

Akers Biosciences Inc
Form 10-Q
November 14, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended: **September 30, 2016**

OR

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

For the transition period from _____ to _____

Commission File No. 333-190456

AKERS BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

New Jersey **22-2983783**
(State or other jurisdiction (IRS Employer
of incorporation) Identification No.)

201 Grove Road

Thorofare, NJ 08086

(Address of principal executive offices)

(856) 848-2116

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months, and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Sec.232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files. Yes ☒ No ☐

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

Large accelerated filer ☐ Accelerated filer ☐
Non-accelerated filer ☐ Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 8, 2016, there were 5,452,545 shares outstanding of the registrant's common stock.

TABLE OF CONTENTS

PART I – FINANCIAL INFORMATION

Item 1.	<u>Financial Statements</u>	F-1
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	3
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	18
Item 4.	<u>Controls and Procedures</u>	18

PART II – OTHER INFORMATION

Item 1.	<u>Legal Proceedings</u>	18
Item 1A.	<u>Risk Factors</u>	19
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	20
Item 3.	<u>Defaults Upon Senior Securities</u>	20
Item 4.	<u>Mine Safety Disclosures</u>	20
Item 5.	<u>Other Information</u>	20
Item 6.	<u>Exhibits</u>	20
	<u>Signatures</u>	21

PART I – FINANCIAL INFORMATION**Item 1. Financial Statements.****AKERS BIOSCIENCES, INC. AND SUBSIDIARIES****Condensed Consolidated Balance Sheets****September 30, 2016 and December 31, 2015**

	2016 (unaudited)	2015 (audited)
ASSETS		
Current Assets		
Cash	\$ 195,860	\$ 402,059
Marketable Securities	599,942	4,025,104
Trade Receivables, net	738,160	609,195
Trade Receivables - Related Party, net	31,892	31,512
Deposits and other receivables	29,722	95,577
Inventories, net	1,942,516	1,131,654
Prepaid expenses	94,261	185,967
Prepaid expenses - Related Party	214,250	-
Total Current Assets	3,846,603	6,481,068
Non-Current Assets		
Prepaid expenses - Related Party	276,385	-
Property, Plant and Equipment, net	245,553	251,145
Intangible Assets, net	1,344,552	1,472,883
Other Assets	66,813	66,813
Total Non-Current Assets	1,933,303	1,790,841
Total Assets	\$5,779,906	\$8,271,909
LIABILITIES		
Current Liabilities		
Trade and Other Payables	\$ 1,249,733	\$ 1,668,731
Trade and Other Payables - Related Party	59,673	-
Total Current Liabilities	1,309,406	1,668,731

Total Liabilities	1,309,406	1,668,731
STOCKHOLDERS' EQUITY		
Convertible Preferred Stock, No par value, 50,000,000 shares authorized, no shares issued and outstanding as of September 30, 2016 and December 31, 2015	-	-
Common Stock, No par value, 500,000,000 shares authorized, 5,452,545 and 5,425,045 issued and outstanding as of September 30, 2016 and December 31, 2015	100,886,637	100,785,408
Deferred Compensation	(29,891)	-
Accumulated Deficit	(96,383,706)	(94,175,999)
Accumulated Other Comprehensive Income/(Loss)	(2,540)	(6,231)
Total Stockholders' Equity	4,470,500	6,603,178
Total Liabilities and Stockholders' Equity	\$5,779,906	\$8,271,909

See accompanying notes to these condensed consolidated financial statements.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES**Condensed Consolidated Statements of Operations and Comprehensive Income****(unaudited)**

	Three months ended September 30		Nine months ended September 30	
	2016	2015	2016	2015
Revenues:				
Product Revenue	\$613,198	\$169,473	\$2,307,708	\$1,325,887
License Revenue	-	-	-	15,000
License Revenue - Related party	-	-	-	305,556
Total Revenues	613,198	169,473	2,307,708	1,646,443
Cost of Sales:				
Product Cost of Sales	(236,700)	(177,952)	(713,576)	(745,319)
Gross Income/(Loss)	376,498	(8,479)	1,594,132	901,124
Administrative Expenses	558,293	760,336	2,298,099	2,341,300
Sales and Marketing Expenses	408,248	725,832	1,647,003	1,854,623
Sales and Marketing Expenses - Related party	117,949	-	117,949	-
Research and Development Expenses	247,578	319,646	932,858	1,003,445
(Reversal of Allowance for) Bad Debt Expenses				
- Related parties	(1,299,609)	-	(1,299,609)	864,000
Impairment of Non-Current Assets	-	466,476	-	466,476
Amortization of Non-Current Assets	42,777	64,643	128,331	193,929
Income/(Loss) from Operations	301,262	(2,345,412)	(2,230,499)	(5,822,649)
Other (Income)/Expenses				
Foreign Currency Transaction Loss	(3,629)	2,001	1,189	7,971
Interest and Dividend Income	(5,264)	(20,478)	(23,981)	(89,647)
Other Income	-	(42)	-	(6,052)
Total Other Income	(8,893)	(18,519)	(22,792)	(87,728)
Income/(Loss) Before Income Taxes	310,155	(2,326,893)	(2,207,707)	(5,734,921)
Income Tax Benefit	-	-	-	-
Net Income/(Loss) Attributable to Common Stockholders	310,155	(2,326,893)	(2,207,707)	(5,734,921)
Other Comprehensive Income				
Net Unrealized (Losses)/Gains on Marketable Securities	(2,837)	8,539	3,691	28,964
Total Other Comprehensive (Loss)/Income	(2,837)	8,539	3,691	28,964

Edgar Filing: Akers Biosciences Inc - Form 10-Q

Comprehensive Income/(Loss)	\$307,318	\$(2,318,354)	\$(2,204,016)	\$(5,705,957)
Basic income/(loss) per common share	\$0.06	\$(0.45)	\$(0.41)	\$(1.12)
Diluted income/(loss) per common share	\$0.06	\$(0.45)	\$(0.41)	\$(1.12)
Weighted average basic common shares outstanding	5,434,212	5,144,837	5,428,859	5,138,573
Weighted average diluted common shares outstanding	5,508,545	5,144,837	5,428,859	5,138,573

See accompanying notes to these condensed consolidated financial statements.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES**Condensed Consolidated Statement of Changes in Stockholder's Equity****For nine months ended September 30, 2016**

	Common Shares Issued and Outstanding	Common Stock	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Equity
Balance at December 31, 2015 (audited)	5,425,045	\$ 100,785,408	\$ -	\$(94,175,999)	\$ (6,231)	\$ 6,603,178
Net loss for the period	-	-	-	(2,207,707)	-	(2,207,707)
Issuance of restricted stock to officers	27,500	54,725	(54,725)	-	-	-
Amortization of deferred compensation	-	-	24,834	-	-	24,834
Options issued to key employees	-	22,828	-	-	-	22,828
Options issued for services	-	23,676	-	-	-	23,676
Net unrealized gain on marketable securities	-	-	-	-	3,691	3,691
Balance at September 30, 2016 (unaudited)	5,452,545	\$ 100,886,637	\$ (29,891)	\$(96,383,706)	\$ (2,540)	\$ 4,470,500

See accompanying notes to these condensed consolidated financial statements.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES**Condensed Consolidated Statements of Cash Flows****For nine months ended September 30, 2016 and 2015****(unaudited)**

	2016	2015
Cash flows from operating activities		
Net loss for the period	\$(2,207,707)	\$(5,734,921)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued income on marketable securities	13,380	8,387
Depreciation and amortization	221,946	241,512
Impairment of non-current assets	-	466,476
Allowance for doubtful accounts	(1,153,413)	864,000
Gain from other non-operating activities	-	(6,010)
Amortization of deferred compensation	24,834	-
Non-cash share based compensation - options	22,828	-
Non-cash share based payments for services - options	23,676	-
Changes in assets and liabilities:		
(Increase)/decrease in trade receivables	(275,541)	45,063
Decrease in notes receivables - related party	-	176,156
(Increase)/decrease in deposits and other receivables	65,855	(60,141)
Increase in inventories	(60,862)	(50,047)
(Increase)/decrease in prepaid expenses	91,706	(60,529)
Decrease in prepaid expenses - related party	58,974	-
Increase/(decrease) in trade and other payables	(418,998)	415,163
Increase in trade and other payables - related party	59,673	-
Decrease in deferred revenue - related party	-	(305,556)
Net cash used in operating activities	(3,533,649)	(4,000,447)
Cash flows from investing activities		
Purchases of property, plant and equipment	(88,023)	(60,254)
Purchases of marketable securities	(37,360)	(52,319)
Investment in Hainan Savy Akers Biosciences, Ltd. joint venture	-	(64,091)
Proceeds from other non-operating activities	-	6,010
Proceeds from sale of marketable securities	3,452,833	4,108,632
Net cash provided by investing activities	3,327,450	3,937,978
Net decrease in cash	(206,199)	(62,469)
Cash at beginning of period	402,059	455,841
Cash at end of period	\$195,860	\$393,372

Supplemental Schedule of Non-Cash Financing and Investing Activities

Issuance of restricted common stock grant to an officer	\$54,725	\$-
---	----------	-----

Edgar Filing: Akers Biosciences Inc - Form 10-Q

Net unrealized gains on marketable securities	\$3,691	\$28,964
Reclassification of note receivable to inventory	\$750,000	\$-
Reclassification of note receivable to prepaid expense	\$549,609	\$-
Issuance of restricted common share grants to directors and officers accrued in 2014	\$-	\$697,300

See accompanying notes to these condensed consolidated financial statements.

F-4

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

Note 1 – Nature of Business

(a) Reporting Entity

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“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 three and nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. 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, 2015 included in Form 10-K of Akers Biosciences, Inc. and Subsidiaries (“the Company”).

The condensed consolidated financial statements include two dormant subsidiaries, Akers Acquisition Sub, Inc. and Bout Time Marketing Corporation. All material intercompany balances 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.

Note 2 - Basis of Presentation and Significant Accounting Policies

(a) Basis of Presentation

The condensed consolidated financial statements of the Company are prepared in U.S. Dollars and in accordance with GAAP.

The Company is an emerging growth company as the term is used in The Jumpstart Our Business Startups Act enacted on April 5, 2012 and has elected to comply with certain reduced public company reporting requirements.

F-5

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

(b) Use of Estimates

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

(c) Functional and Presentation Currency

These condensed 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 condensed consolidated statement of operations.

(d) Comprehensive Income/(Loss)

The Company follows Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) 220 in reporting comprehensive income (loss). Comprehensive income is a more inclusive financial reporting methodology that includes disclosure of certain financial information that historically has not been recognized in the calculation of net income.

(e) Cash and Cash Equivalents

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

consolidated balance sheet.

F-6

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

(f) Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, receivables and trade and other payables. The carrying value of cash and cash equivalents, receivables and trade and other payables approximate their fair value because of their short maturities. The fair value of marketable securities is described in Note 2(g).

(g) Fair Value Measurement – Marketable Securities

The framework for measuring fair value provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1) and the lowest priority to unobservable inputs (level 3). The three levels of the fair value hierarchy under FASB ASC 820 are described as follows:

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

Level 2 Inputs to the valuation methodology include

quoted prices for similar assets or liabilities in active markets;

quoted prices for identical or similar assets or liabilities in inactive markets;

inputs other than quoted prices that are observable for the asset or liability;

inputs that are derived principally from or corroborated by observable market data by correlation or other means.

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

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

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

F-7

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

(h) 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.

As of September 30, 2016 and December 31, 2015, allowances for doubtful accounts were \$1,010,196 and \$864,000. Allowances charged for doubtful accounts amounted to \$- for the three and nine months ended September 30, 2016 and September 30, 2015.

(i) Concentration of Credit Risk

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

Substantially all of the Company's cash is maintained with Fulton Bank of New Jersey and Bank of America. The funds are insured by the Federal Deposit Insurance Corporation up to a maximum of \$250,000 per account or instrument, but are otherwise unprotected. The Company placed \$181,216 and \$369,525 with Fulton Bank of New Jersey, \$10,604 and \$28,494 with Bank of America and \$4,040 with PayPal as of September 30, 2016 and December 31, 2015.

Concentration of credit risk with respect to trade receivables exists as approximately 80% of its revenue was generated by three customers for the nine months ended September 30, 2016. These customers accounted for 38% of gross trade receivables (including related parties) as of September 30, 2016. In order to limit such risks, the Company performs ongoing credit evaluations of its customers' financial condition.

(j) 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.

(k) Property, Plant and Equipment

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

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 condensed consolidated statement of operations.

Depreciation is recognized in the condensed consolidated statement of operations on the accelerated basis over the estimated useful lives of the property, plant and equipment.

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

	Useful Life (in years)
Plant and equipment	5-12
Furniture and fixtures	5-10
Computer equipment & software	3-5
Leasehold Improvements	Shorter of the remaining lease or estimated useful life

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

(I) Intangible Assets

(i) Patents and Trade Secrets

The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person’s breath, blood, urine and saliva. Propriety protection for the Company’s products, technology and process is important to its competitive position. As of September 30, 2016, the Company has ten patents from the United States Patent Office in effect (9,383,368; 7,896,167; 8,097,171; 8,003,061; 8,425,859; 8,871,521; 8,808,639; D691,056; D691,057 and D691,058). Other patents are in effect in Australia through the Design Registry (348,310; 348,311 and 348,312), the Community Trade Mark in the European Union ((OHIM) 002216895-0001; 002216895-0002 and 002216895-0003), in Hong Kong (HK11004006) and in Japan (1,515,170; 4,885,134; 4,931,821 and 5,775,790).

Patents are in the national phase of prosecution in many Patent Cooperation Treaty participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the U.S., European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

F-9

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

(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 the statement of operations the year the patent is rejected.

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

(iii) Other Intangible Assets

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

(iv) Amortization

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

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

(m) Recoverability of Long-lived Assets

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

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

(n) Investments

In accordance with FASB ASC 323, the Company recognizes investments in joint ventures based upon the Company's ability to significantly influence the operational or financial policies of the joint venture. An objective judgment of the level of influence is made at the time of the investment based upon several factors including, but not limited to the following:

- a) Representation on the Board of Directors
- b) Participation in policy-making processes
- c) Material intra-entity transactions
- d) Interchange of management personnel
- e) Technological dependencies
- f) Extent of ownership and the ability to influence decision making based upon the makeup of other owners when the shareholder group is small.

The Company follows the equity method for valuing investments in joint ventures when the existence of significant influence over operational and financial policy has been established, as determined by management; otherwise, the Company will value these investments using the cost method.

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

On March 9, 2015, the Company contributed capital of \$64,675 in Hainan Savy Akers Biosciences, Ltd., a company incorporated in the People's Republic of China, resulting in a 19.9% ownership interest. The contribution was adjusted

downward to \$64,091 on April 8, 2015; the net effect of the currency conversion when the contribution was processed in Hainan. This is included in other assets in the condensed consolidated balance sheet as of September 30, 2016 and is accounted for using the cost method.

(o) Revenue Recognition

In accordance with FASB ASC 605, the Company recognizes revenue when (i) persuasive evidence of a customer or distributor arrangement exists, (ii) a retailer, distributor or wholesaler receives the goods and acceptance occurs, (iii) the price is fixed or determinable, and (iv) the collectability of the revenue is reasonably assured. Subject to these criteria, the Company recognizes revenue from product sales when title passes to the customer based on shipping terms. The Company typically does not accept returns nor offer charge backs or rebates except for certain distributors. Revenue recorded is net of any discount, rebate or sales return. No accrual for estimated sales returns are necessary as of September 30, 2016 and December 31, 2015.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

The Company instituted a significant price increase for certain PIFA products effective May 1, 2015. In an effort to phase in the increase for existing customers, the Company is providing a rebate to its distributors for the price increase through April 30, 2016 for their existing customer base as of April 30, 2015. The Company has recorded rebates of \$84,128 and \$299,781, which is a reduction of revenue, for the three and nine months ended September 30, 2016 and \$70,282 and \$362,150 for the three and nine months ended September 30, 2015 for this program. Accounts receivable will be reduced when the rebates are applied by the customer.

Effective May 1, 2016, the Company completed the implementation of pricing based upon a standardized adjusted dealer cost model. The program allows for pre-existing end-user customers to negotiate pricing contracts directly with the Company or through the distributor network. Rebates are available to the distributors to mitigate the effect of any discounts on these contracts. As of September 30, 2016 and December 31, 2015, accrued rebates amounted to \$255,954 and \$223,542.

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

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

(p) Income Taxes

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

(q) Shipping and Handling Fees and Costs

The Company charges actual shipping plus a handling fee to customers, which amounted to \$12,321 and \$42,754 for the three and nine months ended September 30, 2016 and \$10,998 and \$43,776 for the three and nine months ended September 30, 2015. These fees are classified as part of product revenue in the condensed consolidated statements 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 \$19,418 and \$88,427 for the three and nine months ended September 30, 2016 and \$15,590 and \$82,996 for the three and nine months ended September 30, 2015.

F-12

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

(r) Research and Development Costs

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

(s) Stock-based Payments

The Company accounts for stock-based compensation under the provisions of FASB ASC 718, “Compensation—Stock Compensation”, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. The Company estimates the fair value of stock-based awards on the date of grant using the Black-Scholes model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the 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-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

The Company estimates the fair value of stock-based awards on the date of grant using the Black-Scholes model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the period which services are to be received. At the end of each financial reporting period, prior to vesting or prior to the completion of services, the fair value of equity based payments will be re-measured and the non-cash expense recognized during the period will be adjusted accordingly. Since the fair value of equity based payments granted to non-employees is subject to change in the future, the amount of the future expense will include fair value re-measurements until the equity based payments are fully vested or the service is completed.

(t) Basic and Diluted Earnings per Share of Common Stock

Basic earnings per common share are based on the weighted average number of shares outstanding during the periods presented. Diluted earnings per share are computed using the weighted average number of common shares plus dilutive common share equivalents outstanding during the period.

Potential common shares consist of restricted shares of common stock, options and warrants. Diluted net income per common share for the three months ended September 30, 2016 included 56,000 units of options and 18,333 units of unvested restricted shares of common stock. Diluted net loss per common share was the same as basic loss per common share for the nine months ended September 30, 2016 and for the three and nine months ended September 30, 2015 since the effect of options and warrants would be anti-dilutive due to the net loss attributable to the common stockholders for the periods. Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive were 203,000 units of options and 18,333 units of unvested restricted shares of common stock for the nine months ended September 30, 2016 and 175,000 units of options for the three and nine months ended September 30, 2015.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

The table below details the calculation of the basic and diluted income/(loss) per share for the three and nine months ended September 30, 2016 and 2015:

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Numerator				
Net Income/(Loss)	\$310,155	\$(2,326,893)	\$(2,207,707)	\$(5,734,921)
Denominator				
Weighted Average Basic Common Shares Outstanding	5,434,212	5,144,837	5,428,859	5,138,573
Add the Dilutive Effect of Stock Options	56,000	-	-	-
Unvested Restricted Shares	18,333	-	-	-
Weighted Average Basic and Diluted Common Shares Outstanding	5,508,545	5,144,837	5,428,859	5,138,573
Net Income/(Loss) per Share				
Basic	\$0.06	\$(0.45)	\$(0.41)	\$(1.12)
Diluted	\$0.06	\$(0.45)	\$(0.41)	\$(1.12)

(u) Recently Adopted Accounting Pronouncements

As of September 30, 2016 and for the period then ended, there were no recently adopted accounting pronouncements that had a material effect on the Company's financial statements.

(v) Recently Issued Accounting Pronouncements not Yet Adopted

As of September 30, 2016, there are no recently issued accounting standards not yet adopted which would have a material effect on the Company's financial statements through 2017.

Note 3 – Marketable Securities

Following is a description of the valuation methodologies used for assets measured at fair value as of September 30, 2016 and December 31, 2015.

Money market funds and Corporate and Municipal Securities: Valued using pricing models maximizing the use of observable inputs for similar securities. This includes basing value on yields currently available on comparable securities of issuers with similar credit ratings.

F-14

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

	As of September 30, 2016				
	Cost	Accrued Income	Unrealized Gains	Unrealized Losses	Fair Value
Level 2:					
Money market funds	\$2,966	\$ 17	\$ -	\$ -	\$2,983
Corporate securities	578,308	861	-	(2,560)	576,609
Municipal securities	20,314	16	20	-	20,350
Total Level 2:	601,588	894	20	(2,560)	599,942
Total:	\$601,588	\$ 894	\$ 20	\$ (2,560)	\$599,942

The above securities are classified as available for sale. The securities are valued at fair market value. Maturities of the securities are less than one year. Unrealized gains and losses relating to the available for sale investment securities were recorded in the condensed consolidated statement of changes in stockholders' equity as comprehensive income. The net unrealized loss of \$2,837 and a net unrealized gain of \$3,691 for the three and nine months ended September 30, 2016 and a net unrealized gain of \$5,810 and \$28,965 for the three and nine months ended September 30, 2015 were recorded in the condensed consolidated statement of changes in stockholders' equity as comprehensive income.

As of September 30, 2016, investments in money market funds and corporate securities and municipal securities classified as available for sale mature within one year.

Proceeds from the sale of marketable securities for the three and nine months ended September 30, 2016 were \$950,514 and \$3,452,833 and were \$1,202,311 and \$4,108,632 for the three and nine months ended September 30, 2015. As a result of these sales, a gross gain of \$1,269 and \$3,421 was recorded for the three and nine months ended September 30, 2016 and a gross loss of \$5,213 and \$7,201 was recorded for the three and nine months ended September 30, 2015.

Note 4 - Trade Receivables – Related Party

Trade receivables – related party are made up of amounts due from Hainan Savy Akers Biosciences, a joint venture partner located in the Peoples Republic of China. The amount due is non-interest bearing, unsecured and generally has

a term of 30-90 days.

Note 5 - Inventories

Inventories at September 30, 2016 and December 31, 2015 consists of the following categories:

	2016	2015
Raw Materials	\$396,942	\$348,216
Sub-Assemblies	818,055	786,656
Finished Goods	756,458	25,721
Reserve for Obsolescence	(28,939)	(28,939)
	\$1,942,516	\$1,131,654

For the three and nine months ended September 30, 2016, \$24,965 and \$27,933 were expensed to cost of goods sold for obsolete inventory. For the three and nine months ended September 30, 2015, \$252 was expensed to cost of goods sold for obsolete inventory.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

Note 6 - Property, Plant and Equipment

Property, plant and equipment as of September 30, 2016 and December 31, 2015 are as follows:

	2016	2015
Computer Equipment	\$ 114,771	\$ 100,405
Computer Software	40,681	40,681
Office Equipment	39,959	50,049
Furniture & Fixtures	29,939	29,939
Machinery & Equipment	1,126,134	1,112,060
Molds & Dies	799,202	756,279
Leasehold Improvements	222,593	222,593
	2,373,279	2,312,006
Less		
Accumulated Depreciation	2,127,726	2,060,861
	\$245,553	\$251,145

Depreciation expense was \$65,264 and \$93,615 for the three and nine months ended September 30, 2016 and \$15,938 and \$47,583 for the three and nine months ended September 30, 2015.

The Company disposed of a fully depreciated telephone system with no salvage value during the nine months ended September 30, 2016.

Note 7 - Intangible Assets

Intangible assets as of September 30, 2016 and December 31, 2015 and the movements for the three months then ended are as follows:

	Patents & Trademarks	Distributor & Customer Relationships	Totals
Cost or Deemed Cost			
At December 31, 2015	\$2,626,996	\$ 1,270,639	\$3,897,635
Additions	-	-	-
Disposals	-	-	-
At September 30, 2016	\$2,626,996	\$ 1,270,639	\$3,897,635
Accumulated Amortization			
At December 31, 2015	\$1,154,113	\$ 1,270,639	\$2,424,752
Amortization Charge	128,331	-	128,331
Disposals	-	-	-
At September 30, 2016	\$1,282,444	\$ 1,270,639	\$2,553,083
Net Book Value			
At December 31, 2015	\$1,472,883	\$ -	\$1,472,883
At September 30, 2016	\$1,344,552	\$ -	\$1,344,552

Amortization expense was \$42,777 and \$128,331 for the three and nine months ended September 30, 2016 and \$64,643 and \$193,929 for the three and nine months ended September 30, 2015.

Impairment expense was \$- for the three and nine months ended September 30, 2016 and \$466,476 for the three and nine months ended September 30, 2015.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

Note 8 - Trade and Other Payables and Trade and Other Payables - Related Party

Trade and other payables as of September 30, 2016 and December 31, 2015 are as follows:

	2016	2015
Trade Payables	\$589,108	\$538,449
Accrued Expenses	595,875	1,020,532
Legal Settlements Payable	5,000	50,000
Deferred Compensation	59,750	59,750
	\$1,249,733	\$1,668,731

Trade and other payables – related party as of September 30, 2016 and December 31 2015 are as follows:

	2016	2015
Trade Payables	\$7,607	\$ -
Accrued Expenses	52,066	-
	\$59,673	\$ -

The Company recorded royalty expenses of \$117,949 in the three and nine months ended September 30, 2016 for ChubeWorkx Guernsey Limited (“ChubeWorkx”), a major shareholder, in relation to the settlement of legal claims (Note 12). The expense is included in sales and marketing expenses – related party on the condensed consolidated statement of operations and comprehensive income. As of September 30, 2016, the Company owed ChubeWorkx \$6,908 for the period of August 18, 2016 through September 30, 2016 which was paid on October 20, 2016 and had an accrual of \$52,066 for the period of January 1, 2016 through August 17, 2016 which is payable on January 17, 2017.

As of September 30, 2016, the Company owed Hainan Savy–Akers Biosciences, a joint venture partner, \$699.

Trade and other payables and trade ant other payables – related party are non-interest bearing and are normally settled on 30 day terms.

Note 9 - Share-based Payments

On January 23, 2014, upon effectiveness of the registration statement filed with the SEC, the Company adopted the 2013 Stock Incentive Plan (the “Plan”) which will provide for the issuance of up to 400,000 shares. The purpose of the Plan is to provide additional incentive to those officers, employees, consultants and non-employee directors of the Company and its parents, subsidiaries and affiliates whose contributions are essential to the growth and success of the Company’s business.

F-17

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

On January 9, 2015, the Board of Directors of the Company approved, upon recommendation from the Compensation Committee of the Board, by unanimous written consent the Amended and Restated 2013 Incentive Stock and Award Plan (the “Plan”), which increases the number of authorized shares of common stock subject to the Plan to 800,000 shares.

On September 30, 2016, the Board of Directors increased the number of authorized shares of common stock subject to the Amended and Restated 2013 Incentive Stock and Award Plan to 830,000 shares. As of September 30, 2016, under the 2013 Plan, grants of restricted stock and options to purchase 277,333 shares of common stock have been issued and are unvested or unexercised and 73,292 shares of common stock remain available for grants.

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 the Company’s common stock.

On January 1, 2016, the Company approved the issuance of 12,500 options to purchase common shares to a key consultant for services at an exercise price of \$3.70 per common share with vesting over one year.

On August 9, 2016 the Company approved the issuance of 26,000 options to purchase common shares to two key employees at an exercise price of \$3.25 per common share with vesting over two years.

These options were issued under the Amended and Restated 2013 Incentive Stock and Award Plan. The options have a five-year expiration.

The calculated fair value of the options was distributed to the following categories on the condensed consolidated statement of operations and comprehensive income:

Expense Category	Three months ended		Nine months ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Cost of Goods	\$-	\$-	\$-	\$-
General & Administrative	-	-	-	-
Sales & Marketing	22,828	-	31,069	-
Research & Development	15,435	-	15,435	-
	\$38,263	\$ -	\$46,504	\$ -

The options and warrants issued under the above plan were valued using a Black Scholes option pricing model. The assumptions utilized in calculating the value of the issued options under Black Scholes are as follows:

	2016	2015
Expected option term	5 yrs	n/a
Expected volatility	93.08 %	n/a
Expected dividend yeild	0.00 %	n/a
Risk free interest rate	1.25 %	n/a

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

Qualified option holders may exercise their options at their discretion. Each option granted may be exchanged for a prescribed number of shares of common stock. The following table summarizes the option activities for the nine months ended September 30, 2016:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
<i>Balance at December 31, 2015</i>	220,500	\$ 4.38		
Granted	38,500	3.40		
Exercised	-	-		
Forfeited	-	-		
Canceled/Expired	-	-		
<i>Balance at September 30, 2016</i>	259,000	\$ 4.23		
<i>Exercisable as of September 30, 2016</i>	239,167	\$ 4.31	3.30	\$ 64,853

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$3.36 for the Company's common shares on September 30, 2016. The above intrinsic value represents that of awards with an exercise price below \$3.36.

The total grant date fair value of stock options vested for the three and nine months ended September 30, 2016 was \$35,422 and for the three and nine months ended September 30, 2015 was \$-.

As of September 30, 2016 and December 31, 2015 the Company had 259,000 and 220,500 respectively reserved shares of its common stock for outstanding options.

As of September 30, 2016, there was \$38,444 of unrecognized compensation cost related to outstanding employee stock options.

Note 10 - Equity

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

A restricted stock award is an award of common shares that are subject to certain restrictions during a specified period. Restricted stock awards are independent of option grants and are generally subject to forfeiture if employment terminates prior to the release of the restrictions. The grantee cannot transfer the shares before the restricted shares vest. Shares on non-vested restricted stock have the same voting rights as common stock, are entitled to receive dividends and other distributions thereon and are considered to be currently issued and outstanding. The Company's restricted stock awards vest of a period of one to three years. The Company expenses the cost of the restricted stock awards, which is determined to be the fair market value of the shares at the date of grant, straight-line over the period during which the restrictions lapse. For these purposes, the fair market value of the restricted stock is determined based on the closing price of the Company's common stock on the grant date.

On June 8, 2016, the Company issued 27,500 restricted common shares to an officer in connection with his employment agreement. These shares vest 1/3 immediately on the date of the grant and the remaining 2/3 vests equally on March 1, 2017 and March 1, 2018. The fair value of these shares was \$54,725 and was based on the share price on the date of the grant. \$6,591 and \$24,833 was recorded during the three and nine months ended September 30, 2016 as administrative expense on the condensed consolidated statement of operations and comprehensive income and the remaining \$29,891 was recorded as deferred compensation, a contra equity account, on the condensed consolidated balance sheet as of September 30, 2016.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

Note 11 - Income Tax Expense

There is no income tax expense for the three months ended September 30, 2016 since the income arose from the reversal of an allowance for doubtful collection of a note. This temporary difference has no tax effect for the Company due to the net operating loss carry forwards available.

There is no income tax benefit for the losses for the nine months ended September 30, 2016 and for the three and nine months ended September 30, 2015 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, 2016, the Company had no unrecognized tax benefits, or any tax related interest or penalties. There were no changes in the Company's unrecognized tax benefits during the three and nine months ended September 30, 2016 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, 2012 and thereafter are subject to examination by the relevant taxing authorities.

Note 12 - Related Party Transactions

On June 19, 2012, the Company entered into a 3 year exclusive License & Supply Agreement with ChubeWorkx Guernsey Limited (as successor to SONO International Limited) ("ChubeWorkx") for the purchase and distribution of ABI's proprietary breathalyzers outside North America. ChubeWorkx paid a licensing fee of \$1,000,000 which was recognized over the term of the agreement through September 30, 2015.

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

On February 12, 2016, the Company purchased several manufacturing molds through Hainan Savy – Akers Biosciences, Ltd., the Company’s joint venture partner in the Peoples Republic of China. The total cost of the molds was \$41,073 and is included in property, plant and equipment in the condensed consolidated balance sheet.

F-20

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

On May 25, 2016, the Company ordered additional product molds through Hainan Savy – Akers Biosciences, Ltd. The total cost of the molds was \$27,988 of which \$13,944 was recorded as deposits and other receivables in the condensed consolidated balance sheet.

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

Under the terms of the Settlement Agreement, the Company will recover the full outstanding principal amount in the current fiscal year in the form of \$750,000 of BreathScan® Alcohol Detector inventory – which the Company intends to subsequently sell – and the balance of \$549,609 in cash. Akers Bio established an allowance for this doubtful note in the Company’s financial statements for the year ended December 31, 2015. As a result of the Settlement Agreement, the Company reversed the allowance for doubtful note in the amount of \$1,299,609 which is included in the Condensed Consolidated Statement of Operations and Comprehensive Income for the three and nine months ended September 30, 2016.

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

In return for the Company regaining the full rights to sell breath technology products, under the terms of the Settlement Agreement, ChubeWorkx is entitled to receive a royalty of 5% of the Company’s gross revenues (the “ChubeWorkx Royalty”) until ChubeWorkx has earned an aggregate \$5,000,000, after which point ChubeWorkx will no longer be entitled to receive any royalties from the Company and the Company shall have no further obligation to ChubeWorkx. The Settlement Agreement further allows the Company to retain 50% of the ChubeWorkx Royalty until

the full \$549,609 cash component of the monies owed by ChubeWorkx to the Company as described above has been satisfied. The Company recorded royalty expenses of \$117,949 in the three and nine months ended September 30, 2016 which are included in sales and marketing expenses – related party on the condensed consolidated statement of operations and comprehensive income.

F-21

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

Other terms of the Settlement include: 1) the pledge as security by the Company to ChubeWorkx all Company assets, worthy to satisfy its obligations, including all inventory and receivables, with the exception of (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other equipment; and 2) the grant of voting proxy by ChubeWorkx to the Company which allows the Company to vote ChubeWorkx's shares for corporate formalities under certain conditions.

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

The Company re-classified \$864,000 for an allowance for bad debts in nine months ended September 30, 2015 from general and administrative expenses to (reversal of allowances for) bad debt expense – related party on the condensed consolidated statement of operations and comprehensive income

The Company has begun purchasing plastic and electronic components through Hainan Savy – Akers Biosciences, Ltd (“Hainan Savy”) for use in the production of finished goods. For the three and nine months ended September 30, 2016, these purchases totaled \$79 and \$33,206 respectively. The amount due to Hainan Savy as of September 30, 2016 and December 31, 2015 was \$699 and \$-.

Trade receivables – related party as of September 30, 2016 and December 31, 2015 are \$31,892 and \$31,512. The amounts due are non-interest bearing, unsecured and generally have a term of 30-90 days (Note 4). This receivable is past due and management deemed it fully collectable.

Product revenue – related party for the three and nine months ended September 30, 2016 were \$- and \$380 and were \$12,620 and \$26,963 for the three and nine months ended September 30, 2015. The revenue was the result of sales to Hainan Savy – Akers Biosciences, Ltd, a joint venture partner.

Note 13 - 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.

Rent expense, including related CAM charges, was \$40,290 and \$120,870 for the three and nine months ended September 30, 2016 and 2015.

The Company entered into a 60 month operating lease for equipment with annual rentals of \$6,156 on September 29, 2014. The lease commenced on October 21, 2014 upon the delivery of the equipment.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

The schedule of lease commitments is as follows:

	Building Lease	Equipment Lease	Total
Next 12 Months	\$132,000	\$ 6,156	\$138,156
Next 13-24 Months	132,000	6,156	138,156
Next 25-36 Months	132,000	6,156	138,156
Next 37-40 Months	33,000	513	33,513

Note 14 – Major Customers

For the three months ended September 30, 2016, two customers each generated more than 10% of the Company's product revenue. In aggregate, sales to these customers accounted for 74% of the Company's product revenue. As of September 30, 2016, the amount due from these two customers was \$669,437.

For the nine months ended September 30, 2016, three customers each generated more than 10% of the Company's product revenue. In aggregate, sales to these customers accounted for 80% of the Company's product revenue. As of September 30, 2016, the amount due from these three customers was \$675,838. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

For the three months ended September 30, 2015, two customers each generated more than 10% of the Company's product revenue. In aggregate, sales to these customers accounted for 54% of the Company's product revenue.

For the nine months ended September 30, 2015, two customers each generated more than 10% of the Company's product revenue. In aggregate, sales to these customers accounted for 65% of the Company's product revenue. As of September 30, 2015, the amount due from these two customers was \$397,589.

Note 15 – Major Suppliers

For the three months ended September 30, 2016, one supplier accounted for more than 10% of the Company's purchases. The supplier accounted for 86% of the Company's total purchases. As of September 30, 2016, the amount due to the supplier was \$6,908.

For the nine months ended September 30, 2016, one supplier accounted for more than 10% of the Company's purchases. The supplier accounted for 61% of the Company's total purchases. As of September 30, 2016, the amount due to the supplier was \$6,908.

For the three months ended September 30, 2015, three suppliers each accounted for more than 10% of the Company's purchases. In aggregate, these suppliers accounted for 61% of the Company's total purchases. As of September 30, 2015, the amount due to the suppliers was \$30.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(unaudited)

For the nine months ended September 30, 2015, three suppliers each accounted for more than 10% of the Company's purchases. In aggregate, these suppliers accounted for 47% of the Company's total purchases.

Note 16 – Contingencies

On October 17, 2016 the Company was served with a notice that Pulse Health LLC ("Pulse") filed a lawsuit against the Company on September 30, 2016 in United States Federal District Court, District of Oregon, alleging a breach of contract under the Settlement Agreement entered into by the Company and Pulse on April 8, 2011 which settled all claims and disputes between the Company and Pulse arising from a previously executed Technology Development Agreement entered into by the Company and Pulse and damages resulting from said alleged breach. Additionally, Pulse alleges false advertising and unlawful trade practices in connection with the Company's sales activities of the Company's OxiChek products. The Company disputes such allegations. The lawsuit is in an early stage and the Company intends to establish a rigorous defense of all claims. As a reasonable estimate of any loss from this case cannot be made, no accrual for losses was made as of September 30, 2016.

Note 17 – Subsequent Events

On October 24, 2016, the Company filed a Simplified Registration Statement (Form S-3) with the Security and Exchange Commission for an indeterminate number of shares of common stock, shares of preferred stock, warrants, rights and units that may be sold by the Company from time to time for a maximum aggregate offering price of all securities not to exceed \$7,000,000.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

This quarterly report on Form 10-Q and other reports filed by Akers Biosciences, Inc. (“Akers”, “Akers Bio”, “we” or the “Company”) from time to time with the SEC (collectively, the “Filings”) contain or may contain forward-looking statements and information that are based upon beliefs of, and information currently available to, the Company’s management as well as estimates and assumptions made by Company’s management. Readers are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and speak only as of the date hereof. When used in the Filings, the words “anticipate,” “believe,” “estimate,” “expect,” “future,” “intend,” “plan,” or the neg of these terms and similar expressions as they relate to the Company or the Company’s management identify forward-looking statements. Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions, and other factors, including the risks relating to the Company’s business, industry, and the Company’s operations and results of operations. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended, or planned.

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance, or achievements. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results.

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). These accounting principles require us to make certain estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions upon which we rely are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenues and expenses during the periods presented. Our financial statements would be affected to the extent there are material differences between these estimates and actual results. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP and does not require management’s judgment in its application. There are also areas in which management’s judgment in selecting any available alternative would not produce a materially different result. The following discussion should be read in conjunction with our financial statements and notes thereto appearing elsewhere in this report.

Overview

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

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

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

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

cost pressures/efficiency of healthcare delivery;

need for affordable mass screening tests for key infectious diseases, cardiac conditions, and metabolic markers;

need for easy to use, accurate at-home tests for individuals to monitor their personal health and wellness; and

public health needs in developing countries lacking basic health infrastructure.

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

Management's Plans and Basis of Presentation

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

continuing to advance the development and commercialization of the Company's products, especially those that utilize MPC Biosensor, PIFA and seraSTAT technologies;

continuing to strengthen and forge domestic and international relationships with well-established sales organizations with strong distribution channels in specific target markets for both our currently marketed and emerging products;

establishing clinical protocols that support regulatory submissions and publication of data within peer-reviewed journals; and

continuing to monitor and implement cost control initiatives to conserve cash.

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

some of Akers' distribution partnerships have been recently established or are in the process of being initiated and, therefore, consistent and historical ordering patterns have not been instituted;

the Company continues to incur expenses related to the initial commercialization and marketing activities for its wellness products and product development (research, clinical trials, regulatory tasks) costs for its emerging products including Breath PulmoHealth, BreathScan® DKA and PIFA 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 September 30, 2016, Akers had cash of \$195,860, working capital of \$2,537,197, stockholders' equity of \$4,470,500 and an accumulated deficit of \$96,383,706. The Company believes that its current working capital position will be sufficient to meet its estimated cash needs for at least the next 12 months. The Company closely monitors its cash balances, cash needs and expense levels.

Summary of Statements of Operations for the Three Months Ended September 30, 2016 and 2015**Revenue**

Akers' revenue for the three months ended September 30, 2016 totaled \$613,198, a 262% increase from the same period in 2015. The table below summarizes our revenue by product line for the three months ended September 30, 2016 and 2015 as well as the percentage of change year-over-year:

Product Lines	3 Months Ended September 30, 2016	3 Months Ended September 30, 2015	Percent Change	
Particle ImmunoFiltration Assay ("PIFA")	\$ 514,839	\$ 116,783	341	%
MicroParticle Catalyzed Biosensor ("MPC")	85,338	23,953	256	%
Other	13,021	28,737	(55))%
Product Revenue Total	\$ 613,198	\$ 169,473	262	%
License Fees	-	-	-	%
Total Revenue	\$ 613,198	\$ 169,473	262	%

Revenue from the Company's PIFA Heparin/PF4 Rapid Assay products increased 341% during the three months ended September 30, 2016 over the same period of 2015. The increase is due primarily to two events; first, the implementation of a significant price increase for the product line and second, during 2015, the Company experienced lower than usual distributor stock depletion for the PIFA Heparin/PF4 Rapid Assay products which did not re-occur during the three months ended September 30, 2016.

The Company received a \$2.5 million order for PIFA Heparin/PF4 Rapid Assay products from Novotek on February 29, 2016. The Company received an initial payment of \$250,000 on April 29, 2016 and a second payment of \$250,000 on June 28, 2016 for scheduled product shipments, per the terms of sale. The Company recognized no revenue for PIFA Heparin/PF4 products from Novotek during the three months ended September 30, 2016; however, the remaining products will be scheduled to ship at various points throughout the remainder of the current fiscal year with the remaining \$2,000,000 of revenue under the order being recognized when the criteria for the recognition of revenue is met.

The Company's MPC breathalyzer technology product sales increased 256% during the three months ended September 30, 2016 over the same period of 2015. A distributor's initial stocking order of \$41,800 for the Company's BreathScan Lync and BreathScan OxiChek™ products and renewed interest in the Company's BreathScan Alcohol Breathalyzers,

both domestically and internationally contributed to the increase during the three months ended September 30, 2016.

Other operating revenue decreased due to a decline in miscellaneous component sales during the three months ended September 30, 2016.

The Company's gross margin improved significantly, rising to 61% (2015: (5)%) for the three months ended September 30, 2016. The improvement is attributed to higher selling prices for the PIFA Heparin PF/4 Rapid Assay products, improved volumes and a significantly different component mix for the MPC products and the continued implementation of the new inventory and cost management procedures.

Cost of sales for the three months ended September 30, 2016 totaled \$236,700 (2015: \$177,952). Direct cost of sales decreased to 18% of product revenue while other cost of sales decreased to 21% for the three months ended September 30, 2016 as compared to 42% and 63% respectively for the same period in 2015.

Direct cost of sales for the three-month period ended September 30, 2016 were \$109,835 (2015: \$71,722). Other cost of sales for the three months ended September 30, 2016 were \$126,865 (2015: \$106,230).

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2016, totaled \$558,293, which was a 27% decrease as compared to \$760,336 for the three months ended September 30, 2015.

The table below summarizes our general and administrative expenses for the three months ended September 30, 2016 and 2015 as well as the percentage of change year-over-year:

Description	3 Months Ended September 30, 2016	3 Months Ended September 30, 2015	Percent Change
Personnel Costs	\$ 168,913	\$ 194,740	(13)%
Professional Service Costs	110,101	242,355	(55)%
Stock Market & Investor Relations Costs	88,953	146,859	(39)%
Other General and Administrative Costs	190,326	176,382	8 %
Total General and Administrative Expense	\$ 558,293	\$ 760,336	(27)%

The decrease in personnel costs for the three months ended September 30, 2016 is the result of the transfer of Dr. Akers to the Research and Development Department effective April 25, 2016.

Professional service costs decreased 55% for the three months ended September 30, 2016 as compared to the same period of 2015. Significant decreases in legal fees (\$56,919 (2015: \$146,640)) and in personnel recruiting and general consulting fees (\$2,125 (2015: \$61,292)) were the major contributors.

A significant decline in general consulting, investor relations and transfer agent fees (\$77,122 (2015: \$136,531)) during the three months ended September 30, 2016 resulted in an overall reduction in stock market and investor relations costs.

A significant decrease in travel expenses (\$18,074 (2015: \$65,171)) was offset by increases in depreciation (a one-time non-cash adjustment) and insurance costs (\$98,624 (2015: \$38,989)) accounting for an increase of 8% in other general and administrative costs for the three months ended September 30, 2016.

Sales and Marketing Expenses

Sales and marketing expenses for the three months ended September 30, 2016 totaled \$526,197, which was a 28% decrease as compared to \$725,832 for the three months ended September 30, 2015.

Edgar Filing: Akers Biosciences Inc - Form 10-Q

The table below summarizes our sales and marketing expenses for the three months ended September 30, 2016 and 2015 as well as the percentage of change year-over-year:

Description	3 Months Ended September 30, 2016	3 Months Ended September 30, 2015	Percent Change
Personnel Costs	\$ 222,980	\$ 371,133	(40)%
Professional Service Costs	77,094	170,985	(55)%
Royalties and Outside Commission Costs	128,828	113,308	14 %
Other Sales and Marketing Costs	97,295	70,406	38 %
Total Sales and Marketing Expenses	\$ 526,197	\$ 725,832	(28)%

Personnel costs decreased in the three months ended September 30, 2016 as compared to the same period of 2015. The Company has reduced the number of sales and marketing staff from 11 as of September 30, 2015 to 5 as of September 30, 2016. This reduction in the department's headcount is a result of the transition of the sales and marketing strategy for the PIFA Heparin PF/4 products to focus less on individual hospitals and more on integrated delivery networks which require fewer but more senior level staff. Costs declined in all major categories including base wages, employee benefits, bonuses and commissions and employer taxes.

The decrease in the use of contracted marketing services firms (\$- (2015: \$55,500)) and general sales consultants (\$77,094 (2015: \$115,435)) resulted in a 55% decrease in professional service costs. The Company has refocused its sales and marketing strategy, concentrating on the development of relationships with Independent Manufacturing Representatives that are paid for performance versus the use of contracted sales groups paid fixed monthly fees.

A decrease in outside sales commissions (\$10,879 (2015: \$36,134)) was offset by a significant increase in royalty expenses (\$117,949 (2015: \$77,174)) for the three months ended September 30, 2016.

Other sales and marketing costs increased primarily due to technology and sponsorship expenses (\$35,544 (2015: \$1,788)) and was offset by decrease in advertising expenses (\$2,255 ((2015: \$12,905))).

Research and Development

Research and development expenses for the three months ended September 30, 2016 totaled \$247,578, which was a 23% decrease as compared to \$319,646 for the three months ended September 30, 2015.

The table below summarizes our research and development expenses for the three months ended September 30, 2016 and 2015 as well as the percentage of change year-over-year:

Description	3 Months Ended September 30, 2016	3 Months Ended September 30, 2015	Percent Change	
Personnel Costs	\$ 161,257	\$ 156,569	3	%
Clinical Trial Costs	19,062	12,075	58	%
Professional Service Costs	39,369	106,763	(63))%
Other Research and Development Costs	27,890	44,239	(37))%
Total Research and Development Expenses	\$ 247,578	\$ 319,646	(23))%

Personnel costs increased 3% during the three months ended September 30, 2016 as compared to the same period of 2015 as a result of the transfer of Dr. Akers from the General and Administrative Department effective April 25, 2016 which was offset by an allocation of expenses to direct cost of goods for the use of research and development personnel in manufacturing activities.

The Company had a clinical trial in-process during the three months ended September 30, 2016 resulting in a significant increase in costs associated with these programs. The on-going trial is collecting data to support submissions to the U.S. Food and Drug Administration for approvals and to support the clinical effectiveness of the product.

Professional service costs declined 63% during the three months ended September 30, 2016. During the three months ended September 30, 2015, the Company was expending funds for the engineering and design of the BreathScan Lync™ reader and cartridge being used with the new MPC products. These design projects are now complete.

A reduction in the utilization of inventory resources for development and testing and a decrease in travel expenses (\$4,042 (2015: \$18,720)) resulted in a decrease of 37% for other research and development costs during the three months ended September 30, 2016.

The following table illustrates research and development costs by project for the three months ended September 30, 2016 and 2015, respectively:

Project	2016	2015
Asthma/pH	\$-	\$-
Breath Alcohol	-	54,340
Chlamydia Trachomatis	22,307	18,635
Heparin/PF4	16,885	55,363
HIV	-	-
Ketone	-	14,288
KetoChek / OxiChek	117,871	103,629
Lithium	-	448
METRON	74	16,174
Other Projects	248	3,324
Pulmo Health	5,447	6,745
Troponin (heart attacks)	-	22,503
Tri-Cholesterol	84,746	17,261
VIVO	-	6,936
Total R&D Expenses:	\$ 247,578	\$ 319,646

Reversal of Reserve for Bad Debts

The Company reversed a reserve for bad debts for \$1,299,609 during the three months ended September 30, 2016 as a result of the legal settlement with ChubeWorkx Guernsey Limited (“ChubeWorkx”) on August 17, 2016. Details of the settlement are included in Part II, Section 1, Legal Proceedings.

Other Income and Expense

Other income, net of expense for the three months ended September 30, 2016 totaled \$8,893, which was a 52% decrease as compared to \$18,519 for the three months ended September 30, 2015.

The table below summarizes our other income and expenses for the three months ended September 30, 2016 and 2015 as well as the percentage of change year-over-year:

Description	3 Months Ended September 30, 2016	3 Months Ended September 30, 2015	Percent Change	
Currency Translation Gain/(Loss)	\$ 3,629	\$ (2,001)	281	%
Realized Gain/(Loss) on Investments	1,269	(5,213)	124	%
Interest and Dividends	3,995	25,691	(84)%
Other Income	-	42	(100)%
Total Other Income, Net of Expenses	\$ 8,893	\$ 18,519	(52)%

Gains and losses associated with foreign currency transactions improved by 281% during the three months ended September 30, 2016 as compared to the same period of 2015, primarily a result of improved exchange rates between the US Dollar and the British Pound.

Other income and expenses primarily consist of realized gains on investments totaling \$1,269 (2015: loss of \$5,213) and interest and dividend earnings on the marketable securities and the note receivable totaling \$3,995 (2015: \$25,691).

Income Taxes

As of September 30, 2016, the Company does not believe any uncertain tax positions exist that would result in the Company having a liability to the taxing authorities. The Company's policy is to classify interest and penalties related to unrecognized tax benefits, if and when required, as part of interest expense and general and administrative expense, respectively in the consolidated statement of operations.

Summary of Statements of Operations for the Nine Months Ended September 30, 2016 and 2015:

Revenue

Akers' revenue for the nine months ended September 30, 2016 totaled \$2,307,708, a 40% increase from the nine months ended September 30, 2015. Product revenue increased by 74%, primarily a result of sales of our PIFA Heparin/PF4 Rapid Assay products. Total revenue was impacted by the elimination of license fee revenue following the cancellation of the License and Supply Agreement with ChubeWorkx Guernsey Limited ("ChubeWorkx") in May, 2015 in respect to BreathScan Alcohol Breathalyzer products.

The table below summarizes our revenue by product line for the nine months ended June 30, 2016 and 2015 as well as the percentage of change year-over-year:

Product Lines	9 Months Ended September 30, 2016	9 Months Ended September 30, 2015	Percent Change	
Particle ImmunoFiltration Assay (“PIFA”)	\$2,029,094	\$1,015,742	100	%
MicroParticle Catalyzed Biosensor (“MPC”)	195,040	233,758	(17)%
Other	83,574	76,387	9	%
Product Revenue Total	\$2,307,708	\$1,325,887	74	%
License Fees	-	320,556	(100)%
Total Revenue	\$2,307,708	\$1,646,443	40	%

Revenue from the Company’s PIFA Heparin/PF4 Rapid Assay products increased 100% during the nine months ended September 30, 2016 over the same period of 2015. The increase is due primarily to two events; first, the implementation of a significant price increase for the product line and second, the partial fulfillment of the \$2.5 million order from Novotek, our exclusive distributor in the Peoples Republic of China.

The Company received a \$2.5 million order for our PIFA Heparin/PF4 Rapid Assay products from Novotek on February 29, 2016. The Company received an initial payment of \$250,000 on April 29, 2016 and a second payment of \$250,000 on June 28, 2016 for scheduled product shipments, per the terms of sale resulting in the recognition of \$493,850 for PIFA Heparin/PF4 products and \$12,551 of other products from Novatek for the nine months ended September, 30, 2016. The remaining products will be scheduled to ship at various points throughout the remainder of the current fiscal year with the remaining \$2,000,000 of revenue under the order being recognized when the criteria for the recognition of revenue is met.

The Company’s MPC product sales declined 17% during the nine months ended September 30, 2016 over the same period of 2015. A distributor’s initial stocking order of approximately \$144,000 for the Company’s BreathScan Alcohol Breathalyzer products in Great Britain was included for the nine months ended September 30, 2015 but not repeated in the nine months ended September 30, 2016. Net of this significant order, MPC product sales increased 117% for the nine months ended September 30, 2016.

While most of the MPC product sales in the nine months ended September 30, 2016 came from BreathScan Alcohol Breathalyzers, we have begun generating sales of other MPC products within our health and wellness line, primarily the Company’s BreathScan OxiChek™ disposable breath test for oxidative stress which contributed \$65,969.

Other operating revenue increased due to a rise in miscellaneous component sales and shipping and handling fees.

The Company's gross margin improved significantly, rising to 69% (2015: 54%) for the nine months ended September 30, 2016. The improvement is attributed to improved margins for the PIFA Heparin PF/4 products resulting from the increase in average selling price of these products.

Cost of sales for the nine months ended September 30, 2016 decreased by 4% to \$713,576 (2015: \$745,319). Direct cost of sales decreased to 14% of product revenue while other cost of sales decreased to 17% for the nine months ended September 30, 2016 as compared to 26% and 30% respectively for the same period in 2015.

Direct cost of sales for the nine-month period ended September 30, 2016 were \$325,922 (2015: \$353,659). The decrease is attributed to the offset of manufacturing costs to inventory.

Other cost of sales for the nine months ended September 30, 2016 were \$387,654 (2015: \$391,660). The decrease is attributed to reductions in expenses related to quality control testing and inventory shrinkage and is offset by increases in manufacturing consumable supplies and repairs and maintenance expenses.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2016, totaled \$2,298,099, which was a 2% decrease as compared to \$2,341,500 for the nine months ended September 30, 2015.

The table below summarizes our general and administrative expenses for the nine months ended September 30, 2016 and 2015 as well as the percentage of change year-over-year:

Description	9 Months Ended September 30, 2016	9 Months Ended September 30, 2015	Percent Change	
Personnel Costs	\$712,683	\$611,841	16	%
Professional Service Costs	587,196	740,825	(21)	%
Stock Market & Investor Relations Costs	322,956	418,866	(23)	%
Other General and Administrative Costs	675,264	569,768	19	%
Total General and Administrative Expense	\$2,298,099	\$2,341,300	(2)	%

The increase in personnel costs for the nine months ended September 30, 2016 is the result of increases in costs associated with employee benefits and the addition of a staff accountant in June 2015 and the Company's new Chief Executive Officer in November 2015. These increases were offset by the transfer of Dr. Akers to the Research and Development Department effective April 25, 2016.

Professional service costs decreased 21% for the nine months ended September 30, 2016 as compared to the same period of 2015. Decreases in personnel recruiting, general consulting fees and legal fees (\$448,988 (2015: \$636,014)) was offset by increases in accounting fees (\$80,896 (2015: \$45,160)).

A decline in investor relations and transfer agent fees (\$201,806 (2015: \$315,434)) during the nine months ended September 30, 2016 was partially offset by increases in general consulting (\$121,150 (2015: \$103,436)) resulting in an overall reduction in stock market and investor relations costs.

An increase in bad debts expense (\$146,196 (2015: \$-)) and depreciation expense (\$65,326 (2015: \$9,114)) was offset by a decline in travel expenses (\$114,293 (2015: \$208,567)) which contributed to the 19% increase in other general and administrative costs for the nine months ended September 30, 2016.

Sales and Marketing Expenses

Sales and marketing expenses for the nine months ended September 30, 2016 totaled \$1,764,952, which was a 5% decrease as compared to \$1,854,623 for the nine months ended September 30, 2015.

The table below summarizes our sales and marketing expenses for the nine months ended September 30, 2016 and 2015 as well as the percentage of change year-over-year:

Description	9 Months Ended September 30, 2016	9 Months Ended September 30, 2015	Percent Change
Personnel Costs	\$937,777	\$987,740	(5) %
Professional Service Costs	384,114	537,766	(29) %
Royalties and Outside Commission Costs	178,873	140,762	27 %
Other Sales and Marketing Costs	264,188	188,355	40 %
Total Sales and Marketing Expenses	\$1,764,952	\$1,854,623	(5) %

Personnel costs decreased by 5% during the nine months ended September 30, 2016 as compared to the same period of 2015. The Company has reduced the number of sales and marketing staff from 11 on September 30, 2015 to 5 as of September 30, 2016. The reduction in the department's headcount is a result of the transition in the sales and marketing strategy for the PIFA Heparin PF/4 products to focus less on individual hospitals and more on integrated delivery networks which require fewer but more senior level staff. The Company replaced the sales and marketing senior management team during the first half of 2016 resulting in increased costs associated with severance programs.

The decrease in the use of contracted marketing services firms (\$51,246 (2015: \$176,047)) and general sales consultants (\$332,868 (2015: \$361,669)) resulted in a 29% decrease in professional service costs. The Company has refocused its sales and marketing strategy, concentrating on the development of relationships with Independent Manufacturing Representatives that are paid for performance versus the use of contracted sales groups paid fixed monthly fees.

Royalty and commission costs increased as a result of outside sales commissions (\$60,925 (2015: \$52,966)), due to increased sales of the PIFA products, both domestically and internationally, and royalty expenses (\$117,949 (2015: \$87,796)) in the nine months ended September 30, 2016.

Other sales and marketing costs increased primarily due to technology (\$38,449 (2015: \$12,839)), sponsorships (\$10,500 (2015: \$-)) and travel (\$144,622 (2015: \$93,077)) expenses and was partially offset by decreases in advertising and promotional materials expenses (\$4,663 (2015: \$33,164)).

Research and Development

Research and development expenses for the nine months ended September 30, 2016 totaled \$932,858, which was a 9% decrease as compared to \$1,003,444 for the nine months ended September 30, 2015.

The table below summarizes our research and development expenses for the nine months ended September 30, 2016 and 2015 as well as the percentage of change year-over-year:

Description	9 Months Ended September 30, 2016	9 Months Ended September 30, 2015	Percent Change	
Personnel Costs	\$ 539,810	\$488,260	11	%
Clinical Trial Costs	160,405	35,688	349	%
Professional Service Costs	96,515	352,889	(73)	%
Other Research and Development Costs	136,128	126,608	8	%
Total Research and Development Expenses	\$ 932,858	\$ 1,003,445	(7)	%

Personnel costs increased 11% during the nine months ended September 30, 2016 as compared to the same period of 2015 as a result of the transfer of Dr. Akers from the General and Administrative Department effective April 25, 2016 and the employment of a new Director of Quality Assurance.

The Company had two clinical trials in-process during the nine months ended September 30, 2016 resulting in a significant increase in costs associated with these programs. The trials are collecting data to support submissions to the U.S. Food and Drug Administration for approvals and to support the clinical effectiveness of the products.

Professional service costs declined 73% during the nine months ended September 30, 2016. During the nine months ended September 30, 2015, the Company was expending funds for the engineering and design of the BreathScan Lync™ reader and cartridge being used with the new MPC products. These design projects are now complete.

Increase in supplies (\$47,979 (2015: \$36,221)), seminars and professional development (\$26,849 (2015: \$780)) and waste disposal expenses (\$15,252 (2015: \$11,311)) was offset by a reduction in the utilization of inventory resources for development and testing (\$6,976 (2015: \$34,551)) that resulted in an increase of 8% for other research and development costs during the nine months ended September 30, 2016.

The following table illustrates research and development costs by project for the nine months ended September 30, 2016 and 2015, respectively:

Project	2016	2015
Asthma/pH	\$-	\$4,917
Breath Alcohol	1,381	100,966
Chlamydia Trachomatis	10,685	98,496
CHUBE	22,307	397
Heparin/PF4	72,823	98,876
HIV	16,885	58,718
Ketone	2,125	60,210
KetoChek / OxiChek	365,177	103,629
Lithium	117,871	41,086
METRON	2,507	77,473
Other Projects	101,659	77,625
Pulmo Health	6,126	6,745
Sonicator OQ	5,447	886
Troponin (heart attacks)	-	127,094
Tri-Cholesterol	117,903	82,151
VIVO	89,962	64,176
Total R&D Expenses:	\$932,858	\$1,003,445

Reversal of Reserve for Bad Debts

The Company reversed a reserve for bad debts for \$1,299,609 during the nine months ended September 30, 2016 as a result of the legal settlement with ChubeWorkx Guernsey Limited (“ChubeWorkx”) on August 17, 2016. Details of the settlement are included in Part II, Section 1, Legal Proceedings.

During the nine months ended September 30, 2015, the Company established a reserve for bad debts for \$864,000 for 36 Strategies General Trading, a related party.

Impairment of Non-Current Assets

The Company performed a routine analysis of its intangible assets and determined that two patents and a trademark acquired in the fiscal year ended December 31, 2007 are no longer contributing to the Company’s revenue flows and were therefore impaired for \$466,476 (2014: \$-) during the nine months ended September 30, 2015.

Other Income and Expense

Other income, net of expenses for the nine months ended September 30, 2016 totaled \$22,792, which was a 74% decrease as compared to \$87,729 for the nine months ended September 30, 2015.

The table below summarizes our other income and expenses for the nine months ended September 30, 2016 and 2015 as well as the percentage of change year-over-year:

Description	9 Months Ended September 30, 2016	9 Months Ended September 30, 2015	Percent Change
Currency Translation Loss	\$ (1,189)	\$ (7,970)	85 %
Realized Gain/(Loss) on Investments	3,421	(7,201)	148 %
Interest and Dividends	20,560	96,848	(79)%
Other Income	-	6,052	(100)%
Total Other Income, Net of Expenses	\$ 22,792	\$ 87,729	(74)%

Losses associated with foreign currency transactions improved by 85% during the nine months ended September 30, 2016 as compared to the same period of 2015, primarily a result of improved exchange rates between the US Dollar and the British Pound.

Other income and expenses primarily consist of realized gains on investments totaling \$3,421 (2015: loss of \$7,201) and interest and dividend earnings on the marketable securities and the note receivable totaling \$20,560 (2015: \$96,848).

Income Taxes

As of September 30, 2016, the Company does not believe any uncertain tax positions exist that would result in the Company having a liability to the taxing authorities. The Company's policy is to classify interest and penalties related to unrecognized tax benefits, if and when required, as part of interest expense and general and administrative expense, respectively in the consolidated statement of operations.

Liquidity and Capital Resources

For the nine months ended September 30, 2016 and 2015, the Company generated a net loss attributable to shareholders of \$2,207,707 and \$5,734,921, respectively. As of September 30, 2016 and December 31, 2015, the Company has an accumulated deficit of \$96,383,706 and \$94,175,999 and had cash totaling \$195,860 and \$402,059, respectively.

Currently, our primary focus is to expand the domestic and international distribution of our PIFA Heparin/PF4 rapid assays. The Company's secondary focus is fully commercializing the health and wellness product line linked to smartphones and tablets. The Company continues commercialization tasks for its PIFA PLUS[®] Infectious Disease single-use assays, BreathScan[®] DKA, and Breath PulmoHealth products, including advancement of the steps required for FDA clearance or CE marking in the EU where necessary.

We expect to continue to incur losses from operations for the near-term 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 twelve months. 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 additional health and wellness products, PIFA PLUS[®] Infectious Disease single-use assays, BreathScan[®] DKA and Breath PulmoHealth products, enrolling patients in clinical trials to support performance claims, generating studies in peer-reviewed journals to support product marketing, and provide data for the FDA 510(k) clearance/CE certifications processes when required. We will also continue to support commercialization and marketing activities of commercialized products (PIFA Heparin/PF4 rapid assays, PIFA PLUS[®] PF4 and breath alcohol detectors 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.

Capital expenditures for the nine months ended September 30, 2016 were \$88,023 (2015: \$60,254). Capital expenditures, primarily for production and laboratory costs for the year ending December 31, 2016 are expected to be approximately \$125,000. 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.

During the nine months ended September 30, 2015, the Company invested \$64,091 for a 19.9% ownership position in a joint venture with Hainan Savy Investment Management, Ltd and Mr. Thomas Knox, the Company’s Chairman, to research, develop, produce and sell Akers’ rapid diagnostic screening and testing products in China. The new entity, incorporated in the People’s Republic of China, operates as Hainan Savy Akers Biosciences, Ltd.

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.

Management continues to place increased emphasis on monitoring the risks associated with the current environment, particularly the recoverability of current assets, the fair value of assets, and the Company's liquidity. At this point in time, there has not been a material impact on the Company's assets and liquidity. Management will continue to monitor the risks associated with the current environment and their impact on the Company's results.

The table below summarizes our cash flows for the nine months ended September 30, 2016 and 2015 as well as the percentage of change year-over-year:

Description	9 Months Ended September 30, 2016	9 Months Ended September 30, 2015	Percent Change	
Cash at beginning of period	\$402,059	\$455,841	(12)%
Loss from operations	(2,207,707)	(5,734,921)	62	%
Adjustments				
Non-Operating Gains	(1,153,413)	(6,010)	19,092	%
Non-Cash Activities	306,664	1,580,375	81	%
Cash Used in Operating Activities				
Cash Consumed by Operating Activities	(755,401)	(476,273)	(58)%
Cash Contributed by Operating Activities	276,208	636,382	(57)%
Cash Flows from Investing Activities				
Cash Consumed by Investing Activities	(125,383)	(176,664)	29	%
Cash Contributed by Investing Activities	3,452,833	4,114,642	(16)%
Cash Flows from Financing Activities				
Cash Consumed by Financing Activities	-	-	-	%
Cash Contributed by Financing Activities	-	-	-	%
Cash at end of period	\$195,860	\$393,372	(50)%

The Company's net cash provided by investing and financing activities totaled \$3,327,450 during the nine months ended September 30, 2016. Cash of \$125,383 was consumed by capital expenditures and the purchase of marketable securities. Proceeds from the sale of marketable securities contributed cash of \$3,452,833 for the period ended September 30, 2016.

The Company's net cash provided by investing and financing activities totaled \$3,937,978 during the nine months ended September 30, 2015. Cash of \$176,664 was consumed by capital expenditures, the investment in Hainan Savy Akers Biosciences, Ltd. and the purchase of marketable securities. Proceeds from the sale of marketable securities and a policy renewal incentive from an insurer contributed cash of \$4,114,642 for the period ended September 30, 2015.

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

Our net cash consumed by operating activities totaled \$4,000,447 during the nine months ended September 30, 2015. Cash was consumed by the loss of \$5,734,921 less non-operating gains of \$6,010 plus non-cash adjustments of \$241,512 for depreciation and amortization of non-current assets, \$466,476 for impairment of non-current assets, \$864,000 for an allowance for doubtful accounts and \$8,387 for accrued interest and dividends on marketable securities. For the nine months ended September 30, 2015, decreases in trade receivables and notes receivable – related party \$221,219 and an increase in trade and other payables of \$415,163 provided cash, primarily related to routine changes in operating activities. A net increase in other receivables, inventories, and other assets of \$170,717 and a decrease in deferred revenue – related party of \$305,556 consumed cash from operating activities.

Critical Accounting Policies

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

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

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

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

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

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

level of credit losses in the future.

Fair Value Measurement – Marketable Securities

The framework for measuring fair value provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1) and the lowest priority to unobservable inputs (level 3). The three levels of the fair value hierarchy under FASB ASC 820 are described as follows:

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

Level 2 Inputs to the valuation methodology include

quoted prices for similar assets or liabilities in active markets;

quoted prices for identical or similar assets or liabilities in inactive markets;

inputs other than quoted prices that are observable for the asset or liability;

inputs that are derived principally from or corroborated by observable market data by correlation or other means.

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

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

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

Intangible Assets

The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person's breath, blood, urine and saliva. Propriety protection for the Company's products, technology and process is important to its competitive position. As of September 30, 2016, the Company has ten patents from the United States Patent Office in effect (9,383,368; 7,896,167; 8,097,171; 8,003,061; 8,425,859; 8,871,521; 8,808,639; D691,056; D691,057 and D691,058). Other patents are in effect in Australia through the Design Registry (348,310; 348,311 and 348,312), the Community Trade Mark in the European Union ((OHIM) 002216895-0001; 002216895-0002 and 002216895-0003), in Hong Kong (HK11004006) and in Japan (1,515,170; 4,885,134; 4,931,821 and 5,775,790). Patents are in the national phase of prosecution in many Patent Cooperation Treaty participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the US, European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

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

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

Long-Lived Assets

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

Investments

In accordance with FASB ASC 323, the Company recognizes investments in joint ventures based upon the Company's ability to significantly influence the operational or financial policies of the joint venture. An objective judgment of the level of influence is made at the time of the investment based upon several factors including, but not limited to the following:

- a) Representation on the Board of Directors
- b) Participation in policy-making processes
- c) Material intra-entity transactions
- d) Interchange of management personnel
- e) Technological dependencies
- f) Extent of ownership and the ability to influence decision making based upon the makeup of other owners when the shareholder group is small.

The Company follows the equity method for valuating investments in joint ventures when the existence of significant influence over operational and financial policy has been established, as determined by management; otherwise, the Company will value these investments using the cost method.

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

Revenue Recognition

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

Revenue recorded is net of any discount, rebate or sales return.

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

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

Stock-based Compensation

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

Recently Issued and Adopted Accounting Pronouncements

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

Quantitative and Qualitative Disclosure About Market Risk

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

Interest Rates

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

Off-Balance Sheet Arrangements

We have no significant known off balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We do not hold any derivative instruments and do not engage in any hedging activities.

Item 4. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures.

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

As of September 30, 2016 and based upon that evaluation, the Company's PEO and PFO concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act, are recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Company's PEO and PFO, as appropriate, to allow timely decisions regarding required disclosure.

(b) Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

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

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

Under the terms of the Settlement Agreement, the Company will recover the full outstanding principal amount in the current fiscal year in the form of \$750,000 of BreathScan® Alcohol Detector inventory – which the Company intends to subsequently sell – and the balance of \$549,609 in cash. Akers Bio established an allowance for this doubtful note in the Company's financial statements for the year ended December 31, 2015. As a result of the Settlement Agreement, the Company reversed the allowance for doubtful note in the amount of \$1,299,609 which is included in the Condensed Consolidated Statement of Operations and Comprehensive Income for the three and nine months ended September 30, 2016.

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

In return for the Company regaining the full rights to sell breath technology products, under the terms of the Settlement Agreement, ChubeWorkx is entitled to receive a royalty of 5% of the Company's gross revenues (the "ChubeWorkx Royalty") until ChubeWorkx has earned an aggregate \$5,000,000, after which point ChubeWorkx will no longer be entitled to receive any royalties from the Company and the Company shall have no further obligation to ChubeWorkx. The Settlement Agreement further allows the Company to retain 50% of the ChubeWorkx Royalty until the full \$549,609 cash component of the monies owed by ChubeWorkx to Akers Bio as described above has been satisfied. The Company recorded royalty expenses of \$117,949 in the three and nine months ended September 30, 2016 which are included in sales and marketing expenses – related party on the condensed consolidated statement of operations and comprehensive income.

Other terms of the Settlement include: 1) the pledge as security by the Company to ChubeWorkx all Company assets, worthy to satisfy its obligations, including all inventory and receivables, with the exception of (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other equipment; and 2) the grant of voting proxy by ChubeWorkx to the Company which allows the Company to vote ChubeWorkx's shares for corporate formalities under certain conditions.

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

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

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

Item 1A. Risk Factors.

We believe there are no changes that constitute material changes from the risk factors previously disclosed in our Annual Report on Form 10-K, filed with the SEC on March 30, 2016.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

There were no unregistered sales of the Company's equity securities during the quarter ended September 30, 2015, other than those previously reported in a Current Report on Form 8-K.

Item 3. Defaults Upon Senior Securities.

There has been no default in the payment of principal, interest, sinking or purchase fund installment, or any other material default, with respect to any indebtedness of the Company.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

There is no other information required to be disclosed under this item which was not previously disclosed.

Item 6. Exhibits.

- | | |
|------|--|
| 31.1 | Certification by the Principal Executive Officer of Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Rule 13a-14(a) or Rule 15d-14(a)). * |
| 31.2 | Certification by the Principal Financial Officer of Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Rule 13a-14(a) or Rule 15d-14(a)). * |
| 32.1 | Certification by the Principal Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. * |
| 32.2 | |

Edgar Filing: Akers Biosciences Inc - Form 10-Q

Certification by the Principal Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *

101.INS XBRL Instance Document

101.SCH XBRL Taxonomy Extension Schema

101.CAL XBRL Taxonomy Extension Calculation Linkbase

101.DEF XBRL Taxonomy Extension Definition Linkbase

101.LAB XBRL Taxonomy Extension Label Linkbase

101.PRE XBRL Taxonomy Extension Presentation Linkbase

* Filed herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AKERS BIOSCIENCES, INC.

Date: November 14, 2016 By: */s/ John J. Gormally*
Name: John J. Gormally
Chief Executive Officer
Title:
(Principal Executive Officer)

Date: November 14, 2016 By: */s/ Gary M. Rauch*
Name: Gary M. Rauch
Vice President, Finance & Treasurer
Title:
(Principal Financial Officer)

