

Akers Biosciences, Inc.
Form 10-Q
November 14, 2017

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, 2017**

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. 001-36268

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, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 10, 2017, there were 9,920,552 shares outstanding of the registrant's common stock.

TABLE OF CONTENTS

PART I – FINANCIAL INFORMATION

Item 1.	<u>Financial Statements</u>	3
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	33
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	49
Item 4.	<u>Controls and Procedures</u>	49

PART II – OTHER INFORMATION

Item 1.	<u>Legal Proceedings</u>	50
Item 1A.	<u>Risk Factors</u>	51
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	51
Item 3.	<u>Defaults Upon Senior Securities</u>	51
Item 4.	<u>Mine Safety Disclosures</u>	51
Item 5.	<u>Other Information</u>	51
Item 6.	<u>Exhibits</u>	52
	<u>Signatures</u>	53

PART I – FINANCIAL INFORMATION**Item 1. Financial Statements.****AKERS BIOSCIENCES, INC. AND SUBSIDIARIES****Condensed Consolidated Balance Sheets****September 30, 2017 and December 31, 2016**

	2017 (unaudited)	2016 (audited)
ASSETS		
Current Assets		
Cash	\$ 135,133	\$ 72,700
Marketable Securities	10,178	50,001
Trade Receivables, net	1,125,097	601,271
Trade Receivables - Related Parties, net	125,001	31,892
Deposits and other receivables	21,748	23,782
Inventories, net	2,085,867	2,036,521
Prepaid expenses	99,479	168,277
Prepaid expenses - Related Parties	380,789	202,500
Total Current Assets	3,983,292	3,186,944
Non-Current Assets		
Prepaid expenses - Related Party	53,456	270,183
Property, Plant and Equipment, net	242,048	259,392
Intangible Assets, net	1,173,444	1,301,775
Other Assets	76,093	66,813
Total Non-Current Assets	1,545,041	1,898,163
Total Assets	\$5,528,333	\$5,085,107
LIABILITIES		
Current Liabilities		
Trade and Other Payables	\$ 1,549,047	\$ 1,463,363
Trade and Other Payables - Related Parties	20,245	234,067
Deferred Revenue	12,500	
Total Current Liabilities	1,581,792	1,697,430

Edgar Filing: Akers Biosciences, Inc. - Form 10-Q

Total Liabilities	1,581,792	1,697,430
STOCKHOLDERS' EQUITY		
Convertible Preferred Stock, No par value, 50,000,000 shares authorized, no shares issued and outstanding as of September 30, 2017 and December 31, 2016	-	-
Common Stock, No par value, 500,000,000 shares authorized, 8,901,245 and 5,452,545 issued and outstanding as of September 30, 2017 and December 31, 2016	104,628,437	100,891,786
Deferred Compensation	(8,788)	(24,572)
Accumulated Deficit	(100,673,108)	(97,479,537)
Accumulated Other Comprehensive Income	-	-
Total Stockholders' Equity	3,946,541	3,387,677
Total Liabilities and Stockholders' Equity	\$5,528,333	\$5,085,107

See accompanying notes to these condensed consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Revenues:				
Product Revenue	\$638,331	\$613,198	\$2,378,811	\$2,307,328
Product Revenue - Related parties	-	-	124,631	380
License & Service Revenue	37,500	-	37,500	-
Total Revenues	675,831	613,198	2,540,942	2,307,708
Cost of Sales:				
Product Cost of Sales	(323,527)	(236,700)	(846,487)	(713,576)
Gross Income	352,304	376,498	1,694,455	1,594,132
Administrative Expenses	819,565	558,293	2,440,023	2,298,099
Sales and Marketing Expenses	342,763	408,248	1,254,308	1,647,003
Sales and Marketing Expenses - Related Party	34,328	117,949	128,108	117,949
Research and Development Expenses	290,447	247,578	929,730	932,858
Research and Development Expenses - Related Party	-	-	22,994	-
(Reversal of Allowance for) Bad Debt Expenses- Related parties	-	(1,299,609)	-	(1,299,609)
Amortization of Non-Current Assets	42,777	42,777	128,331	128,331
(Loss)/Income from Operations	(1,177,576)	301,262	(3,209,039)	(2,230,499)
Other (Income)/Expenses				
Foreign Currency Transaction (Gain)/Loss	3,195	(3,629)	(6,172)	1,189
Interest and Dividend Income	(3,127)	(5,264)	(9,296)	(23,981)
Other Income	-	-	-	-
Total Other (Income)/Expense	68	(8,893)	(15,468)	(22,792)
(Loss)/Income Before Income Taxes	(1,177,644)	310,155	(3,193,571)	(2,207,707)
Income Tax Benefit	-	-	-	-
Net (Loss)/Income Attributable to Common Stockholders	(1,177,644)	310,155	(3,193,571)	(2,207,707)
Other Comprehensive Income/(Loss)				
Net Unrealized Gain/(Loss) on Marketable Securities	(1,009)	(2,837)	-	3,691
Total Other Comprehensive Income/(Loss)	(1,009)	(2,837)	-	3,691

Edgar Filing: Akers Biosciences, Inc. - Form 10-Q

Comprehensive (Loss)/Income	\$ (1,178,653) \$ 307,318		\$ (3,193,571) \$ (2,204,016)	
Basic income/(loss) per common share	\$(0.13) \$0.06		\$(0.39) \$(0.41)	
Diluted income/(loss) per common share	\$(0.13) \$0.06		\$(0.39) \$(0.41)	
Weighted average basic common shares outstanding	8,892,079	5,434,212	8,268,851	5,428,859
Weighted average diluted common shares outstanding	8,892,079	5,508,545	8,268,851	5,428,859

See accompanying notes to these condensed consolidated financial statements.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES**Condensed Consolidated Statement of Changes in Stockholder's Equity****For the nine months ended September 30, 2017**

	Common Shares Issued and Outstanding	Common Stock	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Equity
Balance at December 31, 2016 (audited)	5,452,545	\$ 100,891,786	\$ (24,572)	\$(97,479,537)	\$ -	\$3,387,677
Net loss	-	-	-	(3,193,571)	-	(3,193,571)
Public offering of common stock, net of offering costs of \$494,406	1,789,500	1,652,994	-	-	-	1,652,994
Private offering of common stock, net of offering costs of \$267,443	1,448,400	1,760,317	-	-	-	1,760,317
Exercise of warrants for common stock	200,800	301,200	-	-	-	301,200
Amortization of deferred compensation	-	-	15,784	-	-	15,784
Issuance of non-qualified stock options to key employees	-	14,502	-	-	-	14,502
Issuance of non-qualified stock options for services to non-employees	-	2,183	-	-	-	2,183
Issuance of restricted stock for services for non-employees	10,000	5,455	-	-	-	5,455
Balance at September 30, 2017 (unaudited)	8,901,245	\$ 104,628,437	\$ (8,788)	\$(100,673,108)	\$ -	\$3,946,541

See accompanying notes to these condensed consolidated financial statements.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES**Condensed Consolidated Statements of Cash Flows****For the nine months ended September 30, 2017 and 2016****(unaudited)**

	2017	2016
Cash flows from operating activities		
Net loss	\$(3,193,571)	\$(2,207,707)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued income on marketable securities	(148)	13,380
Depreciation and amortization	182,866	221,946
Allowance for/(reversal of) doubtful accounts	46,239	(1,153,413)
Amortization of deferred compensation	15,784	24,834
Share based compensation to employees - options	14,502	22,828
Share based compensation to non-employees - options	2,183	23,676
Share based compensation to non-employees - restricted stock	5,455	-
Changes in assets and liabilities:		
Increase in trade receivables	(570,065)	(275,541)
Increase in trade receivables - related parties	(93,109)	-
Decrease in deposits and other receivables	2,034	65,855
Increase in inventories	(49,346)	(60,862)
Decrease in prepaid expenses	68,797	91,706
Decrease in prepaid expenses - related parties	38,438	58,974
Increase in other assets	(9,280)	-
Increase/(decrease) in trade and other payables	85,685	(418,998)
Increase/(decrease) in trade and other payables - related parties	(213,822)	59,673
Increase in deferred revenue	12,500	-
Net cash used in operating activities	(3,654,858)	(3,533,649)
Cash flows from investing activities		
Purchases of property, plant and equipment	(37,191)	(88,023)
Purchases of marketable securities	(2,709,148)	(37,360)
Proceeds from sale of marketable securities	2,749,119	3,452,833
Net cash provided by investing activities	2,780	3,327,450
Cash flows from financing activities		
Net proceeds from issuance of common stock	3,413,311	-
Net proceeds from exercise of warrants for common stock	301,200	-
Net cash provided by financing activities	3,714,511	-
Net increase/(decrease) in cash	62,433	(206,199)
Cash at beginning of period	72,700	402,059

Cash at end of period	\$ 135,133	\$ 195,860
-----------------------	------------	------------

Supplemental Schedule of Non-Cash Financing and Investing Activities

Issuance of a restricted common stock grant to an officer	\$-	\$ 54,725
Net unrealized gains on marketable securities	\$-	\$ 3,691
Reclassification of note receivable to inventory	\$-	\$ 750,000
Reclassification of note receivable to prepaid expense	\$-	\$ 549,609

See accompanying notes to these condensed consolidated financial statements.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

Note 1 - Nature of Business

(a) Reporting Entity

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

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

(b) Nature of Business

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

Note 2 - Basis of Presentation and Significant Accounting Policies

(a) Basis of Presentation

The Condensed Consolidated Financial Statements of the Company are prepared in U.S. Dollars and in accordance with accounting principles generally accepted in the United States of America (US GAAP).

Certain information and note disclosures normally included in the financial statements prepared in accordance with US GAAP have been condensed. As such, the information included in these financial statements should be read in conjunction with the audited financial statements as of and for the years ended December 31, 2016 and 2015 included in the Company's 2016 Form 10-K. In the opinion of the management, these consolidated financial statements include all adjustments, consisting of only normal recurring nature, necessary for a fair statement of the financial position of the Company as of September 30, 2017 and its results of operations and cash flows for the three and nine months ended September 30, 2017 and 2016. The results of operations for the three and nine months ended September 30, 2017 are not necessarily indicative of the results to be expected for the full fiscal year ending December 31, 2017.

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(b) Use of Estimates and Judgments

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

(c) Functional and Presentation Currency

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

(d) Comprehensive Income (Loss)

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

(e) Cash and Cash Equivalents

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

(f) Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, receivables and trade and other payables. The carrying value of cash and cash equivalents, receivables and trade and other payables approximate their fair value because of their short maturities. The fair value of marketable securities is described in Note 4.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(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.

(h) Trade Receivables, Trade Receivables – Related Parties and Allowance for Doubtful Accounts

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

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

As of September 30, 2017 and December 31, 2016, allowances for doubtful accounts for trade receivables were \$192,435 and \$1,010,196. Bad debt expenses for trade receivables were \$- and \$47,741 for the three month and nine months ended September 30, 2017 and a credit of \$1,299,609 and a credit of \$1,153,414 for the three and nine months ended September 30, 2016. The credit of \$1,153,414 comprises the reversal of an allowance for bad debts expense – related party of \$1,299,609 and an allowance for bad debts for an external party of \$146,195 included in the administrative expenses for the nine months ended September 30, 2016.

As of September 30, 2017 and December 31, 2016, the aging of trade receivables and trade receivables – related parties was as follows:

<i>Aging Period</i>	September 30		December 31	
	2017	%	2016	%
Current	\$1,008,025	70 %	\$464,365	28 %
01-30 Days	41,746	3 %	43,223	3 %
31-60 Days	50,000	3 %	39,203	2 %
61-90 Days	101,093	7 %	6,150	0 %
>90 Days	241,669	17 %	1,090,418	66 %
Subtotal	1,442,533	-	1,643,359	-
Bad Debts Allowance	(192,435)	-	(1,010,196)	-
Total	\$1,250,098	-	\$633,163	-
Average Days in Receivable	166		194	

The aging above represents the number of days that the account receivable balance exceeds the credit terms. Included in the current category is accounts receivable of \$550,800 and \$- as of September 30, 2017 and December 31, 2016 with payment terms extended to 180 days.

(i) Concentration of Credit Risk

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

All of the Company's cash is maintained with Fulton Bank of New Jersey, Bank of America, NA and PayPal. The funds are insured by the FDIC up to a maximum of \$250,000, but are otherwise unprotected. The Company placed \$130,053 and \$67,865 with Fulton Bank of New Jersey, \$1,040 and \$795 with Bank of America, NA and \$4,040 and \$4,040 with PayPal as of September 30, 2017 and December 31, 2016. No losses have been incurred in these accounts.

Concentration of credit risk with respect to trade receivables exists as approximately 68% of the Company's product revenue is generated by three customers. These customers accounted for 59% of trade receivables as of September 30, 2017. To limit such risks, the Company performs ongoing credit evaluations of its customers' financial condition.

(j) Inventories

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

(k) Property, Plant and Equipment

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

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

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

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

(ii) Patent Costs

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

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

(iii) Other Intangible Assets

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(iv) Amortization

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

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

(m) Recoverability of Long Lived Assets

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

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

(n) Investments

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

- a) Representation on the Board of Directors
- b) Participation in policy-making processes
- c) Material intra-entity transactions
- 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.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

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

(o) Revenue Recognition

In accordance with FASB ASC 605, the Company recognizes revenue when (i) persuasive evidence of a customer or distributor arrangement exists, (ii) a retailer, distributor or wholesaler receives the goods and acceptance occurs, (iii) the price is fixed or determinable, and (iv) the collectability of the revenue is reasonably assured. Subject to these criteria, the Company recognizes revenue from product sales when title passes to the customer based on shipping terms. The Company typically does not accept returns nor offer charge backs or rebates except for certain distributors. Revenue recorded is net of any discount, rebate or sales return. The accrual for estimated sales returns was \$- as of September 30, 2017 and December 31, 2016.

The Company implemented a standard dealer cost model during the year ended December 31, 2016 which includes a provision for rebates to the distributors under limited circumstances. The Company established an accrual of \$27,073 and \$18,858, which is a reduction of revenue as of September 30, 2017 and December 31, 2016. Accounts receivable will be reduced when the rebates are applied by the customer. The Company recognized \$51,791 and \$222,469 during the three and nine months ended September 30, 2017 and \$84,128 and \$299,781 for the three and nine months ended September 30, 2016 for rebates, which is included as a reduction of product revenue in the Condensed Consolidated Statement of Operations and Comprehensive Loss.

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

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

(p) Income Taxes

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

(q) Shipping and Handling Fees and Costs

The Company charges actual shipping plus a handling fee to customers, which amounted to \$13,679 and \$12,321 for the three months ended September 30, 2017 and 2016 and to \$47,148 and \$42,754 for the nine months ended September 30, 2017 and 2016. These fees are classified as part of product revenue in the Condensed Consolidated Statement of Operations and Comprehensive Loss. Shipping and other related delivery costs, including those for incoming raw materials are classified as part of the cost of net revenue, which amounted to \$16,148 and \$63,719 for the three and nine months ended September 30, 2017 and to \$19,695 and \$88,427 for the three and nine months ended September 30, 2016.

(r) Research and Development Costs

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

(s) Stock-based Payments

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

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

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

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

Basic earnings per common share are based on the weighted average number of shares outstanding during the periods presented. Diluted earnings per share are computed using the weighted average number of common shares plus dilutive common share equivalents outstanding during the period. Potential common shares that would have the effect of increasing diluted earnings per share are considered anti-dilutive, i.e. the exercise prices of the outstanding stock options were greater than the market price of the common stock.

The table below details the classification of the basic and diluted income/(loss per share for the three and nine months ended September 30, 2017 and 2016:

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Numerator				
Net Income/(Loss)	\$ (1,177,644)	\$ 310,155	\$ (3,193,571)	\$ (2,207,707)
Denominator				
Weighted Average Basic Common Shares Outstanding	8,892,079	5,434,212	8,268,851	5,428,859
Add the Dilutive Effect of Stock Options	-	56,000	-	-
Stock Warrants	-	-	-	-
Unvested Restricted Shares	-	18,333	-	-
Weighted Average Basic and Diluted Common Shares Outstanding	8,892,079	5,508,545	8,268,851	5,428,859
Net Income/(Loss) per Share				
Basic	\$ (0.13	) \$ 0.06	\$ (0.39	) \$ (0.41
Diluted	\$ (0.13	) \$ 0.06	\$ (0.39	) \$ (0.41

(u) Reclassifications

Certain prior year amounts have been reclassified to conform to the current year's presentation.

(v) Recently Adopted Accounting Pronouncements

As of September 30, 2017 and for the period then ended, there were no recently adopted accounting pronouncements that had a material effect on the Company's financial statements.

(w) Recently Issued Accounting Pronouncements Not Yet Adopted

As the Company is an emerging growth company, it has elected to adopt recently issued standards based on effective dates applicable to nonpublic entities. All effective dates as mentioned in the following paragraphs refer to that applicable to nonpublic entities.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In August 2015, FASB issued ASU 2015-14 which deferred the effective date of Update 2014-09 to annual reporting periods beginning after December 15, 2018 and interim reporting periods within annual reporting periods beginning after December 15, 2019. Early application is permitted as of annual reporting periods beginning after December 15, 2016 including interim reporting periods within that reporting period. The Company is currently evaluating the effect of the amendments but it does not anticipate a material impact of its financial statements. The Company expects to use the modified retrospective adoption method.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740), Balance Sheet Classification of Deferred Taxes*. The amendments in this Update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in this Update are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 31, 2018. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. The Company has no deferred tax balances as a 100% valuation allowance has been made. No material impact is expected.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments – Overall (Subtopic 825-10), Recognition and Measurement of Financial Assets and Financial Liabilities*. The amendments in this Update require all equity investments to be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under the equity method of accounting or those that result in consolidation of the investee). The amendments in this Update also require an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. The amendments in this Update are effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. The Company is evaluating the effect of the adoption of this Update on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The amendments in this Update specify the accounting for leases. The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from leases. The amendments in this Update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early application of the amendments in this Update is permitted. The Company is currently evaluating the effect the amendments in this Update will have on its financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, which clarifies certain aspects of the principal versus agent guidance in the new revenue recognition standard. The effective date and transition requirement for this ASU are the same as the effective date and transition requirements of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, as amended by ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which deferred the effective date to annual reporting periods beginning after December 15, 2018. The Company is currently evaluating the effect the amendments in this Update will have on its financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for share-based payment award transactions, including: (1) income tax consequences; (2) classification of awards as either equity or liabilities, and (3) classification on the statement of cash flows. The amendments in this ASU are effective for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Early adoption is permitted in any interim or annual period. The Company is currently evaluating the effect the amendments in this Update will have on its financial statements and related disclosures.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments*. The Update addresses eight specific changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. The amendments in this Update are effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted. An entity that elects early adoption must adopt all of the amendments in the same period. The amendments in this Update should be applied using a retrospective transition method to each period presented. If it is impracticable to apply the amendments retrospectively for some of the issues, the amendments for those issues would be applied prospectively as of the earliest date practicable. The Company is currently evaluating the effect the amendments in this Update will have on its financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718), Scope of Modification Accounting*. The amendments in this Update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The amendments in this Update are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period, for (1) public business entities for reporting periods for which financial statements have not yet been issued and (2) all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments in this Update should be applied prospectively to an award modified on or after the adoption date.

Note 3 – Management Plan

Historically, the Company has relied upon public offerings and private placements of common stock to raise operating capital. During the ten months ending October 31, 2017, the Company raised approximately \$1.7 million in a public offering, \$1.8 million from a private placement of common stock and an additional \$982,000 from the execution of warrants (Notes 11 and 20). As of November 10, 2017, the Company had cash and marketable securities of approximately \$432,000 and working capital of approximately \$2.6 million.

The 2017-19 Strategic Business Plan (“Strat Plan”) was presented to and approved by the Board of Directors on December 12, 2016. The plan outlines the Company’s business objectives for the next three years and sets measurable targets for new product releases, sales and marketing programs to increase market penetration for the Company’s products and operational expense management. The Company has prepared the initial Go-To-Market Plan (“GTM Plan”) for 2018 and will present the completed GTM Plan to the Board of Directors on December 19, 2017 for final approval.

Implementation of the Strat Plan began in January 2017 and although management remains committed to the overall strategy, the Company will not meet the Strat Plan's revenue targets for 2017. The Company had anticipated the market introduction of its over-the-counter Tri-Cholesterol test in the first half and its PIFA Chlamydia Rapid Assay product during the third quarter of 2017, both of which were delayed.

The Company encountered significant delays from raw material vendors for critical components of the Tri-Cholesterol test which resulted in the product's first commercial production to be postponed into the third quarter. The first shipments of the product began at the end of September 2017 and feedback from the customer has been favorable. Three additional orders totaling \$110,000 have been received.

The PIFA Chlamydia Rapid Assay test's introduction has been delayed into 2018 due to unanticipated requests for additional clinical data from the United States Food & Drug Administration ("FDA"). The FDA's approval of the 510(k) application is required to begin production and commercialization of the product.

The Company continues to encounter periods of cash shortages and is proactively working to minimize their impact on operations. The Company expects to achieve a cash-flow positive position during the next twelve months based upon the revised revenue targets as outlined in the Strat Plan and the 2018 GTM Plan. The Company is actively pursuing financing options with various financial institutions, investment banks and other sources to enhance The Company's liquidity while minimizing dilution to the shareholders.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

During the year ended December 31, 2016, the Company significantly reduced operating expenses through a systematic review of operations throughout the organization. As a result, the Company achieved a reduction in our weekly operating cash requirements of approximately 19% to \$80,253 (2015: \$98,699).

The Company achieved the reduction in weekly cash requirements by renegotiating contracts with key consultants and canceling consulting agreements where the cost-benefits are negligible, working with vendors to reduce or eliminate minimum purchasing requirements, to extend payment terms and re-sourcing materials when necessary to reduce costs.

Production cost savings, especially direct manufacturing costs, have been realized by utilizing sub-contractors to perform labor intensive production processes. This improves efficiency for our manufacturing staff, allowing them to concentrate their efforts on more complex assembly and production tasks.

During the nine months ended September 30, 2017, the Company's average weekly operating cash requirement increased to \$93,714 (2016: \$88,341). The increase resulted from payments to vendors and sub-contractors included in the December 31, 2016 accounts payable balance, a significant royalty payment that had been deferred in 2016 as part of a legal settlement, professional service fees and other payments for contractual obligations. Many of these items are one-time events and the Company anticipates the cash requirements to revert to the \$85,000 to \$90,000 per week by the end of 2017.

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

The Company's current working capital position.

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

Edgar Filing: Akers Biosciences, Inc. - Form 10-Q

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

Negotiations are underway with a potential customer for the Company's BreathScan OxiChek products and are anticipated to be completed during the three months ending December 31, 2017; however, they have requested product design changes that must be completed prior to the consummation of the purchase agreement. All parties are confident that a solution can be achieved but a significant delay will impact revenue projections.

The Company's engineers are working with the potential customer's scientific officer to develop a device to support their unique requirements.

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

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

Note 4 - Fair Value Measurement - Marketable Securities

Following is a description of the valuation methodologies used for assets measured at fair value as of September 30, 2017 and December 31, 2016.

U.S. Agency Securities, Corporate and Municipal Securities and Certificates of Deposits: Valued using pricing models maximizing the use of observable inputs for similar securities. This includes basing value on yields currently available on comparable securities of issuers with similar credit ratings.

	As of September 30, 2017				
	Cost	Accrued Income	Unrealized Gains	Unrealized Losses	Fair Value
Level 2:					
Money market funds	\$ 10,000	\$ 1	\$ -	\$ -	\$ 10,001
Municipal securities	-	177	-	-	177
Total Level 2:	10,000	178	-	-	10,178
Total:	\$ 10,000	\$ 178	\$ -	\$ -	\$ 10,178

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

	As of December 31, 2016				
	Cost	Accrued Income	Unrealized Gains	Unrealized Losses	Fair Value
Level 2:					
Money market funds	\$29,657	\$15	\$-	\$-	\$29,672
Municipal securities	20,314	15	-	-	20,329
Total Level 2:	49,971	30	-	-	50,001
Total:	\$49,971	\$30	\$-	\$-	50,001

Marketable securities include U.S. agency securities, corporate securities, and municipal securities, which are classified as available for sale. The securities are valued at fair market value. Maturities of the securities are less than one year. Unrealized gains relating to the available for sale investment securities were recorded in the Condensed Consolidated Statement of Changes in Stockholders' Equity as comprehensive income. These amounts were an unrealized loss of \$1,009 and \$- (net of effect of income tax expense of \$-) for the three and nine months ended September 30, 2017 and an unrealized loss of \$2,837 and an unrealized gain of \$3,691 for the three and nine months ended September 30, 2016.

Proceeds from the sale of marketable securities in the three and nine months ended September 30, 2017 were \$1,003,565 and \$2,749,119 and were \$950,514 and \$3,452,833 for the three and nine months ended September 30, 2016. Gross gains, resulting from these sales, amounted to \$1,719 and \$1,269 for the three months ended September 30, 2017 and 2016 and \$3,375 and \$3,421 for the nine months ended September 30, 2017 and 2016.

Note 5 - Trade Receivables – Related Parties

Trade receivables – related parties are made up of amounts due from related parties of Hainan Savy Akers Biosciences Ltd (“Hainan”), a joint venture between Akers, Thomas Knox, Akers’ former Board Chairman, and Hainan Savy Investment Management Ltd, located in the People’s Republic of China. The Company holds a 19.9% position in the joint venture. The amount due is non-interest bearing, unsecured and generally has a term of 30-90 days (Note 14). Credit terms of 180 days were extended to Hainan for a bulk purchase of BreathScan Breath Alcohol detectors during June 2017 while Hainan expands their market presence in the People’s Republic of China.

Note 6 - Inventories

Inventories consists of the following categories:

	September 30, 2017	December 31, 2016
Raw Materials	\$473,443	\$440,316
Sub-Assemblies	848,078	907,989
Finished Goods	807,973	749,488
Reserve for Obsolescence	(43,627)	(61,272)
	\$2,085,867	\$2,036,521

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

Obsolete inventory charged to cost of goods during the three and nine months ended September 30, 2017 totaled \$2,664 and \$3,158 and \$24,965 and \$27,933 was charged for the three and nine months ended September 30, 2016.

Note 7 - Property, Plant and Equipment

Property, plant and equipment consists of the following:

	September 30, 2017	December 31, 2016
Computer Equipment	\$ 114,771	\$ 114,771
Computer Software	40,681	40,681
Office Equipment	39,959	39,959
Furniture & Fixtures	38,356	29,939
Machinery & Equipment	1,138,134	1,126,134
Molds & Dies	851,254	834,480
Leasehold Improvements	222,593	222,593
	2,445,748	2,408,557
Less		
Accumulated Depreciation	2,203,700	2,149,165
	\$242,048	\$259,392

Depreciation expenses totaled \$18,709 and \$54,536 for the three and nine months ended September 30, 2017 and \$65,264 and \$93,615 for the three and nine months ended September 30, 2016.

Note 8 - Intangible Assets

Intangible assets as of September 30, 2017 and December 31, 2016 and the movements for the periods then ended are as follows:

	Patents & Trademarks	Distributor & Customer Relationships	Totals
Cost or Deemed Cost			
At December 31, 2016	\$2,626,996	\$ 1,270,639	\$3,897,635
Additions	-	-	-
Disposals	-	-	-
At September 30, 2017	\$2,626,996	\$ 1,270,639	\$3,897,635
Accumulated Amortization			
At December 31, 2016	\$1,325,221	\$ 1,270,639	\$2,595,860
Amortization Charge	128,331	-	128,331
Disposals	-	-	-
At September 30, 2017	\$1,453,552	\$ 1,270,639	\$2,724,191
Net Book Value			
At December 31, 2016	\$1,301,775	\$ -	\$1,301,775
At September 30, 2017	\$1,173,444	\$ -	\$1,173,444

Amortization expense totaled \$42,777 and \$128,331 during the three and nine months ended September 30, 2017 and \$42,777 and \$128,331 for the three and nine months ended September 30, 2016.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

The estimated aggregate amortization expense for each of the five succeeding fiscal years is as follows:

Period	Amount
2017	\$ 171,108
2018	\$ 171,108
2019	\$ 171,108
2020	\$ 171,108
2021	\$ 171,108

Note 9 - Trade and Other Payables

Trade and other payables consists of the following:

	September 30, 2017	December 31, 2016
Trade Payables	\$ 1,044,056	\$ 923,311
Accrued Expenses	445,241	480,302
Deferred Compensation	59,750	59,750
	\$ 1,549,047	\$ 1,463,363

Trade and other payables – related party are as follows:

	September 30, 2017	December 31, 2017
Trade Payables	\$ 20,245	\$ 182,001
Accrued Expenses	-	52,066
	\$ 20,245	\$ 234,067

As of September 30, 2017, the Company owed ChubeWorkx Guernsey Limited, a major shareholder, royalties of \$17,164 (Note 14) which was paid on October 24, 2017.

As of September 30, 2017, the Company owed Hainan \$670. Senior management at Hainan are actively involved in Shenzhen Savy-Akers Biosciences (“Shenzhen”) which is therefore being included as a related party. The Company owed Shenzhen \$2,411 as of September 30, 2017.

Trade and other payables are non-interest bearing and are normally settled on 30 – 60 day terms.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

Note 10 - Share-based Payments

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

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

On September 30, 2016, the Board of Directors increased the number of authorized shares of common stock subject to the Amended Plan to 830,000 shares. As of September 30, 2017, under the 2013 Amended Plan, grants of restricted stock and options to purchase 268,166 shares of common stock have been issued and are unvested or unexercised and 7,292 shares of common stock remain available for grants.

On August 7, 2017, the Shareholders approved and the Company adopted the 2017 Equity Incentive Plan (the “Plan”) which will provide for the issuance of up to 1,350,000 shares. The purpose of the Plan is to provide additional incentive to those officers, employees, consultants and non-employee directors of the Company and its parents, subsidiaries and affiliates whose contributions are essential to the growth and success of the Company’s business.

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

Qualified option holders may exercise their options at their discretion. Each option granted may be exchanged for a prescribed number of shares of common stock.

The Company did not issue any options or warrants under the above plan during the three and nine months ended September 30, 2017.

The following table summarizes the option activities for the nine months ended September 30, 2017:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2016	259,000	\$ 4.23	3.05	\$ 20,100
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	(4,000)	3.25	3.89	—
Canceled/Expired	—	—	—	—
Balance at September 30, 2017	255,000	\$ 4.25	2.27	\$ —
Exercisable as of September 30, 2017	250,334	\$ 4.27	2.24	\$ —

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$0.81 for our common shares on September 29, 2017.

A summary of the Company's non-vested shares as of September 30, 2017 and the changes during the period then ended are as follows:

Non-Vested Shares	Shares	Weighted Average Grant Date Fair Value
Non-vested at January 1, 2017	19,834	\$ 2.36
Granted	-	-
Vested	(11,168)	2.07
Forfeited	(4,000)	2.36
Non-vested at September 30, 2017	4,666	\$ 2.36

Unrecognized compensation cost related to non-vested employee stock options totaled \$9,702 as of September 30, 2017. The cost is to be recognized over a weighted average period of 0.88 years.

During the three and nine months ended September 30, 2017, the Company incurred stock option expenses totaling \$4,373 and \$16,685 and totaled \$38,263 and \$46,504 for the three and nine months ended September 30, 2016.

During the nine months ended September 30, 2017, the Company issued 894,750 warrants in conjunction with the January 2017 public offering and an additional 796,620 warrants with the March 2017 private placement. All warrants carry a five-year expiration term. The table below summarizes the warrant activity for the nine months ended September 30, 2017:

Weighted	Weighted
Average	Remaining

	Number of Warrants	Average Exercise Price	Contractual Term (years)
Balance at December 31, 2016	-	\$ -	-
Granted	1,691,370	1.88	-
Exercised	(200,800)	1.50	-
Forfeited	-	-	-
Canceled/Expired	-	-	-
Balance at September 30, 2017	1,490,570	\$ 1.73	4.40
Exercisable as of September 30, 2017	1,490,570	\$ 1.73	4.40

Note 11 - Equity

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

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

On June 8, 2016, the Company issued 27,500 restricted common shares to an officer in connection with his employment agreement. These shares vest 1/3 immediately on the date of the grant and the remaining 2/3 vests equally on March 1, 2017 and March 1, 2018. The fair value of these shares was \$54,725 and was based on the share price on the date of the grant. \$5,374 and \$15,784 was recorded during the three months and nine ended September 30, 2017 as administrative expense on the Condensed Consolidated Statement of Operations and Comprehensive Loss and the remaining \$8,788 is reported as deferred compensation, a contra equity account, on the Condensed Consolidated Balance Sheet as of September 30, 2017.

On January 13, 2017, the Company completed a public offering of 1,789,500 common shares, raising net proceeds of \$1,652,994. Below is a summary of the gross proceeds to net proceeds calculation.

	Shares	\$	\$
Common Shares			
Base Offering	1,667,000	2,000,400	
Over-Allotment	122,500	147,000	
Gross Proceeds			2,147,400
Underwriter/Gunnar Expenses			
Discount		150,318	
Legal Fees		60,000	
Roadshow		1,783	
Miscellaneous		34,005	
Total			246,106
Akers Biosciences Expenses			
Legal & Accounting		197,813	
Registration/Regulatory		50,487	
Total			248,300
Net Proceeds			1,652,994

In addition to the common shares issued, the Company also issued 833,500 warrants with an exercise price of \$1.50 per common share in support of the base offering and 61,250 warrants with an exercise price of \$1.20 per common share. All of the warrants issued have a five-year term.

During the three months ended March 31, 2017, warrant holders from the January 13, 2017 public offering executed 163,300 warrants with an exercise price of \$1.50 per common share, raising net proceeds of \$244,950.

On March 30, 2017, the Company completed a private placement of 1,448,400 unregistered shares of common stock, raising net proceeds of \$1,760,317. The unregistered shares were admitted to trading on June 30, 2017 upon notification from the Securities and Exchange Commission that the Registration Statement, filed April 19, 2017, had been deemed effective. Below is a summary of the gross proceeds to net proceeds calculation.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

	Shares	\$	\$
Common Shares			
Base Offering	1,448,400	2,027,760	
Gross Proceeds			2,027,760
Underwriter/Gunnar Expenses			
Discount		141,943	
Legal Fees		50,000	
Total			191,943
Akers Biosciences Expenses			
Legal & Accounting		75,000	
Filing Fees		500	
Total			75,500
Net Proceeds			1,760,317

In addition to the common shares issued, the Company also issued 796,620 warrants with an exercise price of \$1.96 per common share with a five-year term.

On April 11, 2017, the Company issued 10,000 restricted shares to a consultant for services to be rendered during the year ending December 31, 2017. These shares vested on the date of the grant. The fair value of these shares was \$18,000 and was based on the share price on the date of the grant. The Company recorded \$5,455 during the nine months ended September 30, 2017 as sales and marketing expenses on the Condensed Consolidated Statement of Operations and Comprehensive Loss.

During the three months ended June 30, 2017, warrant holders from the January 13, 2017 public offering executed 37,500 warrants with an exercise price of \$1.50 per common share, raising net proceeds of \$56,250.

Note 12 – Earnings/(Loss) per share

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

Potential common shares consist of options, warrants and unvested restricted stock. Diluted net loss per common share was the same as basic net loss per common share for the three months ended September 30, 2017 since the effect of options and warrants would be anti-dilutive due to the net loss attributable to the common shareholders.

Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were as follows: incentive and award stock options – 255,000; unvested restricted shares of common stock – 9,166; warrants – 1,490,570 as of September 30, 2017.

Potential common shares consist of options, warrants and unvested restricted stock. Diluted net income per common share was the same as basic net income per common share for the three months ended September 30, 2016. Dilutive Instruments included were as follows: incentive and award stock options – 56,000; unvested restricted shares of common stock – 18,333; warrants – - as of September 30, 2016. Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were incentive and award stock options – 203,000 as of September 30, 2016.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

Potential common shares consist of options, warrants and unvested restricted stock. Diluted net loss per common share was the same as basic net loss per common share for the nine months ended September 30, 2017 and 2016 since the effect of options and warrants would be anti-dilutive due to the net loss attributable to the common shareholders. Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were as follows: incentive and award stock options – 255,000 (2016: 203,000); unvested restricted shares of common stock – 9,166 (2016: 18,333); warrants – 1,490,570 (2016: -) as of September 30, 2017.

Note 13 - Income Tax Expense

There is no income tax benefit for the losses for the three ended September 30, 2017 since management has determined that the realization of the net deferred tax asset is not assured and has created a valuation allowance for the entire amount of such benefits.

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

There is no income tax benefit for the losses for the nine months ended September 30, 2017 and 2016 since management has determined that the realization of the net deferred tax asset is not assured and has created a valuation allowance for the entire amount of such benefits.

The Company's policy is to record interest and penalties associated with unrecognized tax benefits as additional income taxes in the statement of operations. As of January 1, 2017, the Company had no unrecognized tax benefits, or any tax related interest or penalties. There were no changes in the Company's unrecognized tax benefits during the three and nine months ended September 30, 2017 related to unrecognized tax benefits. With few exceptions, the U.S. and state income tax returns filed for the tax years ended on December 31, 2013 and thereafter are subject to examination by the relevant taxing authorities.

Note 14 - Related Party Transactions

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

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

On August 17, 2016, the Company entered into a Settlement Agreement (the “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 (i) the action in the United States Federal Court, District of New Jersey brought by the Company against ChubeWorkx for outstanding amounts due to the Company under a promissory note and (ii) the action in The High Court of Justice, Queen’s Bench Division Commercial Court, Royal Courts of Justice, United Kingdom brought by ChubeWorkx against the Company arising from an exclusive licensing agreement between ChubeWorkx and the Company (“Licensing Agreement”).

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

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

In return for the Company regaining the full rights to sell breath technology products, under the terms of the Settlement Agreement, ChubeWorkx is entitled to receive a royalty of 5% of the Company’s gross revenues (the “ChubeWorkx Royalty”) until ChubeWorkx has earned an aggregate \$5,000,000, after which point ChubeWorkx will no longer be entitled to receive any royalties from the Company and the Company shall have no further obligation to ChubeWorkx. The Settlement Agreement further allows the Company to retain 50% of the ChubeWorkx Royalty until the full \$549,609 cash component of the monies owed by ChubeWorkx to the Company as described above has been satisfied. The Company recorded royalty expenses of \$34,328 and \$128,108 for the three and nine months ended September 30, 2017 and \$117,949 for the three and nine months ended September 30, 2016 which are included in sales and marketing expenses – related party on the Condensed Consolidated Statement of Operations and Comprehensive Loss.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

Other terms of the Settlement include: 1) the pledge as security of all earned but unpaid royalties by the Company to ChubeWorkx all Company assets, worthy to satisfy its obligations, including all inventory and receivables, with the exception of (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other equipment; 2) the pledge as security of the settlement sum which remains unpaid by the Company to ChubeWorkx all Company (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other equipment; and 3) the grant of voting proxy by ChubeWorkx to the Company which allows the Company to vote ChubeWorkx's shares for corporate formalities under certain conditions.

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

Prior to the acquisition of the BreathScan® Alcohol Detector inventory pursuant to the Settlement Agreement from ChubeWorkx, the Company had pre-existing inventory totaling \$467,646 for the detectors purchased. During the three and nine months ended September 30, 2017, the Company sold 1.8% and 6.2% of the cumulative unit inventory and recognized revenue totaling \$39,100 and \$139,900 and \$- for the three and nine months ended September 30, 2016.

The Company began purchasing manufacturing molds, plastic components and the assembled BreathScan Lync™ device through Hainan and its related party during the year ended December 31, 2016 (Note 9). The Company purchased a total of \$- during the three months ended September 30, 2017 and 2016 and \$16,774 and \$2,287 for the nine months ended September 30, 2017 and 2016 from this related party. As of September 30, 2017, the Company had a prepayment credit of \$25,989 with Shenzhen and owed two other related companies of Hainan \$3,081 which is included in trade and other payables – related parties on the Condensed Consolidated Balance Sheet.

Trade receivables – related parties as of September 30, 2017 and December 31, 2016 were \$125,001 and \$31,892. The amounts due are non-interest bearing, unsecured and generally have a term of 30-180 days (Note 5).

Product revenue – related parties for the three months ended September 30, 2017 and 2016 were \$- and total \$124,631 and \$380 for the nine months then ended. The revenue was the result of sales to Hainan and its related parties.

Note 15 - Commitments

The Company leases its facility in West Deptford, New Jersey under an operating lease (“Thorofare Lease”) with annual rentals of \$132,000 plus common area maintenance (CAM) charges. The lease, which took effect on January 1, 2008, reduced the CAM charges allowing the Company to reach their own agreements with utilities and other maintenance providers.

On January 7, 2013, the Company extended its lease agreement for a term of 7 years, expiring December 31, 2019.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

Rent expense for the Thorofare Lease, including related CAM charges for the three months ended September 30, 2017 and 2016 totaled \$40,440 and \$40,290, respectively. Rent expenses for the Thorofare Lease, including related CAM charges totaled \$121,220 and \$120,870 for the nine months ended September 30, 2017 and 2016.

The Company entered into a 24-month lease for a satellite office located in Ramsey, New Jersey ("Ramsey Lease") with annual rents of \$25,980 plus common area maintenance (CAM) charges. The lease took effect on June 1, 2017 and runs through May 31, 2019.

Rent expenses for the Ramsey Lease, including related CAM charges totaled \$6,506 and \$6,506 for the three and nine months ended September 30, 2017. The Company posted a security deposit of \$4,330 which is included in other assets on the Condensed Consolidated Balance Sheet.

The Company entered into a 29-month lease for warehouse space located in Pitman, New Jersey ("Pitman Lease") with annual rents of \$39,650. The lease took effect on August 1, 2017 and runs through December 31, 2019.

Rent expenses for the Pitman Lease totaled \$6,608 for the three and nine months ended September 30, 2017. A security deposit of \$4,950 is included in other assets on the Condensed Consolidated Balance Sheet.

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

The schedule of lease commitments is as follows:

	Thorofare Lease	Ramsey Lease	Pitman Lease	Equipment Lease	Total
	\$	\$	\$	\$	\$
Next 12 Months	132,000	25,980	39,650	6,156	203,786
Next 13-24 Months	132,000	17,320	39,650	6,156	195,126

Next 25-36 Months	33,000	-	9,913	513	43,426
-------------------	--------	---	-------	-----	--------

On June 30, 2017, the Company signed the Third Amendment to the exclusive Distribution Agreement with NovoTek Pharmaceuticals Limited ('NovoTek') which expanded the geographic area of coverage to include Poland and grants NovoTek the right to assemble certain PIFA Heparin PF/4 products in their facilities from components acquired from the Company.

The Company has agreed to provide PIFA Heparin/PF4 devices, valued at approximately \$90,000, at no charge to NovoTek for their use and are to be shipped upon their request. To date, the products purchased by NovoTek have been used for regulatory submissions, clinical studies or trials and as product samples to generate interest in the product in the Peoples Republic of China.

As of September 30, 2017, the Company had not incurred any expense related to the program.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

Note 16 - Major Customers

For the three months ended September 30, 2017, two customers generated 10% or more of the Company's revenue. Sales to these customers accounted for 65% of the Company's revenue. As of September 30, 2017, the amount due from these customers was \$345,201. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

For the nine months ended September 30, 2017, three customers generated 10% or more of the Company's revenue. Sales to these customers accounted for 67% of the Company's revenue. As of September 30, 2017, the amount due from these customers was \$854,103 of which \$500,000 has an extended term of 180 days. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

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

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

Note 17 - Major Suppliers

For the three months ended September 30, 2017, two suppliers accounted for 10% or more of the Company's purchases. These suppliers accounted for 31% of the Company's total purchases. As of September 30, 2017, the amount due to these suppliers was \$30,702.

Edgar Filing: Akers Biosciences, Inc. - Form 10-Q

For the nine months ended September 30, 2017, one supplier accounted for 10% or more of the Company's purchases. This supplier accounted for 11% of the Company's total purchases. As of September 30, 2017, the amount due to this supplier was \$-.

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

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

Note 18 – Contingencies

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

The Company filed a series of motions with the Court seeking (1) to dismiss the Pulse complaint for lack of jurisdiction or, in the alternative, transfer the matter to the District Court for the District of New Jersey, Camden Vicinage and (2) to dismiss the unfair competition claims for failure to state a claim on which relief could be granted. Oral arguments on these motions were heard by the Court on March 10, 2017.

The Court decided by order dated April 14, 2017 in favor of the Company and has dismissed with prejudice the claims brought by Pulse for unfair competition (both federal and state counts). The court decided against the Company in its motions for transfer of venue and for lack of jurisdiction. As such, the case shall proceed in the District Court of Oregon.

Pulse subsequently filed an Amended Complaint, in which Pulse seeks not less than \$500,000 in damages and, among other items, an injunction prohibiting the Company from manufacture, use and sale of the OxiChek product. The Company answered the Amended Complaint on May 30, 2017. Discovery has commenced and is scheduled to conclude on January 22, 2018. The Court has set the trial date for July 17, 2018.

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

Note 19 – Segment Information

The Company is organized and operates as one operating segment. In accordance with FASB ASC 280 “Segment Reporting”, the Chief Operating Officer is the chief operating decision-maker who reviews operating results to make decisions on allocation of resources and assessment of performance for the entire company.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

The total revenue by different product lines was as follows:

Product Line	Three months ended		Nine months ended	
	September 30, 2017	2016	September 30, 2017	2016
MicroParticle Catalyzed Biosensor (“MPC”)	\$104,094	\$85,337	\$381,569	\$195,040
Particle ImmunoFiltration Assay (“PIFA”)	490,058	514,840	1,477,726	2,029,095
Rapid Enzymatic Assay (“REA”)	27,500	-	27,500	-
Other	16,679	13,021	616,647	83,573
Product Revenue Total	\$638,331	\$613,198	\$2,503,442	\$2,307,708
License Fees	37,500	-	37,500	-
Total Revenue	\$675,831	\$613,198	\$2,540,942	\$2,307,708

The total revenue by geographic area determined based on the location of the customers was as follows:

Geographic Region	Three months ended		Nine months ended	
	September 30, 2017	2016	September 30, 2017	2016
United States	\$626,077	\$603,006	\$1,755,695	\$1,721,967
People’s Republic of China	-	383	627,132	506,781
Rest of World	49,754	9,809	158,115	78,960
Total Revenue	\$675,831	\$613,198	\$2,540,942	\$2,307,708

The Company had long-lived assets totaling \$55,504 and \$61,081 located in the People’s Republic of China and \$1,359,987 and \$1,500,086 located in the United States as of September 30, 2017 and December 31, 2016, respectively.

Note 20 - Subsequent Events

Edgar Filing: Akers Biosciences, Inc. - Form 10-Q

On October 12, 2017, the Company entered into Warrant Exercise Agreements with the existing holders from the March 2017 private placement to exercise their current warrants at \$1.00 per share and receive a new warrant which would be convertible into the same number of common shares as the original warrant. The new warrants have an exercise price of \$1.26, expire five years from the date of issuance and are not exercisable for six months after issuance. The incremental fair value resulting from the modification of these warrants will be accounted for as a deemed dividend in the statement of operations.

Pursuant to the Warrant Exercise Agreements, as of the date of the filing of this report, 724,200 warrants were exercised for the purchase of 724,200 shares of the Company's common stock raising net proceeds of \$680,748.

On October 17, 2017, the Board of Directors issued 295,107 restricted shares of common stock to key employees and officers of the Company as part of the 2017 Equity Incentive Plan. The restricted stock vested immediately and were issued at the closing price of \$0.88 per share. Expenses related to the grants totaled \$259,694 and will be reported on the Consolidated Statement of Operations for the year ending December 31, 2017 as follows:

Expense Category	2017	2016
General & Administrative	\$ 163,924	-
Sales & Marketing	95,770	-
	\$259,694	\$ -

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

The Company's current working capital position;

Negotiations are underway with a potential customer for the Company's BreathScan OxiChek products and are anticipated to be completed during the three months ending December 31, 2017; however, they have requested product design changes that must be completed prior to the consummation of the purchase agreement. All parties are confident that a solution can be achieved but a significant delay will impact revenue projections; and

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

Please refer to Note 3, Management Plan, of the Financial Statements for the Company's plans to address the going concern.

Summary of Statements of Operations for the Three Months Ended September 30, 2017 and 2016**Revenue**

Akers' revenue for the three months ended September 30, 2017 totaled \$675,831, a 10% increase from the same period in 2016. The table below summarizes our revenue by product line for the three months ended September 30, 2017 and 2016 as well as the percentage of change year-over-year:

Product Lines	3 Months Ended September 30, 2017	3 Months Ended September 30, 2016	Percent Change	
Particle ImmunoFiltration Assay ("PIFA")	\$ 490,058	\$ 514,839	(5	)%
MicroParticle Catalyzed Biosensor ("MPC")	104,094	85,338	22	%
Rapid Enzymatic Assay ("REA")	27,500	-	100	%
Other	16,679	13,021	28	%
Total Product Revenue	638,331	613,198	4	%
License & Service Revenue	37,500	-	100	%
Total Revenue	\$ 675,831	\$ 613,198	10	%

Revenue from the Company's PIFA Heparin/PF4 Rapid Assay products decreased 5% during the three months ended September 30, 2017 over the same period of 2016. The small decrease of \$24,781 is due primarily to changes by the Company's distribution partners to their management of inventory levels.

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

The Company's MPC breathalyzer technology product sales increased 22% during the three months ended September 30, 2017 over the same period of 2016. Sales in this category include the BreathScan OxiChek and BreathScan Lync products as well as the traditional BreathScan Breath Alcohol product lines.

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

continue to expand their markets.

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

Other operating revenue increased to \$16,679 (2016: \$13,021) during the three months ended September 30, 2017. The product group consists of fees received for shipping and handling and the sale of components.

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

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

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

Geographic Region	3 Months Ended September 30, 2017	3 Months Ended September 30, 2016	Percent Change	
United States	\$ 626,077	\$ 603,006	4	%
People's Republic of China	-	383	(100)	)%
Rest of World	49,754	9,809	407	%
Total Revenue	\$ 675,831	\$ 613,198	10	%

Domestic sales represent the most significant portion of the Company's revenue, contributing 92.6% (2016: 98.3%). The primary sales and marketing efforts are concentrated on expanding the Company's domestic market share in the rapid clinical diagnostic and health and wellness segments and the recent introduction of the Tri-Cholesterol test has allowed the Company to re-enter the retail market.

Revenue from China continues to be highly unpredictable. NovoTek Pharmaceuticals ("NovoTek"), our distribution partner for the PIFA Heparin/PF4 Rapid Assay products, continues to pursue approvals for reimbursement rates from the various Provinces and although they anticipate receipt of these approvals, their timing is unknown. Over the past several years, NovoTek has created significant product demand by identifying and working with the key opinion leaders and seeding the marketplace with sample products. As a result, they anticipate strong demand for the PIFA Heparin/PF4 Rapid Assay product once reimbursement rates are approved.

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

The Company's gross margin declined to 52% (2016: 61%) for the three months ended September 30, 2017. The initial commercial production of the Company's new Tri-Cholesterol product contributed to the decline in gross margin. One-time costs associated with the transition from Research and Development to Manufacturing as the production plans were implemented and adjusted included engineering, raw material waste as processes were fine-tuned to meet commercial production levels, training of the production staff and increased quality review and testing. The inclusion of several of the Research and Development department's professional staff as part of the initial production team significantly increased direct labor costs.

Cost of sales for the three months ended September 30, 2017 totaled \$323,526 (2016: \$236,700). Direct cost of sales increased to 31% of product revenue while other cost of sales decreased to 20% for the three months ended September

30, 2017 as compared to 18% and 21% respectively for the same period in 2016.

Direct cost of sales for the three-month period ended September 30, 2017 were \$196,866 (2016: \$109,835). Other cost of sales for the three months ended September 30, 2017 were \$126,660 (2016: \$126,865).

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2017, totaled \$819,565, which was a 47% increase as compared to \$558,293 for the three months ended September 30, 2016.

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

Description	3 Months Ended September 30, 2017	3 Months Ended September 30, 2016	Percent Change	
Personnel Costs	\$ 223,361	\$ 168,913	32	%
Professional Service Costs	320,081	110,101	191	%
Stock Market & Investor Relations Costs	120,807	88,953	36	%
Other General and Administrative Costs	155,316	190,326	(18)	)%
Total General and Administrative Expense	\$ 819,565	\$ 558,293	47	%

Personnel expenses increased by 32% for the three months ended September 30, 2017 as compared to the same period of 2016. The increase is related to the creation of the Controller's position in the Finance department, salary adjustments for executive management and higher employee benefit expenses.

Professional service costs increased by 191% for the three months ended September 30, 2017 as compared to the same period of 2016. A significant increase in legal fees (\$258,026 (2016: \$56,919)) accounted for the majority of the change.

Stock market and investor relations costs increased by 36% for the three months ended September 30, 2017 as compared to the same period of 2016. Expenses related to the Company's annual meeting, transfer agent fees and investor relations fees contributed to the increase.

The Company's other general and administrative expenses declined by 18% for the three months ended September 30, 2017 as compared to the same period of 2016. Continued efforts to reduce costs resulted in savings across several expense categories, the most significant of which resulted from the travel restrictions put in place earlier in the year. Travel expenses for the executive and administrative staff totaled \$10,140 (2016: \$18,074).

Sales and Marketing Expenses

Sales and marketing expenses for the three months ended September 30, 2017 totaled \$377,091, which was a 28% decrease as compared to \$526,197 for the three months ended September 30, 2016.

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

Description	3 Months Ended September 30, 2017	3 Months Ended September 30, 2016	Percent Change
Personnel Costs	\$ 184,835	\$ 222,980	(17)%
Professional Service Costs	67,111	77,094	(13)%
Royalties and Outside Commission Costs	43,635	128,828	(66)%
Other Sales and Marketing Costs	81,510	97,295	(16)%
Total Sales and Marketing Expenses	\$ 377,091	\$ 526,197	(28)%

Personnel costs decreased in the three months ended September 30, 2017 as compared to the same period of 2016. The Company has reduced its sales and marketing staff from 10 members on January 1, 2016 to 4 as of September 30, 2017. The new sales and marketing strategy targets large integrated delivery networks instead of individual facilities. This strategy requires fewer, but more experienced and technically knowledgeable sales personnel to interact with executive management, laboratory and medical directors.

The Company renegotiated or eliminated several consulting arrangements targeted at improving market penetration or identifying marketing or distribution partners during the first half of 2016. The result is a reduction of 13% in professional service costs with general consulting services (\$60,862 (2016: \$75,010)) accounting for the majority of the savings for the three months ended September 30, 2017.

The legal settlement with ChubeWorkx Guernsey, Ltd (“ChubeWorkx”), signed on August 11, 2016, requires the Company to pay a 5% royalty on adjusted gross sales to ChubeWorkx on a quarterly basis. During the three months ended September 30, 2017, this royalty totaled \$34,328 (2016: \$117,949).

A decline in travel expenses (\$37,405 (2016: \$46,189)), sponsorships (\$- (2016: \$10,500)) and small decreases in other expenses resulted in an overall decline of 16% in other sales and marketing costs.

Research and Development

Research and development expenses for the three months ended September 30, 2017 totaled \$290,447, which was a 17% increase as compared to \$247,578 for the three months ended September 30, 2016.

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

Description	3 Months Ended September 30, 2017	3 Months Ended September 30, 2016	Percent Change	
Personnel Costs	\$ 214,369	\$ 161,257	33	%
Clinical Trial Costs	2,153	19,062	(89)	%
Professional Service Costs	41,829	39,369	6	%
Other Research and Development Costs	32,096	27,890	15	%
Total Research and Development Expenses	\$ 290,447	\$ 247,578	17	%

Personnel costs increased 33% during the three months ended September 30, 2017 as compared to the same period of 2016. The increase is related to salary adjustments and higher employee benefit expenses.

Clinical trial costs decreased 89% during the three months ended September 30, 2017 as compared to the same period of 2016. The Company continued to perform two clinical trials during the three months ended September 30, 2016, one to test the effectiveness of the PIFA Chlamydia assay and one for the KetoChek™ health and wellness product. Both studies were completed during 2016 and no significant expense was incurred during the three months ended September 30, 2017.

An increase in travel expenses (\$9,282 (2016: \$2)) was offset by reduced costs in several other expense categories which accounted for the 15% increase in other research and development expenses.

Edgar Filing: Akers Biosciences, Inc. - Form 10-Q

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

Project	2017	2016
Asthma/pH	\$52,368	\$-
Breath Alcohol	1,714	-
Chlamydia Trachomatis	32,791	22,307
Heparin/PF4	19,257	16,885
Ketone	3,689	-
KetoChek / OxiChek	70,056	117,871
METRON	-	74
Other Projects	-	248
Pulmo Health	-	5,447
Tri-Cholesterol	110,572	84,746
Total R&D Expenses:	\$290,447	\$247,578

Other Income and Expense

Other expense, net of income for the three months ended September 30, 2017 totaled \$68, which was a 101% decrease as compared to other income, net of expense of \$8,893 for the three months ended September 30, 2016.

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

Description	3 Months Ended September 30, 2017	3 Months Ended September 30, 2016	Percent Change
Currency Translation Gain/(Loss)	\$ (3,195)	\$ 3,629	(188)%
Realized Gain/(Loss) on Investments	1,719	1,269	35 %
Interest and Dividends	1,408	3,995	(65)%
Other Income	-	-	- %
Total Other Income, Net of Expenses	\$ (68)	\$ 8,893	(101)%

Gains and losses associated with foreign currency transactions declined by 188% during the three months ended September 30, 2017 as compared to the same period of 2016, primarily a result of the increased strength of the British Pound compared to the US Dollar.

Realized gains, interest and dividend income declined to \$3,127 (2016: \$5,264). The Company's available capital for investment activities was limited during the three months ended September 30, 2017 resulting in the decline in investment income.

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

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

Product Lines	9 Months Ended September 30, 2017	9 Months Ended September 30, 2016	Percent Change	
Particle ImmunoFiltration Assay (“PIFA”)	\$1,477,726	\$2,029,095	(27	)%
MicroParticle Catalyzed Biosensor (“MPC”)	381,569	195,040	96	%
Rapid Enzymatic Assay (“REA”)	27,500	-	100	%
Other	616,647	83,573	638	%
Total Product Revenue	2,503,442	2,307,708	8	%
License & Service Revenue	37,500	-	100	%
Total Revenue	\$2,540,942	\$2,307,708	10	%

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

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

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

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

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

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

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

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

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

Geographic Region	9 Months	9 Months	Percent
	Ended September 30, 2017	Ended September 30, 2016	
			Change

Edgar Filing: Akers Biosciences, Inc. - Form 10-Q

United States	\$1,755,695	\$1,721,967	2	%
People's Republic of China	627,132	506,781	24	%
Rest of World	158,115	78,960	100	%
Total Revenue	\$2,540,942	\$2,307,708	10	%

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

Revenue from China continues to be highly unpredictable. NovoTek Pharmaceuticals ("NovoTek"), our distribution partner for the PIFA Heparin/PF4 Rapid Assay products, continues to pursue approvals for reimbursement rates from the various Provinces and although they anticipate receipt of these approvals, their timing is unknown. Over the past several years, NovoTek has created significant product demand by identifying and working with the key opinion leaders and seeding the marketplace with sample products. As a result, they anticipate strong demand for the PIFA Heparin/PF4 Rapid Assay product once reimbursement rates are approved.

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

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

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

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

General and Administrative Expenses

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

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

Description	9 Months Ended September 30, 2017	9 Months Ended September 30, 2016	Percent Change	
Personnel Costs	\$781,833	\$712,683	10	%
Professional Service Costs	866,403	587,196	48	%
Stock Market & Investor Relations Costs	320,446	322,956	(1)	)%
Other General and Administrative Costs	471,341	675,264	(30)	)%

Total General and Administrative Expense \$2,440,023 \$2,298,099 6 %

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

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

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

Sales and Marketing Expenses

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

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

Description	9 Months Ended September 30, 2017	9 Months Ended September 30, 2016	Percent Change
Personnel Costs	\$702,319	\$937,777	(25)%
Professional Service Costs	204,237	384,114	(47)%
Royalties and Outside Commission Costs	192,470	178,873	8 %
Other Sales and Marketing Costs	283,390	264,188	7 %
Total Sales and Marketing Expenses	\$1,382,416	\$1,764,952	(22)%

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

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

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

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

Research and Development

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

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

Description	9 Months Ended September 30, 2017	9 Months Ended September 30, 2016	Percent Change	
Personnel Costs	\$ 727,206	\$ 539,810	35	%
Clinical Trial Costs	2,453	160,405	(98)	)%
Professional Service Costs	89,541	96,515	(7)	)%
Other Research and Development Costs	133,524	136,128	(2)	)%
Total Research and Development Expenses	\$ 952,724	\$ 932,858	2	%

Personnel costs increased 35% during the nine months ended September 30, 2017 as compared to the same period of 2016. This increase was a result of the transfer of Dr. Akers' salary and benefits from the General and Administrative department to Research and Development as he assumed his new responsibilities for the Company. In addition, employee benefit expenses (\$72,026 (2016: \$45,052)) also contributed to the increase.

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

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

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

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

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

Total R&D Expenses: \$952,724 \$932,858

Other Income and Expense

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

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

Description	9 Months Ended September 30, 2017	9 Months Ended September 30, 2016	Percent Change	
Currency Translation Gain/(Loss)	\$ 6,172	\$ (1,189)	619	%
Realized Gain on Investments	3,375	3,421	(1	)%
Interest and Dividends	5,921	20,560	(71	)%
Other Income	-	-	-	%
Total Other Income, Net of Expenses	\$ 15,468	\$ 22,792	(32	)%

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

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

Liquidity and Capital Resources

For the nine months ended September 30, 2017 and 2016, the Company generated a net loss attributable to shareholders of \$3,193,571 and \$2,207,707, respectively. As of September 30, 2017 and December 31, 2016, the Company has an accumulated deficit of \$100,673,108 and \$94,479,537 and had cash and equivalents totaling \$145,311 and \$72,700, respectively.

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.

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

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

The Company's current working capital position

Negotiations are underway with a potential customer for the Company's BreathScan OxiChek products and are anticipated to be completed during the three months ending December 31, 2017; however, they have requested

product design changes that must be completed prior to the consummation of the purchase agreement. All parties are confident that a solution can be achieved but a significant delay will impact revenue projections.

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

Please refer to Note 3, Management Plan, of the Financial Statements for the Company’s plans to address the going concern.

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

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

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

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

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

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

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

Description	9 Months Ended September 30, 2017	9 Months Ended September 30, 2016	Percent Change	
Cash at beginning of period	\$72,700	\$402,059	(82	)%
Loss from operations	(3,193,571)	(2,207,707)	(45	)%
Adjustments				
Non-Operating Gains	-	-	-	%
Non-Cash Activities	266,881	(846,749	) 129	%
Cash Used in Operating Activities				
Cash Consumed by Operating Activities	(935,622	) (754,781	) (12	)%
Cash Contributed by Operating Activities	207,454	275,588	(50	)%
Cash Flows from Investing Activities				
Cash Consumed by Investing Activities	(2,746,339)	(125,383	) (2,090	)%
Cash Contributed by Investing Activities	2,749,119	3,452,833	(20	)%
Cash Flows from Financing Activities				
Cash Consumed by Financing Activities	-	-	-	%
Cash Contributed by Financing Activities	3,714,511	-	100	%
Cash at end of period	\$135,133	\$195,860	(31	)%

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

securities. Proceeds from the sale of marketable securities contributed cash of \$2,749,119 for the period ended September 30, 2017.

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

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

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

Critical Accounting Policies

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

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

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

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

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

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

Fair Value Measurement – Marketable Securities

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

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

Level 2 Inputs to the valuation methodology include

quoted prices for similar assets or liabilities in active markets;

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

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

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

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

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

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

Intangible Assets

The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person's breath, blood, urine and saliva. Propriety protection for the Company's products, technology and process is important to its competitive position. As of September 30, 2017, the Company has eleven patents from the United

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

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

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

Long-Lived Assets

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

Investments

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

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

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

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

valuation.

Revenue Recognition

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

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

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

Stock-based Compensation

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

Recently Issued and Adopted Accounting Pronouncements

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

Quantitative and Qualitative Disclosure About Market Risk

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

Interest Rates

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

Off-Balance Sheet Arrangements

We have no significant known off balance sheet arrangements.

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, 2017 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 Deed (the “Settlement Agreement”) by and among the Company, ChubeWorkx Guernsey Limited (“Chube”), Thirty Six Strategies, LLC (“36S”), Gavin Moran (“Mr. Moran”) and Frank Runge (“Mr. Runge”) (each, a “Party” and, collectively, the “Parties”) to resolve disputes related to (i) the Company’s claims brought against Chube in United States District Court, District of New Jersey for outstanding amounts due to the Company pursuant to that certain promissory note (the “Note”) issued in favor of Chube on December 31, 2014 (“Dispute 1”); (ii) various claims brought by Chube against the Company brought in The High Court of Justice, Queen’s Bench Division Commercial Court, Royal Courts of Justice, United Kingdom arising out that certain Licensing and Supply Agreement, as amended (the “License Agreement”), pursuant to which Chube was granted a worldwide, exclusive license to import, offer for sale, sell, distribute, use, promote or label certain products using the Company’s intellectual property (“Dispute 2”) and (iii) various claims brought by the Company against 36S, Mr. Moran and Mr. Runge in the United States District Court, District of New Jersey, related to that certain Distribution Agreement entered into by and between the Company and 36S on October 5, 2015 (“Dispute 3” and, together with Dispute 1 and Dispute 2, the “Disputes”).

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

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

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

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

The Company filed a series of motions with the Court seeking (1) to dismiss the Pulse complaint for lack of jurisdiction or, in the alternative, transfer the matter to the District Court for the District of New Jersey, Camden Vicinage and (2) to dismiss the unfair competition claims for failure to state a claim on which relief could be granted. Oral arguments on these motions were heard by the Court on March 10, 2017.

The Court decided by order dated April 14, 2017 in favor of the Company and has dismissed with prejudice the claims brought by Pulse for unfair competition (both federal and state counts). The court decided against the Company in its motions for transfer of venue and for lack of jurisdiction. As such, the case shall proceed in the District Court of Oregon.

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

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

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

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 April 11, 2017.

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, 2017, 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.

- 10.1 Form of Akers Biosciences, Inc. 2017 Equity Incentive Plan (incorporated by reference to Akers Biosciences, Inc. Current Report on Form 8-K filed with the SEC on August 11, 2017).
- 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** 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.

** Furnished 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, 2017 By: */s/ John J. Gormally*
Name: John J. Gormally
Chief Executive Officer
Title:
(Principal Executive Officer)

Date: November 14, 2017 By: */s/ Gary M. Rauch*
Name: Gary M. Rauch
Vice President, Finance & Treasurer
Title:
(Principal Financial Officer)

