	division of Fisher Scientific Company, L.L.C.			
By:		By:	/s/ Thomas a. Nicolette	
Name:		Name:	THOMAS A. NICOLETTE	
Title:		Title:	PRESIDENT AND CEO	

#### NATIONAL BRAND DISTRIBUTION AGREEMENT

This Agreement, effective May 1, 2007 ("Effective Date"), is between Akers Biosciences, Inc., a New Jersey corporation with its principal offices located at 201 Grove Rd., Thorofare, New Jersey 08086, hereinafter called "SUPPLIER," and Cardinal Health 200, Inc. a Delaware Corporation that is the Medical Products and Services Group of Cardinal Health, with offices located at 1450 Waukegan Road, McGaw Park, Illinois 60085, hereinafter called "DISTRIBUTOR."

#### BACKGROUND

SUPPLIER manufactures and/or markets certain products (specifically, the "Products" as defined in Section 1 below). SUPPLIER desires to appoint DISTRIBUTOR as an authorized DISTRIBUTOR of the Products and DISTRIBUTOR desires to accept such appointment on the terms and subject to the conditions described in this Agreement.

SUPPLIER and DISTRIBUTOR agree as follows:

- 1. **Products Covered by this Agreement.** The products covered by this Agreement are those products manufactured by SUPPLIER bearing a SUPPLIER owned trademark and listed on Schedule "A" (the "Products"), all of which are identified herein by DISTRIBUTOR catalog number, together with the parts and components necessary for the repair and replacement thereof, and all modifications, improvements, and developments pertaining to such products, accessories and components. Products may be added to or deleted from this Agreement by mutual consent of the parties.
- 2. **Grant of Distributorship**. SUPPLIER hereby appoints DISTRIBUTOR as an exclusive distributor in the USA of the PIFA Heparin / PF4 Rapid Assay (#4036025) and Serum Panel (#4036027, #4036028) Products and DISTRIBUTOR accepts such grant for the term and on the conditions stated in this Agreement. SUPPLIER agrees that it shall not, during the term of this Agreement, solicit interest from or negotiate with Thermo Fisher Scientific regarding the sale of the Products for resale or sell the Products to Thermo Fisher Scientific. DISTRIBUTOR agrees that, during the term of this Agreement, the Products shall be included on its master merchandise file and categorized as National Brand. SUPPLIER acknowledges and agrees that DISTRIBUTOR has no marketing or promotional obligations with regard to the Products and that DISTRIBUTOR is not prohibited from using, selling or promoting any products which are competitive with the Products, to include its Best Value Product offering.
- 3. <u>Term and Renewal</u>. The term of this Agreement shall begin on the Effective Date and shall continue until terminated in accordance with the provisions of Section 8 below.

#### 4. **Pricing and Payment Terms**

- a. The prices for Products ordered by the DISTRIBUTOR shall be as set forth on Schedule A. All such prices shall remain firm until December 31, 2007. SUPPLIER agrees to abide by DISTRIBUTOR's then-current "Supplier Price Change and Notification Policy", a current copy of which SUPPLIER acknowledges receiving prior to the execution of this Agreement.
  - b. Terms of payment are 2%/30 days, net 31 days from DISTRIBUTOR's receipt of Product.
- c. DISTRIBUTOR shall deduct an administrative fee of 3% at time of invoice payment to cover the costs of trace sales reporting, the rebate process, contract administration, master merchandise file costs and other costs to administer the procurement of inventory and other associated processes. The trace sales report shall be provided on a monthly basis.
- d. If SUPPLIER approves adjusted cost contracts for specific customer then SUPPLIER agrees to the following process with regard to rebates: DISTRIBUTOR uses an auto-debit system where rebate dollars are automatically deducted from a supplier's payables balance upon the sale to the end-user customer. Rebate dollars are accumulated until a specified time period (usually one month) and then the deduction is made. A remittance advice will follow showing which deductions have been made.

NATIONAL BRAND DISTRIBUTION AGREEMENT

#### 5. **DISTRIBUTOR's Duties**

#### DISTRIBUTOR shall:

- a. Upon customer request, offer the Products as a part of its generally available distribution offering and provide non-technical distribution support for the Products to its customers.
- b. Submit its order for Products via EDI transaction (see Section 6.c.i. below) on its standard purchase order form the terms and conditions of which are incorporated herein by reference thereto to the extent such terms and conditions do not conflict with the terms and conditions of this Agreement. To the extent there is such a conflict, the terms and conditions of this Agreement shall control.
  - c. Pay for such orders in accordance with the payment terms specified in Section 4 above.
  - Participate with SUPPLIER in business reviews, as mutually agreed by the parties.
  - e. Provide a sales tracing report on a monthly basis.
  - f. Maintain complete and accurate records for such periods as may be required by applicable law, of all the Products sold by it.
  - g. Designate Products on the attached Schedule "A" as Focus Products for FY2007 and FY 2008
  - h. Ensure field force, including sales management, has adequate training on the product(s) and is engaged in actively selling a Focus Product during the term of the Focus Program.
  - i. Provide quarterly updates to sales rep roster for new representatives and allow SUPPLIER to train new hires on Focus Product(s) via phone and/or direct mail periodically.

#### 6. SUPPLIER's Duties

# SUPPLIER shall:

- a. Promptly ship to all DISTRIBUTOR Distribution Centers, F.O.B. Destination. It is understood that SUPPLIER's pricing for the Products purchased by DISTRIBUTOR includes transportation expenses. All Direct (Drop) shipments to DISTRIBUTOR's customers by SUPPLIER must be F.O.B.Destination, Prepaid and Add. DISTRIBUTOR reserves the right to determine the carriers to be selected for shipment to its customers. Any deviation from these terms must be agreed upon prior to shipment by both SUPPLIER and the DISTRIBUTOR's Transportation Department, McGaw Park, IL.
- b. Use best efforts to maintain 98% Fill Rate (defined below) on all orders for Products. Fill Rate is defined as complete line items shipped within 48 hours of receipt of DISTRIBUTOR's purchase order.
- c. In addition to any electronic data interchange (EDI) transactions which are required under DISTRIBUTOR's "Supplier Price Change & Notification Policy", maintain the systems necessary and utilize the following:
  - i. Purchase Order (EDI #850): Transmitted by DISTRIBUTOR to SUPPLIER and received electronically by SUPPLIER without data entry.
  - . Invoice (EDI #810): Received electronically by DISTRIBUTOR from SUPPLIER without data entry.
  - iii. Shipment Notice (EDI #856): Transmitted by SUPPLER to DISTRIBUTOR when shipment leaves SUPPLIER's facility.

iv. Price/Sales Catalogue (EDI #832): Transmitted by SUPPLER to DISTRIBUTOR for new product adds, product deletions, invoice cost/list price changes and certain other data changes.

In the event SUPPLIER does not utilize all required EDI transactions within 90 days after DISTRIBUTOR's request that it do so, DISTRIBUTOR shall have the right thereafter to deduct 1% from its payment of any invoices issued hereunder per each EDI transaction not implemented until SUPPLIER begins utilizing each such EDI transaction.

- d. Adequately label, package and deliver the Products. SUPPLIER shall bear all costs associated with label printing, labeling, and packaging of the Product.
- e. Notify DISTRIBUTOR immediately in writing should SUPPLIER become aware of any defect or condition which may render any of the Products in violation of the Food, Drug and Cosmetic Act or any other applicable law.
- f. Make any claims for unpaid invoices in writing within ninety (90) days of the date of SUPPLIER's first invoice for such amount. DISTRIBUTOR will not be obligated to make payments for, or investigate, entries which are dated more than ninety (90) days before SUPPLIER's written claim or request for investigation.
  - g. Participate with DISTRIBUTOR in business reviews, as mutually agreed to by the parties.
  - h. Provide DISTRIBUTOR sales rep support and training.
  - i. Offer DISTRIBUTOR the same promotional opportunities afforded to other distributors of the Products
  - j. Provide DISTRIBUTOR customer leads generated at industry trade shows.
- k. Notify the appropriate federal, state and local authorities of any customer complaints or other occurrences regarding the Products which are required to be so reported. SUPPLIER shall be responsible for evaluating all complaints regarding the Products and for responding to DISTRIBUTOR's customers in writing.
  - 1. On a quarterly basis, SUPPLIER will accept returns of product in unopened saleable full case quantities without a restocking fee.
  - m. SUPPLIER has a purchase order minimum of 48 sleeves (1 CS) of the PIFA<sup>â</sup> Heparin/PF4 Rapid Assay, vendor # 4036025
- n. Produce unitized pallet bar coding within one (1) year of DISTRIBUTOR's request, shipping Product unitized, shrink wrapped and on slip sheets. In the event SUPPLIER does not ship produce unitized pallet bar coding as provided above within one year after DISTRIBUTOR's request that it do so, DISTRIBUTOR shall have the right thereafter to deduct a one percent (1%) administrative fee from its payment of any invoices issued hereunder until SUPPLIER begins production thereof.
- o. On or before the Effective Date, provide to DISTRIBUTOR, electronically via Excel or Access or such other format as the parties shall agree, such competitive cross referencing information with regard to the Products as DISTRIBUTOR shall reasonably request and, thereafter, update such information no less frequently than quarterly.
- 7. Product Warranties, Indemnification and Insurance. SUPPLIER specifically warrants to DISTRIBUTOR that the Products are free from defects in design, workmanship and materials and are in compliance with the specifications and claims made by SUPPLIER for them. SUPPLIER further agrees to execute and comply with the provisions of the Continuing Guaranty attached hereto as Exhibit 1, the terms and conditions of which are made part hereof to the extent consistent with the terms set out in the body of this Agreement.
- 8. **Termination**. Either party shall have the right to terminate this Agreement on written notice if the other (a) commits or suffers any act of bankruptcy or insolvency, or (b) fails to cure any material breach of the provisions of this Agreement within thirty (30) days after written notice of such breach. In addition, each party shall have the right to terminate this Agreement, with or without cause, upon ninety (90) days written notice to the other party.

- 9. **Procedures on Termination**. On the termination or expiration of this Agreement, for whatever reason, SUPPLIER shall continue to honor DISTRIBUTOR's orders for Products up to the effective date of termination and for a period of at least one (1) year thereafter, and DISTRIBUTOR shall pay for such Products on the terms and conditions of this Agreement. In addition, SUPPLIER shall, upon DISTRIBUTOR's request, accept the return of any Products that have become excess or no move for full credit with no restocking fee. Excess/no move inventory is any inventory of Products in a given distribution center that exceeds four (4) months of customer demand for that distribution center. "Salable" Product is defined as undamaged Product in its original sealed shipping carton.
- 10. <u>Force Majeure</u>. The obligations of either party to perform under this Agreement shall be excused during each period of delay caused by matters such as strikes, shortages of power or raw material, government orders or acts of God, which are reasonably beyond the control of the party obligated to perform.
- 11. Confidential Information. SUPPLIER acknowledges and agrees that pursuant to this Agreement valuable information of a confidential nature, which includes but is not limited to marketing, sales and new Product development information may be disclosed by DISTRIBUTOR to SUPPLIER; that such information will be retained by SUPPLIER in confidence; and that SUPPLIER shall not, either during the term of this Agreement or after its termination, disclose to any third party or cause anyone else to disclose to any third party confidential information supplied to SUPPLIER by DISTRIBUTOR. Notwithstanding anything in the foregoing, the above restrictions on disclosure shall not apply to: (a) information (other than trace sales and rebate information submitted to SUPPLIER by DISTRIBUTOR, which shall be considered DISTRIBUTOR's confidential information for purposes of this Agreement) which is not identified in writing at the time of disclosure as "confidential" and is confirmed to be confidential in writing at the time of disclosure as "confidential" and is confirmed to be confidential in writing within 30 days after the date of disclosure); (b) information which SUPPLIER can show by written evidence was known to it at the time of receipt thereof from DISTRIBUTOR; (c) information which is subsequently obtained from sources other than DISTRIBUTOR who are not bound by a confidentiality agreement with DISTRIBUTOR. The above restrictions shall not prohibit any disclosure which is required pursuant to a court order or administrative proceeding; provided that SUPPLIER shall promptly notify DISTRIBUTOR of the need for any such disclosure and shall give DISTRIBUTOR a reasonable time to oppose such process. The above restrictions shall apply during the term of this Agreement and for a period of two years thereafter.

#### 12. Miscellaneous

a . **Notices**. Any notice required or permitted under this Agreement shall be in writing and shall be deemed to have been given upon receipt if forwarded by personal delivery, certified mail, or facsimile transmission (transmission confirmed) properly addressed to the respective parties as set forth below until notice of a different address is supplied in accordance with this Section:

If to SUPPLIER:

Akers Biosciences, Inc.
201 Grove Road
Thorofare, NJ 08086
Attn:Thomas A. Nicolette, President

Facsimile: 856.848.0269

NATIONAL BRAND DISTRIBUTION AGREEMENT

If to DISTRIBUTOR:

Cardinal Health Medical Products and Services

1450 Waukegan Road McGaw Park, IL 60085

Attn: Howard Jagoda, VP Supplier Relations

Facsimile: 847-689-0366

b. **Entire Agreement.** This Agreement is the entire agreement between the parties hereto with regard to the subject matter of this Agreement, there being no prior written or oral promises or representations not incorporated herein with respect to such matters.

- c. Applicable Law. This Agreement shall be governed by the laws of the State of Illinois, applicable to contracts made and to be performed in that state.
- d. **Amendments**. No amendment or modification of the terms of this Agreement shall be binding on either party unless reduced to writing and signed by an authorized employee of the party to be bound.
- e. Waiver of Punitive Damages and Jury Trial. Both parties irrevocably waive trial by jury in any action, proceeding or counterclaim, whether at law or in equity, brought by either of them arising out of this Agreement. Except with respect to SUPPLIER's obligation to indemnify DISTRIBUTOR pursuant to the Continuing Guaranty, SUPPLIER and DISTRIBUTOR waive to the fullest extent permitted by law any right to or claim for any punitive or exemplary damages against the other and agree that, in the event of a dispute between them regarding this Agreement, the party making a claim will be limited to equitable relief and to recovery of any actual damages it sustains.
- Publicity. Neither party will make any press release or other public announcement regarding this Agreement without the other party's express prior written consent, except as required under applicable law or by any governmental agency, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public announcement prior to issuing the press release or making the public announcement provided that DISTRIBUTOR acknowledges that as per Transparency Directive set forth by the London Stock Exchange, SUPPLIER must subscribe to the practice of immediate disclosure of price sensitive information and that DISTRIBUTOR will be required to respond to any approval request for such a disclosure within 24 hours of that request.
- 13. <u>Assignment</u>. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, provided, however, that neither party shall have the right to assign its interest in this Agreement without the prior written authorization of the other party.

purposes.							
IN '	WITNESS WHEREOF, the parties have by their d	aly authorized officers executed this Agreement as of the Effe	ective Date.				
[SUPPLIER	]						
By: Title:							
	HEALTH 200, INC., the Medical Products Group of Cardinal Health						
By:							
		SCHEDULE "A"					
		Product Listing and Prices					
Vendor Mtl			Purchasing Order	Acqu	istion	Minimum Lot Size –	Rounding Value –
Num	Material Description	Material Desc 2	Unit	cost		master	master
4036025	RAPID ASSAY PIFA HEPARIN PLATELET FACT4	6TST/SL 6TST/BX 48SL/BX	SL	\$	144.00	48	48
4036027	PANEL SERUM 2 MEMBER POS AND NEG	DROP SHIP ONLY 2EA/BX 1BX/CS	CS	\$	39.00	1	1
4036028		DROP SHIP ONLY 6EA/BX 1BX/CS	CS	\$	117.00	1	1
4000124			CS	\$	200.00	100	1
4000128	DETECTOR ALCOHOL BREATHSCAN 0.08PERCEN	Γ I AR PACK 100FA/RY 1RY/CS	CS	•	200.00	100	1

NATIONAL BRAND DISTRIBUTION AGREEMENT 6

Counterparts. For convenience of the parties hereto, this Agreement may be executed in one or more counterparts, each of which shall be deemed an original for all

# **EXHIBIT 1**

# **Continuing Guaranty**

# THE CG ON FILE IS TO BE USED DATED 6/1/05

NATIONAL BRAND DISTRIBUTION AGREEMENT

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#### AMENDMENT TO NATIONAL BRAND DISTRIBUTION AGREEMENT

This amendment (the "Amendment") is entered into effective as of June 1, 2008by and between Cardinal Health 200, Inc. having a place of business at 7000 Cardinal Place Dublin Ohio 43017 (hereinafter referred to as "DISTRIBUTOR"), and Akers Biosciences, Inc., having a place of business at 201 Grove Road, Thorofare, New Jersey 08086 (hereinafter "SUPPLIER").

WHEREAS, SUPPLIER and DISTRIBUTOR are parties to a National Brand Distribution Agreement dated as of May 1, 2007 (the "Agreement"); and

WHEREAS, the parties wish to amend the Agreement in certain respects.

NOW THEREFORE, in consideration of the mutual promises of the parties contained herein, and for other good and valuable consideration, the parties hereby agree as follows:

- 1. The parties agree that "PIFA Heparin / PF4 Rapid Assay (# 4036025) and Serum Panel (#4036027, #4036028) Products" shall no longer be exclusively distributed by DISTRIBUTOR as of the effective date of the Amendment.
- 2. All defined terms used in this Amendment shall have the meaning ascribed to them in the Agreement unless otherwise defined herein. All other terms and conditions of the Agreement remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed by their duly authorized employees as of the effective date set forth above.

AKERS BIOSCIENCES, INC.	CARDINAL HEALTH 200, INC.
By: Title: Date:	By: Title: Date:

# Consent of Independent Registered Public Accounting Firm

We consent to the use in the Amendment No. 1 to the Registration Statement on Form S-1 of Akers Biosciences, Inc. of our report, dated July 23, 2013, with respect to the consolidated balance sheets of Akers Biosciences, Inc. and its Subsidiaries as of December 31, 2012 and 2011 and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years then ended appearing in the Prospectus, which is part of this registration Statement.

We also consent to the reference to our firm under the caption "Experts" in such Prospectus.

/s/ MORISON COGEN LLP

Bala Cynwyd, Pennsylvania October 7, 2013

# **Consent of Director Nominee**

In accordance with Rule 438 under the Securities Act of 1933, as amended (the "Securities Act"), the undersigned hereby consents to being named as a director nominee and impending board member of Akers Biosciences, Inc. (the "Company") in the Company's Registration Statement on Form S-1 (Registration No. 333-190456) and in all amendments (including post-effective amendments) thereto.

Dated:	October	2	2013

	/s/	Brand	on	Knox
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#### AKERS BIOSCIENCES, INC. 201 GROVE ROAD THOROFARE, NJ 08086

October 7, 2013

#### VIA ELECTRONIC MAIL

Jeffrey Riedler
Assistant Director
U.S. Securities & Exchange Commission
Division of Corporation Finance
100 F Street, N.E.
Washington, D.C. 20549

Re: Akers Biosciences, Inc. Registration Statement on Form S-1

Filed August 7, 2013 File No. 333-190456

Dear Mr. Riedler:

By letter dated August 26, 2013, the staff (the "Staff," "you" or "your") of the U.S. Securities & Exchange Commission (the "Commission") provided Akers Biosciences, Inc. (the "Company," "we," "us" or "our") with its comments to the Company's Registration Statement on Form 10, filed on July 30, 2013 (the "Registration Statement"). We are in receipt of your letter and set forth below are the Company's responses to the Staff's comments. For your convenience, the comments are listed below, followed by the Company's responses.

#### Summary General

1. Please note that when you file a pre-effective amendment containing pricing-related information, we may have additional comments. As you are likely aware, you must file this amendment prior to circulating the prospectus. Please note that when you file a pre-effective amendment that includes your price range, it must be bona fide. We interpret this to mean that your range may not exceed \$2 if you price up to \$10 and 20% if you price above \$10.

RESPONSE: The Company acknowledges the information presented in the comment above.

- 2. Please confirm that the images included in your registration statement are all of the graphic, visual or photographic information you will be including. If you intend to use any additional images, please provide us proofs of such materials. Please note that we may have comments regarding this material.
  - RESPONSE: We confirm that the images included in our registration statement are all of the graphic, visual or photographic information we will be including.
- 3. Please revise your prospectus to remove your statement on page 1 that you have not independently verified market and industry data from third-party sources and prepared by management. It is not appropriate to directly or indirectly disclaim liability for information in the registration statement.
  - **RESPONSE:** We have revised our prospectus to remove the statement on page 1 that we have not independently verified market and industry data from third-party sources and prepared by management.
- 4. Please include in this part of your disclosure a brief description of your platform technologies, as well as both your marketed products and your pipeline products.
  - RESPONSE: We have included a brief description of our platform technologies, as well as both our marketed products and our pipeline products.
- 5. Please revise your disclosure to provide a summary of the material risks concerning your company and your proposed offering, including but not necessarily limited to the following:
- · Your history of operating losses, including your large accumulated deficit, and your inability to date to achieve profitability;
- · Your reliance on a small number of customers for the vast majority of your revenues;
- · Your need for additional capital to support your operations and the possibility that you may not be able to obtain such capital;
- Your limited marketing resources and sales capabilities and your resulting dependence on distributors; and
- · The disproportionate share ownership by your directors, executive officers and affiliates and the lack of influence your shareholders will have over corporate affairs.

RESPONSE: We have revised our disclosure to provide a summary of the material risks concerning the Company and our proposed offering.

Market Overview, page 3

6. Please identify your products that have received FDA clearance for over-the-counter use and your other products that do not fall within the oversight of regulatory authorities in this section and elsewhere, as necessary, throughout your registration statement.

**RESPONSE:** We have revised our disclosure to identify the products that have received FDA clearance for over-the-counter use and other products that do not fall within the oversight of regulatory authorities.

#### Risk Factors

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," page 7

7. In this risk factor, you state that your net loss for the six months ended June 30, 2013 was \$200,962, which is also reflected in your financial statements. However, your summary financial data on page 6 indicates that your net loss during this period was over \$3.6 million. Please reconcile this discrepancy.

RESPONSE: We have revised our disclosure accordingly.

"Due to our dependence on a limited number of customers and the loss of any such customer would have a material adverse effect...," page 7

8. Please indicate whether you have entered into any agreement with Cardinal Health or Fisher Healthcare with respect to the distribution of your PIFA Heparin/PF4 Rapid Assays. If so, please describe the material terms of any such agreement and file the agreement as an exhibit to your registration statement or provide an analysis as to why your business is not substantially dependent on any such agreement.

**RESPONSE:** We have revised our disclosure to indicate that we have entered into distribution agreements with Cardinal Health and Fisher Healthcare with respect to our PIFA Heparin/PF4 Rapid Assays and described the material terms of those agreements. The agreements have been filed as exhibits to the registration statement.

"If we fail to obtain regulatory approval in foreign jurisdictions...," page 10

9. Please identify the specific foreign jurisdictions in which you plan to market your products.

RESPONSE: We have revised our disclosure to identify specific jurisdictions in which we plan to market 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," page 10

10. The final two paragraphs in this risk factor relate to meeting certain regulatory requirements outside of the Federal Food, Drug and Cosmetic Act. Please include these two paragraphs under a separate risk factor heading discussing risks stemming from a failure to meet the regulatory requirements in foreign markets. You should also list here and wherever else appropriate the six products for which you have received CE marks.

**RESPONSE:** We have revised our disclosure to include a separate risk factor discussing risks stemming from failure to meet the regulatory requirements in foreign markets. Additionally, we have listed the six products for which we have received CE marks.

"Clinical trials that may be required to support regulatory submissions in the United States and in international markets are expensive . . .," page 11

11. Please include in this risk factor the amount that you estimate you will spend on R&D over the next fiscal year.

**RESPONSE:** We have revised our disclosure accordingly.

"The results of our clinical trials may not support either further clinical development of the commercialization of our product candidates," page 12

12. Please explain in this risk factor that each medical device marketed in the United States must receive a 510(k) clearance from the Food and Drug Administration.

RESPONSE: We have revised our disclosure accordingly.

"Modification 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," page 12

13. Please briefly explain the term "PMA approval" in this risk factor.

RESPONSE: We have revised our disclosure accordingly.

"We may not have sufficient resources to effectively introduce and market our products, which could materially harm our operating results," page 13

14. The last two sentences of this risk factor appear to have been included in error. Please revise your risk factor accordingly.

**RESPONSE:** We have revised our disclosure accordingly.

15. Please consider combining this risk factor with the final risk factor on this page as both risk factors appear to relate to the same issue. Also, in relation to your limited sales capabilities, please revise your risk factor to note that you reduced your account executive sales force by 40% during the six month period ended June 30, 2013, discuss the reasons for this decision, and highlight any resulting impact on your sales efforts.

RESPONSE: We have combined the risk factors and revised our disclosure to note the reasons for our reduction in sales force and its impact on our sales efforts.

"We may incur substantial costs as a result of litigation or other proceedings relating to patent or other intellectual property rights ...." page 19

16. Please include in this risk factor examples of such litigation that has been filed against you or any of your founders, executive officers, and/or directors, if any.

RESPONSE: We have revised our disclosure accordingly.

"We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employees," page 20

17. Please include in this risk factor examples of such claims made against your employees, if any.

RESPONSE: To date, there have been no such claims made against our employees.

"If we deliver products with defects, we may be subject to product recalls or negative publicity...,"page 21

18. Please disclose the amount of product liability insurance you have obtained.

RESPONSE: We have revised our disclosure to indicate that we have product liability insurance in the amount of \$10,000,000.

"There can be no assurance that our shares will be listed on the NASDAQ Capital Market . . .," page 23

19. Please note in this risk factor that you may not yet qualify for listing on NASDAQ and that you will need to take certain measures to do so, including effecting a reverse split of your common shares.

**RESPONSE:** We have noted in this risk factor that we may not yet qualify for listing on NASDAQ and that we will need to take certain measures to do so, including effecting a reverse split of our common shares.

"We will incur significant costs as a result of being a publicly traded company . . .," page 27

20. Please include in this risk factor, to the extent practicable, an estimate of the annual costs associated with being a public company.

RESPONSE: We have revised our disclosure accordingly.

"A sale of a substantial number of shares of the common stock...," page 27

21. Please revise your risk factor heading to note that investors in the offering may experience immediate dilution of their ownership following completion of the offering.

RESPONSE: We have revised the risk actor heading to note that investors in the offering may experience immediate dilution of their ownership following completion of the offering.

#### Dilution, page 30

22. You state on page 70 that the holder of the preferred stock has agreed to convert such shares into 50,000,000 shares of common stock immediately prior to the consummation of this offering. Please revise the presentation to separately disclose the effect of the conversion of preferred stock to common stock.

**RESPONSE:** We have revised our disclosure accordingly

Management's Discussion and Analysis of Financial Condition and Results of Operations, page 32

23. Please describe the equity financing you have relied upon over the last two years.

**RESPONSE**: We have revised our disclosure to indicate that the Company has in large part relied on equity financing to fund its operations, raising \$3,200,000 in 2011 in a secondary public offering, \$675,000 in private placements in 2012 and \$1,600,000 in private placements in 2013.

#### General and Administrative Expenses, page 34

24. Please disclose why you wrote-off the long-term note receivable of \$151,569 from ChubeWorkx in June 2012. In addition, you state on page F-14 that accounts receivable of \$1,041,388 was due from ChubeWorkx at June 30, 2013. Please clarify why you believe that amount is collectible.

**RESPONSE:** We have revised our disclosure to indicate that the long-term note receivable of \$151,569 arose from sales to en(10) prior to entering the license and supply agreement with Chubeworkx in June 2012. The June 2012 agreement, among other things, discharged all prior agreements and all liabilities arising from prior transactions. The license and supply agreement was amended in June 2013 to include the North American region. The current accounts receivable arose from products delivered in 2013 and are within credit terms as of June 30, 2013.

25. Please explain why you recorded bad debt expense of only \$9,047 in 2012, given bad debt expense of \$1,650,185 in 2011. Revise your disclosure accordingly.

**RESPONSE:** The bad debt expense of \$1,650,185 in 2011 represents an increase in the allowance for doubtful accounts due from a foreign customer who entered bankruptcy proceedings in 2011 and thus collection was doubtful. The receivable was written off in 2012 with a corresponding reduction in the allowance. We have revised our disclosure accordingly.

#### Research and Development Expenses, page 34

26. Please provide a breakdown of research and development expense by major project for each period presented.

RESPONSE: The Company does not currently track R&D expenditures by project.

#### Other Income and Expenses, page 35

27. Please explain how you determined the \$99,710 gain on the transaction, involving the sale of (en) 10 in exchange for the expansion of the ChubeWorkx marketing rights and its commitment to purchase 80 million shares of your common stock. Revise your disclosure accordingly.

**RESPONSE**: We have revised our disclosure to indicate that the Company sold its interest in (en)10, the Company's exclusive CHUBE distributor based in the UK, to Chubeworkx for \$100,000; a realized gain of \$99,710. We have determined that the sale of our interest was an independent transaction, unrelated to the extension of the licensing agreement to include North America.

28. Please explain how you determined the \$91,286 gain on the demutualization of your insurer. Revise your disclosure accordingly.

**RESPONSE:** The \$91,286 gain on the demutualization of our insurer represents our share of the demutualization as determined by the insurer. We received a payment of the same amount and since we had expensed off the premiums as and when incurred, a gain equivalent to the proceeds received was recorded. We have revised our disclosure accordingly.

29. Please explain your accounting treatment for the re-acquisition of technology from Pulse and the forgiveness of its obligations to you, as disclosed on page F-28, and quantify the related impact on your operating results for 2011. Revise your disclosure accordingly.

**RESPONSE:** The technology was booked at fair value as of April 8, 2011. The fair value was determined to be \$2,062,410 which was equal to the consideration given up to reacquire the technology from Pulse. The company accounted for this transaction by debiting Intangible Assets for \$2,062,410, debiting deferred revenue for \$155,311 and crediting long-term receivable for \$2,217,721. There was no impact from this transaction on our 2011 operating results.

#### Critical Accounting Policies, page 38

30. We note that you have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. Please include a statement in your critical accounting policy disclosures which explains that this election allows you to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. Please also state that your financial statements may not be comparable to companies that comply with public company effective dates.

**RESPONSE:** We have revised our disclosure to note that we have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. We have included a statement in our critical accounting policy disclosures which explains that this election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. We have also stated that our financial statements may not be comparable to companies that comply with public company effective dates.

#### Revenue Recognition, page 39

- 31. Please disclose in the notes to the financial statements your accounting policy for estimates of items that reduce gross revenue such as product returns, chargebacks, customer rebates and other discounts and allowances. In addition, please provide us proposed disclosure to address the following:
  - · Nature and amount of each accrual at the balance sheet date;
  - The factors that you consider in estimating each accrual such as historical return of products, levels of inventory in the distribution channel, etc.;
  - To the extent that information you consider in the preceding bullet is quantifiable, disclose both quantitative and qualitative information and to what extent information is from external sources (e.g., end-customer prescription demand, third-party market research data comparing wholesaler inventory levels to end-customer demand). For example, in discussing your estimate of product that may be returned, consider disclosing and discussing, preferably by product and in tabular format, the total amount of product (in sales dollars) that could be potentially be returned as of the balance sheet date;

- · Include a roll forward of the liability for each estimate for each period presented showing the following:
  - o Beginning balance,
  - o Current provision related to sales made in current period,
  - o Current provision related to sales made in prior periods,
  - o Actual returns or credits in current period related to sales made in current period,
  - o Actual returns or credits in current period related to sales made in prior periods, and
  - o Ending balance; and
- · In your discussion of results of operations for the period to period revenue comparisons, discuss the amount of and reason for fluctuations for each type of reduction of gross revenue (i.e. product returns, chargebacks, customer rebates and other discounts and allowances) including the effect that changes in your estimates of these items had on your revenues and operations.

**RESPONSE:** The Company does not accept returns nor offer chargebacks or rebates. One customer is entitled to a payment discount, but the amount is immaterial (less than \$1,000 at any period end). Footnote 3(i) Revenue Recognition in the notes to the financial statements as of and for the year ended December 31, 2012 has been updated accordingly.

#### **Business**

#### Product Portfolio, page 43

32. Please indicate which of your marketed or pipeline products, if any, are required or are expected to require clinical trials to support your 510(K) submission. Please provide disclosure that describes these trials, if applicable.

**RESPONSE:** We have revised our disclosure to indicate that 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), the Company does not anticipate needing to fund additional clinical trials to facilitate or initiate product marketing in other international regions thus far.

33. Please indicate whether the products marketed under the PIFA platform have received FDA 510(k) approval. If any have not, please describe the exemption you relied upon.

RESPONSE: We have revised our disclosure accordingly

Distribution, page 48

- 34. Please amend your disclosure to identify the material terms of your License and Supply Agreement with Chubeworkx Guernsey Limited, including the following:
  - · continuing obligations of both parties under the agreement;
  - · payment obligations (including applicable any royalties to be paid on product sales);
  - · duration of the agreement; and,
  - any termination provisions.

In addition, we note that you filed an amendment to your License and Supply Agreement with Chubeworkx as Exhibit 10.4 to the registration statement but that you have not filed the original agreement between the parties. Please amend your registration statement to also include your original agreement with Chubeworkx as an exhibit.

RESPONSE: We have revised our disclosure accordingly and have included the original agreement with Chubeworkx (as successor to Sono International Limited) as an exhibit to the amended registration statement.

#### Intellectual Property, page 49

35. In this disclosure, please list all of your material patents, the products to which they relate, their expiration dates, and their jurisdictions. Please also consider indicating the type of protection you have under each patent, e.g. composition of matter, use or process.

RESPONSE: We have revised our disclosure accordingly.

# Principal Stockholders, page 67

36. Please include footnote disclosure indicating the individual(s) who have voting and/or investment power over the common shares held by Chubeworkx Guernsey Limited and Legal & General Group plc.

RESPONSE: We have revised our disclosure accordingly. Please note that Legal & General Group plc. no longer holds shares in the Company.

#### <u>Shares Eligible for Future Sale</u> <u>Lock-Up Arrangements, page 72</u>

37. Please file a copy of the form lock-agreement as an exhibit to your registration statement. If it is to be filed as an exhibit to your underwriting agreement, please confirm this for us.

RESPONSE: The form lock-up agreement will be filed as an exhibit to the Underwriting Agreement which will be filed as an exhibit to a subsequent amendment to the registration statement.

#### Financial Statements

General

38. Please revise to disclose all related party transactions on the face of the financial statements and/or notes, as required by Rule 4-08(k) of Regulation S-X and ASC 850-10-50

**RESPONSE:** We have revised our disclosure accordingly.

Condensed Consolidated Financial Statements for the Six Months Ended June 30, 2013 and 2012

Notes to Condensed Consolidated Financial Statements

Note 4-Note Receivable, page F-9

39. Please clarify here and on page F-26 that this note was repaid in cash and that it was from a related party.

RESPONSE: We have revised the note on page F-9 and F-26 to indicate that the note was paid in cash and that it was a related party

#### Note 11-Share-Based Payments, page F-10

40. You disclose on page 61 that 7,000,000 warrants were cancelled in 2013. Please revise to clarify how this cancellation is reflected in the table or clarify in the notes to the financial statements that these warrants were cancelled subsequent to the balance sheet date.

RESPONSE: We have revised Note 19 Subsequent Events to indicate that these warrants were cancelled in August 2013.

#### Note 18-Other Income, page F-14

41. Please clarify that \$91,286 of the miscellaneous income represents the gain from the demutualization of your insurer as stated on page 35. In addition, clarify the nature of this gain and the accounting treatment thereof.

RESPONSE: \$91,286 on page 35 refers to "Gain from demutualization of insurance carrier". The nature and the accounting treatment of this gain is explained in our reply to your comment number 28. We have revised the language on page 35 accordingly.

The other income in Note 18 on page F-14 does not include the above mentioned gain of \$91,286 as it is reported under the line item gain from demutualization of insurance carrier.

Miscellaneous income of \$91,905 included in other income in Note 18 on page F-14 represents reversal of accounts payable dating back to 2004 which we believe are no longer valid obligations of the Company.

#### Note 19-Subsequent Events, page F-14

42. Please disclose any equity issuances made subsequent to the balance sheet date, such as common stock, preferred stock, options, warrants, etc. Provide us an analysis of how you determined the fair value of the common stock and your intended accounting treatment for any transactions. Disclose the reasons for any differences between the fair value used for the equity issuances and your anticipated IPO price.

RESPONSE: No additional equity issuances have been made.

Consolidated Financial Statements for Years Ended December 31, 2012 and 2011
Notes to Consolidated Financial Statements
Note 3-Significant Accounting Policies
(i) Revenue Recognition, page F-24

43. You state that revenue is allocated to the separate elements based on the relative fair value. Please clarify in the note how your policy complies with ASU 2009-13, which states that arrangement consideration shall be allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price.

RESPONSE: We have revised our disclosure to indicate that revenue is allocated to the separate elements based on relative selling prices.

# Note 12-Equity, page F-31

44. Please explain your planned accounting treatment for the \$500,000 one-time payment to be received upon conversion of the preferred stock.

RESPONSE: We will account for the conversion as a standard equity transaction, debit preferred shares (\$225,000), debit cash (\$500,000) and credit common shares (\$725,000).

45. Please clarify why you believe the 30,000,000 common stock and 10,000,000 preferred stock issued to Thomas Knox on September 14, 2012 have been recorded at fair value. In addition, please tell us what consideration was given to recording a beneficial conversion feature for the convertible preferred stock. Your disclosure on page 66 indicates that the conversion rate is equivalent to .0145 per common share. Refer to ASC 470-20-30.

**RESPONSE:** At the time of the transaction, the common stock is traded on the AIM Market of the London Stock Exchange ("AIM"). The market price of the common stock as reported on AIM on September 14, 2012 was \$0.012/share and the common shares were issued at \$0.015, a premium. The 10,000,000 shares of preferred stock are convertible into 50,000,000 shares of common stock. The conversion price was deemed to be \$0.145 which is higher than the \$0.012 fair value of the common stock on the date of the agreement and thus it was deemed that there was no beneficial conversion feature. The \$0.0145 conversion price was arrived by taking the proceeds of the preferred shares \$775,000 (\$225,000 original proceeds plus \$500,000 due at conversion) divided by the 50,000,000 shares of common stock.

#### Note 16-Commitments, page F-35

46. Please disclose the information required by ASC 450-20-50. Also, include an explanation of the legal settlement payable, described on page F-29.

**RESPONSE:** On April 18, 2012 the Company agreed to an arbitration settlement of \$137,791 for disputed royalties. The settlement is to be paid over 12 months, with an initial payment of \$50,000 and 11 equal payments of \$7,981.

On October 16, 2012 the Company agreed to an arbitration settlement of \$118,000 for disputed licensing fees. The settlement is to be paid over 13 months, with an initial payment of \$18,000 and 12 equal payments of \$8,333.

We have revised Note 9 on page F-10 and Note 9 on page F-28 accordingly.

#### Note 18-Subsequent Events, page F-36

47. You disclose that on June 13, 2013, simultaneous with entering into the Amended License and Supply Agreement, the Company and Chubeworkx entered into a purchase agreement, pursuant to which Chubeworkx purchased 80,000,000 shares of the Company's common shares for an aggregate purchase price of \$1,600,000. You also state on page 33 that on June 13, 2013, ABI announced that the Company had extended Chubeworkx' exclusive territory in return for selling its equity ownership of (en) 10 to Chubeworkx for \$100,000. As these transactions appear to be done simultaneously, it appears you should consider all of these transactions together when determining how to record the revenue. Please revise to clarify the accounting treatment. Refer to ASC 605-25-3. Provide the required disclosures under ASC 605-25-50. If you believe any of the deliverables have standalone value, please clarify the basis for your conclusions. The disclosure has been amended accordingly.

**RESPONSE:** The sale of en(10) to Chubeworkx for \$100,000 was an independent transaction from the extension of the licensing agreement to include North America. We have concluded that there is no stand-alone value to the extension of the territory as we and Chubeworkx are still developing appropriate marketing plans for the region.

48. The purchase price of the 80,000,000 shares, issued in June 2013, appears to equate to \$0.02 per share. Please tell us how the \$0.02 per share price compares to the fair value of your common stock on the date of this transaction. Provide additional disclosure in the filing to explain the difference between \$0.02 and your anticipated IPO price. We may have further comments once the IPO price has been set.

RESPONSE The \$0.02/share price is equivalent to fair value on June 12, 2013. The daily trading range of the stock on the AIMwas \$0.019 to \$0.021 per share.

Further, the Company acknowledges that:

- (1) should the Commission or the Staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing:
- (2) the action of the Commission or the Staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- (3) the Company may not assert Staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Very Truly Yours,

/s/ Thomas A. Nicolette

Thomas A. Nicolette President and Chief Executive Officer Akers Biosciences, Inc.