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, 2018**

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 of incorporation)	(IRS Employer Identification No.)

201 Grove Road
Thorofare, NJ 08086
(Address of principal executive offices)

(856) 848-8698
(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 [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes [X] 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	[X]
		Emerging growth company	[X]

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 [X]

As of November 13, 2018, there were 12,474,028 shares outstanding of the registrant's Common Stock, after accounting for the one-for-eight reverse stock split effectuated by the Company on November 7, 2018.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
September 30, 2018 and December 31, 2017

	As of	
	September 30, 2018 (unaudited)	**December 31, 2017** (audited)
ASSETS		
Current Assets		
Cash	$ 1,301,418	$ 438,432
Marketable Securities	4,866,033	5,011,607
Trade Receivables, net	283,228	964,671
Deposits and other receivables	30,426	16,590
Deposits and other receivables - Related Party	30,243	-
Inventories, net	807,975	947,612
Prepaid expenses	513,348	145,488
Prepaid expenses - Related Party	77,500	251,499
Total Current Assets	7,910,171	7,775,899
Non-Current Assets		
Prepaid expenses - Related Party	273,411	120,118
Restricted Cash	500,000	-
Property, Plant and Equipment, net	258,611	235,113
Intangible Assets, net	1,002,336	1,130,667
Other Assets	76,093	76,093
Total Non-Current Assets	2,110,451	1,561,991
Total Assets	$ 10,020,622	$ 9,337,890
LIABILITIES		
Current Liabilities		
Trade and Other Payables	$ 2,254,199	$ 1,745,216
Trade and Other Payables - Related Party	47,187	39,821
Total Current Liabilities	2,301,386	1,785,037
Total Liabilities	2,301,386	1,785,037
SHAREHOLDERS' EQUITY		
Convertible Preferred Stock, No par value, 50,000,000 shares authorized, 0 and 1,755 shares issued and outstanding as of September 30, 2018 and December 31, 2017	-	1,755,000
Common Stock, No par value, 500,000,000 shares authorized, 11,779,584 and 5,543,867 issued and outstanding as of September 30, 2018 and December 31, 2017	119,582,020	110,647,169
Deferred Compensation	-	(3,469)
Comprehensive Loss	(5,543)	-
Accumulated Deficit	(111,857,241)	(104,845,847)
Total Shareholders' Equity	7,719,236	7,552,853
Total Liabilities and Shareholders' Equity	$ 10,020,622	$ 9,337,890

See accompanying notes to these condensed consolidated financial statements.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
For the three and nine months ended September 30, 2018 and 2017
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenues:				
Product Revenue	$ 557,089	$ 638,331	$ 1,386,165	$ 2,378,441
License & Service Revenue	-	37,500	-	37,500
Total Revenues	557,089	675,831	1,386,165	2,415,941
Cost of Sales:				
Product Cost of Sales	(476,453)	(323,527)	(1,076,779)	(872,847)
Gross Income	80,636	352,304	309,386	1,543,094
Administrative Expenses	1,650,226	819,565	4,112,444	2,440,023
Administrative Expenses – Related Party	56,425	-	75,342	-
Sales and Marketing Expenses	381,994	342,763	1,292,844	1,254,308
Sales and Marketing Expenses - Related Party	(17,353)	34,328	41,418	128,108
Research and Development Expenses	160,867	290,447	805,619	929,730
Research and Development Expenses – Related Party	-	-	54,342	22,994
Litigation Settlement Expenses	930,000	-	930,000	-
Amortization of Non-Current Assets	42,777	42,777	128,331	128,331
Loss from Operations	(3,124,300)	(1,177,576)	(7,130,954)	(3,360,400)
Other (Income)/Expenses				
Foreign Currency Transaction (Gain)/Loss	(634)	3,195	5,271	(6,172)
Other Income	(4,172)	-	(4,172)	-
Interest and Dividend Income	(35,545)	(3,127)	(120,659)	(9,296)
Total Other Income	(40,351)	68	(119,560)	(15,468)
Loss Before Income Taxes	(3,083,949)	(1,177,644)	(7,011,394)	(3,344,932)
Income Tax Benefit	-	-	-	-
Net Loss Attributable to Common Shareholders	(3,083,949)	(1,177,644)	(7,011,394)	(3,344,932)
Other Comprehensive Income/(Loss)				
Net Unrealized Gain/(Loss) on Marketable Securities	6,900	(1,009)	(5,543)	-
Total Other Comprehensive Income/(Loss)	6,900	(1,009)	(5,543)	-
Comprehensive Loss	$ (3,077,049)	$ (1,178,653)	$ (7,016,937)	$ (3,344,932)
Basic and Diluted loss per common share	$ (0.26)	$ (1.04)	$ (0.65)	$ (3.20)
Weighted average basic and diluted common shares outstanding	11,779,584	1,111,510	10,805,151	1,033,606

See accompanying notes to these condensed consolidated financial statements.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Condensed Consolidated Statement of Changes in Shareholder's Equity
For the nine months ended September 30, 2018

	Preferred Shares Issued and Outstanding	Preferred Stock	Common Shares Issued and Outstanding	Common Stock	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Equity
Balance at December 31, 2017 (audited)	1,755	$ 1,755,000	5,543,867	$ 110,647,169	$ (3,469)	$ (104,845,847)	$ -	$ 7,552,853
Net loss	-	-	-	-	-	(7,011,394)	-	(7,011,394)
Exercise of warrants for common stock	-	-	4,770,092	7,155,200	-	-	-	7,155,200
Conversion of preferred stock to common stock	(1,755)	(1,755,000)	1,462,500	1,755,000	-	-	-	-
Amortization of deferred compensation	-	-	-	-	3,469	-	-	3,469
Issuance of restricted stock to key employees	-	-	3,125	5,175	-	-	-	5,175
Issuance of non-qualified stock options to key employees	-	-	-	6,931	-	-	-	6,931
Issuance of restricted stock for services for non-employees	-	-	-	12,545	-	-	-	12,545
Net unrealized loss on marketable securities	-	-	-	-	-	-	(5,543)	(5,543)
Balance at September 30, 2018 (unaudited)	-	$ -	11,779,584	$ 119,582,020	$ -	$ (111,857,241)	$ (5,543)	$ 7,719,236

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, 2018 and 2017
(unaudited)

	For the Nine Months Ended September 30,	
	2018	**2017**
Cash flows from operating activities		
Net loss	$ (7,011,394)	$ (3,344,932)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued income on marketable securities	(10,633)	(148)
Depreciation and amortization	173,047	182,866
Charge for obsolescence	218,799	-
Allowance for doubtful accounts	97,000	46,239
Amortization of deferred compensation	3,469	15,784
Share based compensation to employees – options	6,931	14,502
Share based compensation to employees - restricted stock	5,175	-
Share based compensation to non-employees – options	-	2,183
Share based compensation to non-employees - restricted stock	12,545	5,455
Changes in assets and liabilities:		
(Increase)/decrease in trade receivables	584,443	(570,065)
Decrease in trade receivables - related party	-	31,892
(Increase)/decrease in deposits and other receivables	(13,836)	2,034
Increase in deposit and other receivables - related party	(30,243)	-
Increase in inventories	(79,162)	(111,486)
(Increase)/decrease in prepaid expenses	(367,860)	68,797
Decrease in prepaid expenses - related party	20,706	38,438
Increase in other assets	-	(9,280)
Increase in trade and other payables	508,983	174,185
Increase/(decrease) in trade and other payables - related party	7,366	(213,822)
Increase in deferred revenue	-	12,500
Net cash used in operating activities	(5,874,664)	(3,654,858)
Cash flows from investing activities		
Purchases of property, plant and equipment	(68,214)	(37,191)
Purchases of marketable securities	(5,309,998)	(2,709,148)
Proceeds from sale of marketable securities	5,460,662	2,749,119
Net cash provided by investing activities	82,450	2,780
Cash flows from financing activities		
Net proceeds from issuance of common stock	-	3,413,311
Net proceeds from exercise of warrants for common stock	7,155,200	301,200
Net cash provided by financing activities	7,155,200	3,714,511
Net increase in cash and restricted cash	1,362,986	62,433
Cash and restricted cash at beginning of period	438,432	72,700
Cash and restricted cash at end of period	$ 1,801,418	$ 135,133
Supplemental Schedule of Non-Cash Financing and Investing Activities		
Net unrealized losses on marketable securities	$ (5,543)	$ -
Conversion of Series B Preferred Stock to common shares	$ 1,755,000	$ -

See accompanying notes to these condensed consolidated financial statements.

Note 1 – Organization and Description of Business

Akers Biosciences, Inc. ("Akers"), is a New Jersey corporation. These condensed consolidated financial statements include two wholly owned subsidiaries, Akers Acquisition Sub, Inc. and Bout Time Marketing Corporation, (together, the "Company"). All material intercompany transactions have been eliminated in consolidation.

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.

Note 2 - 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, 2017 and 2016 included in the Company's 2017 Form 10-K/A, Amendment No. 1, as filed on July 13, 2018. In the opinion of the management, these condensed 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, 2018 and its results of operations and cash flows for the three and nine months ended September 30, 2018 and 2017. The results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the full fiscal year ending December 31, 2018.

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.

On November 8, 2018, the Company effectuated a reverse stock split of its shares of common stock whereby every eight (8) pre-split shares of common stock were exchanged for one (1) post-split share of the Company's common stock ("Reverse Stock Split"). No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise have held a fractional share of the common stock were given one additional full share of the Company's common stock. Numbers presented in these financial statements have been adjusted to reflect the Reverse Stock Split.

(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.

Note 2 - Significant Accounting Policies, continued

(c) Functional and Presentation Currency

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

(f) Restricted Cash

At September 30, 2018, restricted cash included in non-current assets on the Company's condensed consolidated balance sheet was $500,000 representing cash in trust for the purpose of funding legal fees for certain threatened litigation.

(g) 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 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.

Note 2 - Significant Accounting Policies, continued

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.

Following is a description of the valuation methodologies used for assets measured at fair value as of September 30, 2018 and December 31, 2017.

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

	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Quoted Prices for Similar Assets or Liabilities in Active Markets (Level 2)	Significant Unobservable Inputs (Level 3)
Marketable securities at September 30, 2018	$ -	$ 4,866,033	$ -
Marketable securities at December 31, 2017	$ -	$ 5,011,607	$ -

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 and losses relating to the available for sale investment securities were recorded in the Condensed Consolidated Statement of Changes in Shareholders' Equity as comprehensive income. These amounts were an increase of $6,900 and a decrease of $5,543 in unrealized losses for the three and nine months ended September 30, 2018. These amounts were a decrease of $1,009 and $0 in unrealized gains for the three and nine months ended September 30, 2017.

Proceeds from the sale of marketable securities in the three and nine months ended September 30, 2018 were $3,153,987 and $5,460,662. 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. Gross gains and losses, resulting from these sales, amounted to a loss of $6,900 and a gain of $1,719 for the three months ended September 30, 2018 and 2017 and a loss of $11,300 and a gain of $3,375 for the nine months ended September 30, 2018 and 2017.

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

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

Note 2 - Significant Accounting Policies, continued

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.

As of September 30, 2018 and December 31, 2017, allowances for doubtful accounts for trade receivables were $693,196 and $596,196. Bad debt expenses for trade receivables were $0 and $0 for the three months ended September 30, 2018 and 2017, respectively, and $125,500 and $47,741 for the nine months ended September 30, 2018 and 2017, respectively.

(i) Concentrations

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash on deposit with financial institutions and accounts receivable. At times, the Company's cash in banks is in excess of the FDIC insurance limit. The Company has not experienced any loss as a result of these cash deposits. These cash balances are maintained with four banks.

Major Customers

For the three months ended September 30, 2018, three customers generated 61%, 18% and 16%, or 95% in the aggregate, of the Company's revenue. For the nine months ended September 30, 2018, two customers generated 55% and 17%, or 72% in the aggregate, of the Company's revenue. As of September 30, 2018, the amount due from these two customers was $69,567. This concentration makes the Company vulnerable to a near-term severe impact should these relationships be terminated.

For the three months ended September 30, 2017, two customers generated 42% and 27%, or 69% in the aggregate, of the Company's revenue. For the nine months ended September 30, 2017, three customers generated 34%, 21% and 17%, or 72% in the aggregate, of the Company's revenue.

Three customers accounted for 47%, 15%, and 13% or 75%, in the aggregate, of gross trade receivables, before accounting for allowance for doubtful accounts, as of September 30, 2018. To limit such risks, the Company performs ongoing credit evaluations of its customers' financial condition. As of September 30, 2018, the Company had $457,881, $146,196 and $127,329 in trade receivables, respectively, from these customers.

Major Suppliers

For the three months ended September 30, 2018, three suppliers accounted for 25%, 18% and 11%, or 54% in the aggregate, of the Company's purchases. For the nine months ended September 30, 2018, one supplier accounted for 14% of the Company's purchases.

For the three months ended September 30, 2017, two suppliers accounted for 18% and 13%, or 31% in the aggregate, of the Company's purchases. For the nine months ended September 30, 2017, one supplier accounted for 11% of the Company's purchases.

Two vendors accounted for 21% and 14%, or 35%, in the aggregate, of trade payables as of September 30, 2018. As of September 30, 2018, the Company had $150,668 and $98,738 in trade payables, respectively, from these vendors.

Note 2 - Significant Accounting Policies, continued

(j) 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 Condensed 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.

Depreciation expense totaled $17,366 and $18,709 for the three months ended September 30, 2018 and 2017, respectively, and $44,716 and $54,536 for the nine months ended September 30, 2018 and 2017, respectively.

(k) Intangible Assets

The Company’s long-lived intangible assets, other than goodwill, are assessed for impairment when events or circumstances indicate there may be an impairment. These assets were initially recorded at their estimated fair value at the time of acquisition and assets not acquired in acquisitions were recorded at historical cost. However, if their estimated fair value is less than the carrying amount, other intangible assets with indefinite life are reduced to their estimated fair value through an impairment charge to our condensed consolidated statements of income.

Intangible assets as of September 30, 2018 and December 31, 2017 were $1,002,336 and $1,130,667, respectively. Intangible assets at September 30, 2018 consisted of patents, trademarks and customer lists of $3,897,635 net of accumulated amortization and impairment of $2,895,299.

Effective on October 9, 2018, the Company pulled the OxiChek product line from the market (See note 3). This served as a triggering event for testing whether or not our intangible assets were impaired. The Company then preformed a recoverability analysis and determined that as of September 30, 2018, there was no indication of impairment.

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. Amortization expense was $42,777 for the three months ended September 30, 2018 and 2017 and $128,331 for the nine months ended September 30, 2018 and 2017.

The following is an annual schedule of approximate future amortization of the Company’s intangible assets:

Period	Amount
2018 (three months)	$ 42,777
2019	171,108
2020	149,298
2021	147,315
2022	147,315
2023	147,315

Note 2 - Significant Accounting Policies, continued

(l) 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, 2018 and December 31, 2017. In cases where the right of return is granted, and the Company does not have historical experience to reasonably estimate the sales returns, the revenue is recognized when the return privilege has substantially expired.

The Company may provide for rebates to the distributors under limited circumstances. The Company established an accrual of $71,632 and $126,471 as of September 30, 2018 and December 31, 2017. Accounts receivable will be reduced when the rebates are applied by the customer. The Company recognized $26,262 and $51,791 during the three months ended September 30, 2018 and 2017, respectively, for rebates and $70,156 and $224,469 during the nine months ended September 30, 2018 and 2017, respectively, 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.

(m) Income Taxes

The Company utilizes an asset and liability approach for financial accounting and reporting for income taxes. The provision for income taxes is based upon income or loss after adjustment for those permanent items that are not considered in the determination of taxable income. Deferred income taxes represent the tax effects of differences between the financial reporting and tax basis of the Company's assets and liabilities at the enacted tax rates in effect for the years in which the differences are expected to reverse.

The Company evaluates the recoverability of deferred tax assets and establishes a valuation allowance when it is more likely than not that some portion or all the deferred tax assets will not be realized. Management makes judgments as to the interpretation of the tax laws that might be challenged upon an audit and cause changes to previous estimates of tax liability. In management's opinion, adequate provisions for income taxes have been made. If actual taxable income by tax jurisdiction varies from estimates, additional allowances or reversals of reserves may be necessary.

Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon settlement. A liability for "unrecognized tax benefits" is recorded for any tax benefits claimed in the Company's tax returns that do not meet these recognition and measurement standards. As of September 30, 2018 and 2017, no liability for unrecognized tax benefits was required to be reported.

Note 2 - Significant Accounting Policies, continued

There was no income tax expense for the three and nine months ended September 30, 2018 and 2017. There is no income tax benefit for the losses for the three and nine months ended September 30, 2018 and 2017 since management has determined that the realization of the net deferred assets is not assured and has created a valuation allowance for the entire amount of such tax benefits.

The Company's policy for recording interest and penalties associated with tax audits is to record such items as a component of general and administrative expense. There were no amounts accrued for penalties and interest for the nine months ended September 30, 2018 and 2017. The Company does not expect its uncertain tax position to change during the next twelve months. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

The Company has identified its federal tax return and its state tax returns in New Jersey, California, Connecticut and Minnesota as its "major" tax jurisdictions, and such returns for the years 2015 through 2017 remain subject to examination.

The Tax Cuts and Jobs Act (the "Tax Act") was enacted on December 22, 2017. The Tax Act reduced the U.S. federal corporate tax rate from 35% to 21%. As December 31, 2017, the Company had made a reasonable estimate of the effects of the Tax Act. This estimate incorporates assumptions made based upon the Company's current interpretation of the Tax Act and may change as the Company may receive additional clarification and implementation guidance and as the interpretation of the Tax Act evolves. In accordance with Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("SAB 118"), which allows us to record provisional amounts during a measurement period not to extend beyond one year form the enactment date. SAB 118 was codified by the FASB as part of ASU No. 2018-05, *Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118* As of June 30, 2018, we have not made any additional measurement period adjustments. Such adjustments may be necessary in future periods due to, among other things, the significant complexity of the Act and anticipated additional regulatory guidance that may be issued by the Internal Revenue Service ("IRS"), changes in analysis, interpretations and assumptions the Company has made and actions the Company may take as a result of the Act. We are continuing to gather information to assess the application of the Act and expect to finalize the accounting for the effects of the Tax Act no later than the fourth quarter of 2018. Future adjustments made to the provisional effects will be reported as a component of income tax expense in the reporting period in which any such adjustments are determined. Based on the new tax law that lowers corporate tax rates, on December 31, 2017, the Company revalued its deferred tax assets.

Note 2 - Significant Accounting Policies, continued

(n) Shipping and Handling Fees and Costs

The Company charges actual shipping plus a handling fee to customers, which amounted to $8,625 and $13,679 for the three months ended September 30, 2018 and 2017, respectively, and $41,006 and $47,148 for the nine months ended September 30, 2018 and 2017, respectively. 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 consumed are classified as part of the cost of sales, which amounted to $18,126 and $16,148 for the three months ended September 30, 2018 and 2017, respectively, and $83,063 and $63,719 for the nine months ended September 30, 2018 and 2017, respectively.

(o) 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 calculation of basic and diluted loss per share for the three months ended September 30, 2018 and 2017 was based on the loss attributable to common shareholders of $3,083,949 and $1,177,644, respectively, and $7,011,394 and $3,344,932 for the nine months ended September 30, 2018 and 2017, respectively. The basic and diluted weighted average number of common shares outstanding for the three months ended September 30, 2018 and 2017 was 11,779,584 and 1,111,510, respectively, and 10,805,151 and 1,033,606 for the nine months ended September 30, 2018 and 2017, respectively.

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

The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	For the Three and Nine Months Ended September 30,	
	2018	2017
Incentive and Award Stock Options	10,500	31,875
Unvested Restricted Shares of Common Stock	-	1,146
Warrants	1,416,229	186,321
Total potentially dilutive shares	1,426,729	219,342

Note 2 - Significant Accounting Policies, continued

(p) Recently Issued Accounting Pronouncements

Recently Issued Accounting Pronouncements Adopted

As the Company is an emerging growth company, it has elected to adopt recently issued accounting pronouncements based on effective dates applicable to other than public business entities.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230), Restricted Cash. The amendments in this Update require that a statement of cash flows explains the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of period and end-of-period total amounts shown on the statement of cash flows. The amendments in this Update do not provide a definition of restricted cash or restricted cash equivalents. The amendments in this Update are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. For all other entities, the amendments 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. The Company adopted this as of January 1, 2018 (See note 2(f)).

Recently Issued Accounting Pronouncements Not Adopted

In May 2014 and April 2016, the FASB issued ASU No. 2014-09 and ASU No. 2016-10, 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 for entities other than public business entities, and to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period for public business entities. 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 and will adopt this Update as of January 1, 2019.

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. For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is evaluating the impact of adopting this pronouncement.

Note 2 - Significant Accounting Policies, continued

In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is effective for public business entities, certain not-for-profit entities, and certain employee benefit plans for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. For all other entities, ASU 2018-07 is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company is evaluating the impact of adopting this pronouncement.

In July 2018, the FASB issued ASU No. 2018-09, *Codification Improvements*, to makes changes to a variety of topics to clarify, correct errors in, or make minor improvements to the Accounting Standards Codification. Certain items of the amendments in ASU 2018-09 will be effective for the Company in annual periods beginning after December 15, 2018. The Company is currently evaluating the effects the adoption of ASU 2018-09 will have on the consolidated financial statements.

Note 3 – Key Recent Events and Management Plans

By way of a letter dated November 28, 2017, the Listing Qualifications Department of NASDAQ advised the Company that it did not comply with NASDAQ Listing Rule 5550(a)(2) for continued listing, because the Company's common stock did not meet NASDAQ's minimum $1.00 bid price requirement (the "Price Requirement"). The Company informed Nasdaq that the Company is fully committed to regain compliance with the Price Requirement as quickly as possible and, therefore, proposed to institute a reverse stock split. NASDAQ approved of the Company's proposal of a reverse stock split and granted the Company until November 26, 2018, for the Company to be in compliance with the Price Requirement. The Company's latest reported stock price on November 13, 2018 was $2.46. If the Company's stock remains priced above $1.00 by the end of trading on November 21, 2018, it is expected that Nasdaq would give the Company notice of its compliance with the Price Requirement.

On April 25, 2018, the Board of Directors of the Company terminated Dr. Raymond F. Akers from his position as Executive Chairman of the Board and from each of his officer positions as Chief Scientific Director and Secretary of the Company. Dr. Raymond F. Akers continued as a member of the Board of Directors until his resignation on May 27, 2018.

On April 25, 2018, the Board appointed Richard Carlyle Tarbox III, a director of the Company as the interim Non-Executive Chairman of the Board, to hold that position until his successor is appointed, and to the position of Secretary of the Company.

By way of a letter dated May 22, 2018, the Listing Qualifications Department of NASDAQ advised the Company that it did not comply with NASDAQ Listing Rule 5250(c)(1) for continued listing because NASDAQ has not received the Company's Quarterly Report. Company filed a Current Report on a Form 8-K with the Securities and Exchange Commission on May 25, 2018, that NASDAQ has informed the Company that the Company is required to submit a plan to regain compliance with NASDAQ's filing requirements for continued listing within 60 calendar days of the date of the Notice. NASDAQ informed the Company that it is in Compliance with NASDAQ Listing Rule 5250(c)(1) on July 12, 2018.

On June 11, 2018, the Company received a letter from the Listing Qualifications Department NASDAQ notifying the Company that it has determined that the Company violated the shareholder approval requirements of Listing Rule 5635(c). Listing Rule 5635(c) requires shareholder approval prior to the issuance of securities when a stock option or purchase plan is to be established or materially amended or other equity compensation arrangement made or materially amended, pursuant to which stock may be acquired by officers, directors, employees or consultants.

Note 3 – Key Recent Events and Management Plans, continued

Prior to the Company's public offering and listing on NASDAQ, the Company's 2013 Incentive Stock and Award Plan (the "2013 Plan") was approved by its Board of Directors. NASDAQ has concluded that the 2013 Plan was materially amended on two occasions after the Company's public offering and listing on NASDAQ. The first amendment, as approved by the Board on January 9, 2015, increased the number of shares available under the 2013 Plan from 50,000 to 100,000 shares and the second amendment, as approved by the Board on October 5, 2016, increased the number of shares under the 2013 Plan from 100,000 to 103,750 shares (the "2013 Plan Amendments").

During the first quarter of 2018, the Company promptly notified NASDAQ, as required by Listing Rule 5625, when it became aware of its potential non-compliance with Listing Rule 5635(c). On May 4, 2018, the Staff requested additional information from the Company with respect to such non-compliance and on May 31, 2018, the Company responded. On June 25, 2018, the Company submitted a plan to NASDAQ to remediate this matter (the "5635 Compliance Plan"). The 5635 Compliance Plan included that a proposal for shareholders of the Company to ratify the 2013 Plan Amendments be included in the proxy statement for the Company's 2018 annual meeting of the shareholders of the Company and that the Company shall suspend the trading of each share granted, and each share granted upon the exercise of any option granted, in excess of 50,000 shares under the 2013 Plan (the number of shares properly approved pursuant to the 2013 Plan prior to the 2013 Plan Amendments until shareholder ratification). The 5635 Compliance Plan also proposes to prevent the exercise of any option granted under the 2013 Plan until shareholder ratification.

On July 12, 2018, NASDAQ approved of the 5635 Compliance Plan and granted the Company until December 10, 2018, to regain compliance with Listing Rule 5635. The Company intends to have a shareholder meeting on December 7, 2018 to approve the amendments to the 2013 Plan.

On or about June 15, 2018, certain parties brought certain class action lawsuits against the Company. See Note 10 - Contingencies for details.

On July 26, 2018, the Company implemented a reduction in workforce plan which resulted in the elimination of six staff positions in four operating departments.

On September 6, 2018, with the recommendation of the Nominating and Corporate Governance Committee (the "N&G Committee") of the Board appointed Mr. Joshua Silverman as a Director of the Company for a term that expires at the Company's 2018 Annual Meeting of Stockholders, or until his earlier death, disability, resignation or removal.

On September 17, 2018, the Company reached an amicable resolution by way of a settlement agreement and release (the "Settlement Agreement") with Pulse Health, LLC, an Oregon limited liability company (the "Plaintiff") with respect to the lawsuit Plaintiff filed against the Company, in the United States District Court, District of Oregon (the "Court"), Case No.:3:16-CV-01919-HZ (the "Litigation"), effective upon the Court entering a permanent injunction against the Company, which the Court has entered on to the docket on October 4, 2018. Pursuant to the settlement reached between the Plaintiff and the Company, on October 9, 2018 the Company paid $930,000 to the Plaintiff. The Company has also agreed to a permanent injunction and will not make, use, sell or offer to sell the BreathScan OxiChek™ product, any product that detects aldehydes or oxidative stress in exhaled human breath or breath condensate using either basic fuchsin or sodium metabisulfite or any form, analog or equivalent thereof, and the BreathScan Lync device, or any equivalent thereof, as part of a test for aldehydes or oxidative stress in human exhaled breath or breath condensate. The Company does not anticipate a material impact on revenues as a result of the withdrawal of the BreathScan OxiChek™ product from sale. The Settlement Agreement does not contain any admission of liability, wrongdoing, or responsibility by any of the parties.

Note 3 – Key Recent Events and Management Plans, continued

On October 5, 2018, John J. Gormally submitted to the Board his resignation from his position as the Chief Executive Officer of the Company and as a member of the Board, effective immediately. Mr.

Gormally's resignation was voluntary and not a result of any disagreement with the Company or its executive officers on any matter relating to the Company's operations, policies or practices. In connection with his resignation from the Board, Mr. Gormally entered into a Resignation Agreement with the Company.

Effective on October 5, 2018, the Board appointed Howard R. Yeaton, who through Financial Consulting Strategies LLC ("FCS") served previously as a consultant to the Company, to serve as the Chief Executive Officer and interim Chief Financial Officer of the Company. Mr. Yeaton is the managing principal of FCS and the Company's relationship with FCS shall continue, with FCS continuing to provide accounting services to the Company. FCS is considered to be a related party. During the three and nine months ended September 30, 2018, the Company expensed $56,425 and $75,342, respectively, to FCS in connection with these services. As of September 30, 2018, the Company owed FCS $22,862 which is included in trade and other payables – related party on the Condensed Consolidated Balance Sheet.

On October 6, 2018, finnCap Ltd, the Company's Nominated Adviser on the AIM market of the London Stock Exchange ("finnCap"), gave the Company formal three months' notice of its resignation as the Company's Nominated Adviser and Broker. Should finnCap cease to act as the Company's Nominated Adviser and the Company does not appoint a replacement Nominated Adviser, the Company's shares will be suspended from trading on AIM with immediate effect. The Company would then have one further month to appoint a replacement Nominated Adviser failing which the admission of its AIM securities will be cancelled.

On October 8, 2018, the Board, following a review of the Company's commercial and product development strategies, determined that it is in the best interests of the Company to focus primarily on the commercialization of its Particle Immuno-Filtration Assay (PIFA®) Technology platform, and to explore other commercial opportunities for the deployment of PIFA® technology, which is also utilized in the Company's core commercialized products, the PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays, which test for an allergic reaction to Heparin. The Company will continue to manufacture BreathScan Alcohol Detectors (based on the Company's Micro Particle Catalyzed (MPC®) Biosensor technology platform) and Tri-Cholesterol products (based on the Company's Rapid Enzymatic Assay (REA™) technology platform. The Company is taking steps to improve its market presence for these products including the use of specialized independent sales representatives and through a program to educate the marketplace through the preparation and publication of additional clinical studies and physician seminars on the risks associated with heparin induced thrombocytopenia.

On October 18, 2018, Richard C. Tarbox III submitted to the Board his resignation from his positions as interim Non-Executive Chairman of the Board, as Secretary of the Company, as a member of the Board and as a member of each of the committees of the Board upon which he serves, effective immediately. Mr. Tarbox's resignation was voluntary and as a result of his other business commitments, and not a result of any disagreement with the Company or its executive officers on any matter relating to the Company's operations, policies or practices.

On October 19, 2018, as a result of Mr. Tarbox's resignation from the Board and its committees the Board appointed Joshua Silverman to its Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee, having determined that he satisfies all applicable requirements to serve on such committees, including without limitation the applicable requirements of NASDAQ.

Note 3 – Key Recent Events and Management Plans, continued

On November 2, 2018, the Company entered into a securities purchase agreement with certain investors (the "Purchase Agreement") pursuant to which the Company agreed to sell an aggregate of 694,445 shares of common stock and warrants to purchase approximately 694,445 shares of common stock (the "Warrants"). The combined purchase price for one share of common stock and each Warrant will be priced at $2.88 (the "Offering"). The Purchase Agreement contains customary representations, warranties, and covenants by the Company.

Each Warrant has an initial exercise price of $3.76 per share, will be exercisable immediately after the date of issuance and will expire five years from the date it becomes exercisable. Subject to limited exceptions, a holder of the Warrants will not have the right to exercise any portion of such securities if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after the exercise. The exercise price of the Warrants, and in some cases the number of shares of common stock issuable upon exercise of the Warrants, will be subject to adjustment in the event of stock splits, stock dividends, combinations, rights offerings and similar events affecting the common stock.

In addition, the Warrants provide that, in the event of a fundamental transaction (as such term is described in the Warrant), the holder of such Warrant, at the holder's option, may receive, for each warrant share (as such term is described in the Warrant) that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock for which the Warrant is exercisable immediately prior to such fundamental transaction. If holders of common stock are given any choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the alternate consideration it receives upon any exercise of the Warrant following such fundamental transaction. The Company shall cause any successor entity (as such term is described in the Warrant), at the option of the holder, to deliver to the holder in exchange for the Warrant a security of the successor entity evidenced by a written instrument substantially similar in form and substance to the Warrant which is exercisable for a corresponding number of shares of capital stock of such successor entity (or its parent entity) equivalent to the shares of common stock acquirable and receivable upon exercise of the Warrant (without regard to any limitations on the exercise of this Warrant) prior to such fundamental transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock.

The Offering was made pursuant to a shelf registration statement on Form S-3 (File No. 333-214214), previously filed with the Securities and Exchange Commission on October 24, 2016 and declared effective on November 16, 2016. Such securities are being offered only by means of a prospectus.

On November 7, 2018, effective as of November 8, 2018, the Company filed a Certificate of Amendment (the "Certificate of Amendment") to its Amended and Restated Certificate of Incorporation with the Secretary of State of the State of New Jersey to effect a reverse stock split of its common stock at a ratio of eight-for-one (8-for-1). As a result of the reverse stock split, there are approximately 12,474,028 shares of common stock outstanding. The reverse stock split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity, except to the extent that the reverse stock split would have resulted in a stockholder owning a fractional share. Fractional shares have not been issued as a result of the reverse stock split; instead, the board of directors of the Company determined to effect an issuance of shares to holders that would otherwise have been entitled to a fractional share such that any fractional shares were rounded up to the nearest whole number.

Note 3 – Key Recent Events and Management Plans, continued

On November 7, 2018, the announced that the Board of Directors has initiated a process to evaluate strategic alternatives to maximize shareholder value. This process will consider a range of potential strategic alternatives including, but not limited to, business combinations, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities. The Company does not plan to disclose or comment on developments regarding the strategic review process until it is complete or further disclosure is deemed appropriate. There can be no assurance that the exploration of strategic alternatives will result in any transaction or other alternative.

Historically, the Company has relied upon public offerings and private placements of Common Stock to raise operating capital. During the year ended December 31, 2017, the Company raised $9,478,897, net of expenses, in public and private offerings and an additional $981,948, net of expenses, from the exercise of warrants. During the first quarter of 2018, the Company raised an additional $7,155,200 from the exercise of warrants (Note 7). On November 2, 2018, the Company raised gross proceeds of $2,000,000 through the sale of 694,445 shares of the Company’s common stock. Each share includes a warrant to purchase one share of common stock at an exercise price of $3.76. As of November 7, 2018, the Company had cash and marketable securities of approximately $6.2 million and working capital of approximately $6.2 million.

The Company believes that its current working capital position will be sufficient to meet its obligations as they fall due within one year after these financial statements are issued.

Note 4 - 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 overhead based on normal operating capacity.

Inventories consist of the following:

	September 30, 2018	December 31, 2017
Raw Materials	$ 562,175	$ 458,441
Sub-Assemblies	907,381	886,274
Finished Goods	582,427	815,505
Reserve for Obsolescence	(1,244,008)	(1,212,608)
	$ 807,975	$ 947,612

Obsolete inventory charged to cost of goods during the three months ended September 30, 2018 and 2017 totaled $219,701 and $2,664, respectively, and $251,984 and $3,158 during the nine months ended September 30, 2018 and 2017, respectively. In the three and nine months ended September 30, 2018, the Company reserved $218,799 of inventory for the removal of OxiChek from the market which is included in cost of goods sold and wrote-off, against the reserve, $187,399 of expired BreathScan Alcohol products, resulting in a net increase of $31,400 in the reserve for obsolescence as of September 30, 2018 compared to that as of December 31, 2017.

Note 5 - Trade and Other Payables

Trade and other payables consist of the following:

	September 30, 2018	December 31, 2017
Trade Payables	$ 684,966	$ 948,951
Accrued Expenses	1,509,483	736,515
Deferred Compensation	59,750	59,750
	$ 2,254,199	$ 1,745,216

Trade and other payables – related party are as follows:

	September 30, 2018	December 31, 2017
Trade Payables	$ 47,187	$ 39,821
	$ 47,187	$ 39,821

Note 6 - 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 50,000 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 100,000 shares (Note 3).

On September 30, 2016, the Board of Directors increased the number of authorized shares of Common Stock subject to the Amended Plan to 103,750 shares. As of September 30, 2018, grants of restricted stock and options to purchase 10,500 shares of Common Stock have been issued, pursuant to the Amended Plan, and are unvested or unexercised and 22,287 shares of Common Stock remain available for grants under the Amended Plan (Note 3).

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 168,750 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. As of September 30, 2018, grants totaling 40,013 shares of restricted Common Stock have been issued pursuant to the Plan and 128,737 shares of Common Stock remain available for grants under the Plan.

The Plan is 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.

The Company did not issue any options or warrants under the above plan during the nine months ended September 30, 2018.

Note 6 - Share-based Payments, continued

Stock Options

The following table summarizes the option activities for the nine months ended September 30, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2017	31,875	$ 34.00	$ 20.48	2.02	$ -
Granted	-	-	-	-	-
Exercised	-	-	-	-	-
Forfeited	(21,375)	35.76	22.00	1.07	-
Canceled/Expired	-	-	-	-	-
Balance at September 30, 2018	10,500	$ 30.40	$ 17.44	1.69	$ -
Exercisable as of September 30, 2018	10,500	$ 30.40	$ 17.44	1.69	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $2.27 for the Company's common shares on September 30, 2018.

As of September 30, 2018, all of the Company's outstanding stock options were fully vested and exercisable.

During the three months ended September 30, 2018 and 2017, the Company incurred stock option expenses totaling $1,477 and $4,373, respectively, and $6,931 and $16,685 during the nine months ended September 30, 2018 and 2017, respectively.

Note 6 - Share-based Payments, continued

Stock Warrants

The table below summarizes the warrant activity for the nine months ended September 30, 2018:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2017	6,186,321	$ 1.76	4.95	$ -
Granted	-	-	-	
Exercised	(4,770,092)	1.52	-	
Forfeited	-	-	-	
Canceled/Expired	-	-	-	
Balance at September 30, 2018	1,416,229	$ 2.80	4.15	$ 947,029
Exercisable as of September 30, 2018	1,416,229	$ 2.80	4.15	$ 947,029

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $2.27 for the Company's common shares on September 30, 2018. All warrants were vested on date of grant.

Note 7 – Equity

The holders of common shares are entitled to one vote per share at meetings of the Company. Holders of Series B convertible preferred shares have no voting rights 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.

On April 11, 2017, the Company issued 1,250 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. During the year ended December 31, 2017, $5,455 was recognized as stock-based compensation expense. The remaining $12,545 fair value of restricted shares issued was recognized during the three months ended March 31, 2018 as sales and marketing expenses on the Condensed Consolidated Statement of Operations and Comprehensive Loss.

On January 16, 2018, the Board of Directors issued 3,125 restricted shares of Common Stock to a key employee of the Company as part of the Plan. The fair value of the shares was $5,175 and was based on the closing share price of $1.66 per share. The share grants vested immediately. The Company recorded the expense as sales and marketing expenses on the Condensed Consolidated Statement of Operations and Comprehensive Loss for the nine months ended September 30, 2018.

Note 7 – Equity, continued

During the nine months ended September 30, 2018, 1,755 shares of the Company's Series B Preferred Stock, no par value, were converted into 1,462,500 shares of Common Stock.

During the nine months ended September 30, 2018, warrant holders from the December 21, 2017 public offering exercised 4,770,092 warrants with an exercise price of $1.50 per common share, raising net proceeds of $7,155,200.

Note 8 - 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.

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 would receive the full outstanding principal amount in the year ended December 31, 2016 in the form of $750,000 of BreathScan® Alcohol Detector inventory 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 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 several commercialized products including BreathScan® Alcohol Detector.

Note 8 - Related Party Transactions, continued

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 $(17,353) and $34,328 for the three months ended September 30, 2018 and 2017, respectively, and $41,418 and $128,108 for the nine months ended September 30, 2018 and 2017, respectively, which are included in sales and marketing expenses – related party on the Condensed Consolidated Statement of Operations and Comprehensive Loss.

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.

During the three months ended September 30, 2018 and 2017, the Company recognized sales of $- and $-, respectively, for the BreathScan Breath Alcohol products acquired from the Settlement and $20,265 and $- during the nine months ended September 30, 2018 and 2017, respectively.

As of September 30, 2018, the Company owed ChubeWorkx Guernsey Limited, previously a major shareholder, royalties of $4,864 which is included in trade and other payables – related party on the condensed consolidated financial statements.

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. The Company purchased a total of $16,300 and $- during the three months ended September 30, 2018 and 2017, respectively, and $20,936 and $16,774 during the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, the Company owed Hainan and its related party $19,460 which is included in trade and other payables – related party on the Condensed Consolidated Balance Sheet.

As of September 30, 2018, 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 $18,790 as of September 30, 2018.

Note 8 - Related Party Transactions, continued

On January 31, 2018, the Company engaged Medical Horizons, Inc. ("Medical Horizons"), a company owned and operated by the spouse of a member of the Company's leadership team, to provide engineering and design services. The Company recorded $- and $54,342 during the three and nine months ended September 30, 2018, respectively, related to the engagement of Medical Horizons which is included in research and development – related party on the Condensed Consolidated Statement of Operations and Comprehensive Loss. As of September 30, 2018, the Company owed Medical Horizons $-.

Product revenue – related party for the three and nine months ended September 30, 2018 and 2017 were $-.

Effective on October 5, 2018, the Board appointed Howard R. Yeaton, who through FCS served previously as a consultant to the Company, to serve as the Chief Executive Officer and interim Chief Financial Officer of the Company. Mr. Yeaton is the managing principal of FCS and the Company's relationship with FCS shall continue, with FCS continuing to provide accounting services to the Company. FCS is considered to be a related party. During the three and nine months ended September 30, 2018, the Company expensed $56,425 and $75,342, respectively, to FCS in connection with these services. As of September 30, 2018, the Company owed FCS $22,862 which is included in trade and other payables – related party on the Condensed Consolidated Balance Sheet.

Note 9 – 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. Rent expense for the Thorofare Lease, including related CAM charges for the three months ended September 30, 2018 and 2017 totaled $40,926 and $40,440, respectively, and $124,070 and $121,220 for the nine months ended September 30, 2018 and 2017, respectively.

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 $6,522 and $6,506 for the three months ended September 30, 2018 and 2017, respectively, and $19,512 and $6,506 for the nine months ended September 30, 2018 and 2017, respectively. 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 $10,210 and $6,608 for the three months ended September 30, 2018 and 2017, respectively, and $30,035 and $6,608 for the nine months ended September 30, 2018 and 2017, respectively. 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 Company entered into a 36-month contract with Oracle Corporation for the NetSuite accounting platform in March 2018 with annual cost commitments pursuant to the table below. During the three and nine months ended September 30, 2018, the Company expensed $46,670 related to this contract.

Note 9 – Commitments, continued

The schedule of lease commitments is as follows:

	Thorofare Lease	Ramsey Lease	Pitman Lease	Equipment Lease	Oracle NetSuite	Total
Next 12 Months	$ 132,000	$ 17,320	$ 39,650	$ 6,156	$ 102,766	$ 297,892
Next 13-24 Months	33,000	-	9,912	513	100,281	143,706
Next 25-36 Months	-	-	-	-	46,157	46,157

Note 10 – 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.

The Company filed a Motion for Summary Judgment on January 24, 2018. On June 21, 2018, the Court ruled in favor of the Company on some issues and determined that other issues warranted a trial. As part of its ruling on the Motion for Summary Judgment, the Court held "While it seems likely that Plaintiff did suffer some amount of damages, Plaintiff has so far failed to provide a sufficient evidentiary foundation from which the trier of fact could reasonably calculate the value of its injury." The Court stated that it was "reasonably certain that Plaintiff suffered some damage" and found that Pulse Health "may be entitled to nominal damages." The Court further determined that equitable relief, such as an injunction, "may be warranted." Following such rulings, the Company discovered certain deficiencies in its discovery responses and is taking the appropriate steps to supplement the record and correct these deficiencies. In addition, the Court has ordered a settlement conference in front of a U.S. magistrate that was held on August 31, 2018.

On September 17, 2018, the Company and Pulse entered into a settlement. Pursuant to the settlement reached between the Plaintiff and the Company, the Company accrued $930,000 payable to Pulse as of September 30, 2018, which was paid on October 9, 2018. The Company has also agreed to a permanent injunction and will not make, use, sell or offer to sell the BreathScan OxiChek™ product, any product that detects aldehydes or oxidative stress in exhaled human breath or breath condensate using either basic fuchsin or sodium metabisulfite or any form, analog or equivalent thereof, and the BreathScan Lync device, or any equivalent thereof, as part of a test for aldehydes or oxidative stress in human exhaled breath or breath condensate. The Company does not anticipate a material impact on revenues as a result of the withdrawal of the BreathScan OxiChek™ product from sale. The Settlement Agreement does not contain any admission of liability, wrongdoing, or responsibility by any of the parties.

Note 10 – Contingencies, continued

On or about June 15, 2018, certain parties brought certain class action lawsuits against the Company.

Faulkner v. Akers Biosciences, Inc., No. 2:18-cv-10521 (D.N.J.)

On June 13, 2018, Plaintiff Tim Faulkner filed a class action complaint alleging securities violations against Akers Biosciences, Inc. ("Akers"), John J. Gormally, and Gary M. Rauch ("Individual Defendants") (together with Akers, "Defendants") on behalf of all persons and entities who purchased publicly traded Akers securities from May 15, 2017 through June 5, 2018. The complaint alleges violations of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants, and violations of Section 20(a) of the Exchange Act against the Individual Defendants. In particular, the complaint alleges that Defendants made false and/or misleading statements and/or failed to disclose in its first, second, and third quarter 2017 10-Qs and its 2017 10-K that: (1) Akers was improperly recognizing revenue for the fiscal year ended December 31, 2017; and, (2) Akers had downplayed weaknesses in its internal controls over financial reporting and failed to disclose the true extent of those weaknesses. On July 10, 2018, Plaintiff and Defendants entered into a stipulation that Defendants are not required to respond to the complaint until the court appoints a lead plaintiff and lead counsel for the class, and then after the lead plaintiff chooses whether to file an amended complaint or whether to designate the complaint as the operative complaint.

Gleason v. Akers Biosciences, Inc., No. 2:18-cv-10805 (D.N.J.)

On June 20, 2018, Plaintiff David Gleason filed a class action complaint alleging securities violations against Akers Biosciences, Inc. ("Akers"), John J. Gormally, and Gary M. Rauch ("Individual Defendants") (together with Akers, "Defendants") on behalf of all persons and entities who purchased publicly traded Akers securities from May 15, 2017 through June 5, 2018. The complaint alleges violations of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants, and violations of Section 20(a) of the Exchange Act against the Individual Defendants. In particular, the complaint alleges that Defendants made false and/or misleading statements and/or failed to disclose in its first, second, and third quarter 2017 10-Qs and its 2017 10-K that: (1) Akers was improperly recognizing revenue for the fiscal year ended December 31, 2017; and, (2) Akers had downplayed weaknesses in its internal controls over financial reporting and failed to disclose the true extent of those weaknesses. No Defendant has been served yet, and no response is due at this time.

Other class action lawsuits have been threatened against the Company and may be filed shortly. Although there are currently two separate actions pending, we anticipate that the two actions will be consolidated into one action.

The Company maintains D&O liability insurance coverage, insuring both the Company and the Directors and Officers for covered defense and indemnification, and has noticed these matters thereunder.

Additionally, a former executive has threatened to sue the Company, Board members, and executives under CEPA over the termination of his employment. That statute prohibits any retaliatory action against an employee who discloses, or threatens to disclose to a supervisor or to a public entity any activity, policy or practice of the employer that is a violation of a law, or a rule or regulation. Remedies may include a counter claim for back pay, reinstatement, compensatory and punitive damages and attorneys' fees if appropriate. The Company will vigorously defend any litigation brought by this former executive.

The Company intends to establish a rigorous defense of all claims. The Company is unable to assess the potential outcome, so no accrual for losses was made as of September 30, 2018. All legal fees were expensed as and when incurred.

Note 11 – Revenue Information

Revenue by product lines was as follows:

Product Line	Three months ended September 30, 2018	Three months ended September 30, 2017	Nine months ended September 30, 2018	Nine months ended September 30, 2017
MicroParticle Catalyzed Biosensor ("MPC")	$ (18,798)	$ 104,094	$ 106,832	$ 259,601
Particle ImmunoFiltration Assay ("PIFA")	567,262	490,058	1,183,327	1,477,726
Rapid Enzymatic Assay ("REA")	-	27,500	55,000	27,500
Other	8,625	16,679	41,006	613,614
Product Revenue Total	557,089	638,331	1,386,165	2,378,441
License Fees	-	37,500	-	37,500
Total Revenue	$ 557,089	$ 675,831	$ 1,386,165	$ 2,415,941

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

Geographic Region	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
United States	$ 554,269	$ 626,077	$ 1,311,360	$ 1,755,558
People's Republic of China	-	-	-	502,268
Rest of World	2,820	49,754	74,805	158,115
Total Revenue	$ 557,089	$ 675,831	$ 1,386,165	$ 2,415,941

The Company had long-lived assets totaling $59,355 and $59,830 located in the People's Republic of China and $1,201,592 and $1,305,950 located in the United States as of September 30, 2018 and December 31, 2017, respectively.

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 negative of these terms and similar expressions as they relate to the Company or the Company's management identify forward-looking statements. Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions, and other factors, including the risks relating to the Company's business, industry, and the Company's operations and results of operations. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended, or planned.

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

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

Overview

Akers Bio develops, manufactures, and supplies rapid, point-of-care screening and testing products designed to bring health-related information directly to the patient or clinician in a timely 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 focus on delivering diagnostic assistance in a variety of healthcare fields/specialties, including diagnostic rapid manual point-of-care tests for the detection of allergic reactions to Heparin, for cholesterol screening and 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 a medical condition 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; and
- need for easy to use, accurate at-home tests for individuals to monitor their personal health and wellness

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

Following a review of the Company's commercial and product development strategies, the Board of Directors has determined that it is in the best interests of the Company to focus primarily on the commercialization of its Particle Immuno-Filtration Assay (PIFA®) Technology platform. PIFA® technology is a cutting-edge, patented immunoassay method which rapidly and accurately detects target antigens or antibodies. It is the technology platform utilized in the Company's core commercialized products, the PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays, which test for an allergic reaction to Heparin. These products account for the significant majority of the Company's current revenues. The Company is taking steps to improve its market presence for these products including the use of specialized Independent Sales Representatives and through a program 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 will continue to explore other commercial opportunities for the deployment of PIFA® technology. Akers Bio will continue to manufacture BreathScan Alcohol Detectors and METRON breath ketone tests (based on the Company's Micro Particle Catalyzed (MPC®) Biosensor technology platform), and Tri-Cholesterol products (based on the Company's Rapid Enzymatic Assay (REA™) technology platform).

Key Events, Management's Plans and Basis of Presentation

By way of a letter dated November 28, 2017, the Listing Qualifications Department of NASDAQ advised the Company that it did not comply with NASDAQ Listing Rule 5550(a)(2) for continued listing, because the Company's common stock did not meet NASDAQ's minimum $1.00 bid price requirement (the "Price Requirement"). The Company informed Nasdaq that the Company is fully committed to regain compliance with the Price Requirement as quickly as possible and, therefore, proposed to institute a reverse stock split. NASDAQ approved of the Company's proposal of a reverse stock split and granted the Company until November 26, 2018, for the Company to be in compliance with the Price Requirement. The Company's latest reported stock price on November 13, 2018 was $2.46. If the Company's stock remains priced above $1.00 by the end of trading on November 21, 2018, it is expected that Nasdaq would give the Company notice of its compliance with the Price Requirement.

On April 25, 2018, the Board of Directors of the Company terminated Dr. Raymond F. Akers from his position as Executive Chairman of the Board and from each of his officer positions as Chief Scientific Director and Secretary of the Company. Dr. Raymond F. Akers continued as a member of the Board of Directors until his resignation on May 27, 2018.

On April 25, 2018, the Board appointed Richard Carlyle Tarbox III, a director of the Company as the interim Non-Executive Chairman of the Board, to hold that position until his successor is appointed, and to the position of Secretary of the Company.

By way of a letter dated May 22, 2018, the Listing Qualifications Department of NASDAQ advised the Company that it did not comply with NASDAQ Listing Rule 5250(c)(1) for continued listing because NASDAQ has not received the Company's Quarterly Report. Company filed a Current Report on a Form 8-K with the Securities and Exchange Commission on May 25, 2018, that NASDAQ has informed the Company that the Company is required to submit a plan to regain compliance with NASDAQ's filing requirements for continued listing within 60 calendar days of the date of the Notice. NASDAQ informed the Company that it is in Compliance with NASDAQ Listing Rule 5250(c)(1) on July 12, 2018.

On June 11, 2018, the Company received a letter from the Listing Qualifications Department NASDAQ notifying the Company that it has determined that the Company violated the shareholder approval requirements of Listing Rule 5635(c). Listing Rule 5635(c) requires shareholder approval prior to the issuance of securities when a stock option or purchase plan is to be established or materially amended or other equity compensation arrangement made or materially amended, pursuant to which stock may be acquired by officers, directors, employees or consultants.

Prior to the Company's public offering and listing on NASDAQ, the Company's 2013 Incentive Stock and Award Plan (the "2013 Plan") was approved by its Board of Directors. NASDAQ has concluded that the 2013 Plan was materially amended on two occasions after the Company's public offering and listing on NASDAQ. The first amendment, as approved by the Board on January 9, 2015, increased the number of shares available under the 2013 Plan from 50,000 to 100,000 shares and the second amendment, as approved by the Board on October 5, 2016, increased the number of shares under the 2013 Plan from 100,000 to 103,750 shares (the "2013 Plan Amendments").

During the first quarter of 2018, the Company promptly notified NASDAQ, as required by Listing Rule 5625, when it became aware of its potential non-compliance with Listing Rule 5635(c). On May 4, 2018, the Staff requested additional information from the Company with respect to such non-compliance and on May 31, 2018, the Company responded. On June 25, 2018, the Company submitted a plan to NASDAQ to remediate this matter (the "5635 Compliance Plan"). The 5635 Compliance Plan included that a proposal for shareholders of the Company to ratify the 2013 Plan Amendments be included in the proxy statement for the Company's 2018 annual meeting of the shareholders of the Company and that the Company shall suspend the trading of each share granted, and each share granted upon the exercise of any option granted, in excess of 50,000 shares under the 2013 Plan (the number of shares properly approved pursuant to the 2013 Plan prior to the 2013 Plan Amendments until shareholder ratification). The 5635 Compliance Plan also proposes to prevent the exercise of any option granted under the 2013 Plan until shareholder ratification.

On July 12, 2018, NASDAQ approved of the 5635 Compliance Plan and granted the Company until December 10, 2018, to regain compliance with Listing Rule 5635. The Company intends to have a shareholder meeting on December 7, 2018 to approve the amendments to the 2013 Plan.

On or about June 15, 2018, certain parties brought certain class action lawsuits against the Company. See Note 10 - Contingencies for details.

On July 26, 2018, the Company implemented a reduction in workforce plan which resulted in the elimination of six staff positions in four operating departments.

On or about June 15, 2018, certain parties brought certain class action lawsuits against the Company.

Faulkner v. Akers Biosciences, Inc., No. 2:18-cv-10521 (D.N.J.)

On June 13, 2018, Plaintiff Tim Faulkner filed a class action complaint alleging securities violations against Akers Biosciences, Inc. ("Akers"), John J. Gormally, and Gary M. Rauch ("Individual Defendants") (together with Akers, "Defendants") on behalf of all persons and entities who purchased publicly traded Akers securities from May 15, 2017 through June 5, 2018. The complaint alleges violations of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants, and violations of Section 20(a) of the Exchange Act against the Individual Defendants. In particular, the complaint alleges that Defendants made false and/or misleading statements and/or failed to disclose in its first, second, and third quarter 2017 10-Qs and its 2017 10-K that: (1) Akers was improperly recognizing revenue for the fiscal year ended December 31, 2017; and, (2) Akers had downplayed weaknesses in its internal controls over financial reporting and failed to disclose the true extent of those weaknesses. On July 10, 2018, Plaintiff and Defendants entered into a stipulation that Defendants are not required to respond to the complaint until the court appoints a lead plaintiff and lead counsel for the class, and then after the lead plaintiff chooses whether to file an amended complaint or whether designate the complaint as the operative complaint.

Gleason v. Akers Biosciences, Inc., No. 2:18-cv-10805 (D.N.J.)

On June 20, 2018, Plaintiff David Gleason filed a class action complaint alleging securities violations against Akers Biosciences, Inc. ("Akers"), John J. Gormally, and Gary M. Rauch ("Individual Defendants") (together with Akers, "Defendants") on behalf of all persons and entities who purchased publicly traded Akers securities from May 15, 2017 through June 5, 2018. The complaint alleges violations of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants, and violations of Section 20(a) of the Exchange Act against the Individual Defendants. In particular, the complaint alleges that Defendants made false and/or misleading statements and/or failed to disclose in its first, second, and third quarter 2017 10-Qs and its 2017 10-K that: (1) Akers was improperly recognizing revenue for the fiscal year ended December 31, 2017; and, (2) Akers had downplayed weaknesses in its internal controls over financial reporting and failed to disclose the true extent of those weaknesses. No Defendant has been served yet, and so no response is due at this time.

Other class action lawsuits have been threatened against the Company and may be filed shortly. Although there are currently two separate actions pending, we anticipate that the two actions will be consolidated into one action.

The Company maintains D&O liability insurance coverage, insuring both the Company and the Directors and Officers for covered defense and indemnification, and has noticed these matters thereunder.

On September 6, 2018, with the recommendation of the Nominating and Corporate Governance Committee (the "N&G Committee") the Board appointed Mr. Joshua Silverman as a Director of the Company for a term that expires at the Company's 2018 Annual Meeting of Stockholders, or until his earlier death, disability, resignation or removal.

On September 17, 2018, the Company reached an amicable resolution by way of a settlement agreement and release (the "Settlement Agreement") with Pulse Health, LLC, an Oregon limited liability company (the "Plaintiff") with respect to the lawsuit Plaintiff filed against the Company, in the United States District Court, District of Oregon (the "Court"), Case No.:3:16-CV-01919-HZ (the "Litigation"), effective upon the Court entering a permanent injunction against the Company, which the Court has entered on to the docket on October 4, 2018. Pursuant to the settlement reached between the Plaintiff and the Company, on October 9, 2018 the Company paid $930,000 to the Plaintiff. The Company has also agreed to a permanent injunction and will not make, use, sell or offer to sell the BreathScan OxiChek™ product, any product that detects aldehydes or oxidative stress in exhaled human breath or breath condensate using either basic fuchsin or sodium metabisulfite or any form, analog or equivalent thereof, and the BreathScan Lync device, or any equivalent thereof, as part of a test for aldehydes or oxidative stress in human exhaled breath or breath condensate. The Company does not anticipate a material impact on revenues as a result of the withdrawal of the BreathScan OxiChek™ product from sale. The Settlement Agreement does not contain any admission of liability, wrongdoing, or responsibility by any of the parties.

On October 5, 2018, John J. Gormally submitted to the Board his resignation from his position as the Chief Executive Officer of the Company and as a member of the Board, effective immediately. Mr. Gormally's resignation was voluntary and not a result of any disagreement with the Company or its executive officers on any matter relating to the Company's operations, policies or practices. In connection with his resignation from the Board, Mr. Gormally entered into a Resignation Agreement with the Company.

Effective on October 5, 2018, the Board appointed Howard R. Yeaton, who through Financial Consulting Strategies LLC ("FCS") served previously as a consultant to the Company, to serve as the Chief Executive Officer and interim Chief Financial Officer of the Company. Mr. Yeaton is the managing principal of FCS and the Company's relationship with FCS shall continue, with FCS continuing to provide accounting services to the Company. FCS is considered to be a related party. During the three and nine months ended September 30, 2018, the Company expensed $56,425 and $75,342, respectively, to FCS in connection with these services. As of September 30, 2018, the Company owed FCS $22,862 which is included in trade and other payables – related party on the Condensed Consolidated Balance Sheet.

On October 6, 2018, finnCap Ltd, the Company's Nominated Adviser on the AIM market of the London Stock Exchange ("finnCap"), gave the Company formal three months' notice of its resignation as the Company's Nominated Adviser and Broker. Should finnCap cease to act as the Company's Nominated Adviser and the Company does not appoint a replacement Nominated Adviser, the Company's shares will be suspended from trading on AIM with immediate effect. The Company would then have one further month to appoint a replacement Nominated Adviser failing which the admission of its AIM securities will be cancelled.

On October 8, 2018, the Board, following a review of the Company's commercial and product development strategies, determined that it is in the best interests of the Company to focus primarily on the commercialization of its Particle Immuno-Filtration Assay (PIFA®) Technology platform, and to explore other commercial opportunities for the deployment of PIFA® technology, which is also utilized in the Company's core commercialized products, the PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays, which test for an allergic reaction to Heparin. The Company will continue to manufacture BreathScan Alcohol Detectors (based on the Company's Micro Particle Catalyzed (MPC®) Biosensor technology platform) and Tri-Cholesterol products (based on the Company's Rapid Enzymatic Assay (REA™) technology platform. The Company is taking steps to improve its market presence for these products including the use of specialized independent sales representatives and through a program to educate the marketplace through the preparation and publication of additional clinical studies and physician seminars on the risks associated with heparin induced thrombocytopenia.

On October 18, 2018, Richard C. Tarbox III submitted to the Board his resignation from his positions as interim Non-Executive Chairman of the Board, as Secretary of the Company, as a member of the Board and as a member of each of the committees of the Board upon which he serves, effective immediately. Mr. Tarbox's resignation was voluntary and as a result of his other business commitments, and not a result of any disagreement with the Company or its executive officers on any matter relating to the Company's operations, policies or practices.

On October 19, 2018, as a result of Mr. Tarbox's resignation from the Board and its committees the Board appointed Joshua Silverman to its Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee, having determined that he satisfies all applicable requirements to serve on such committees, including without limitation the applicable requirements of NASDAQ.

On November 7, 2018, effective as of November 8, 2018, the Company filed a Certificate of Amendment (the "Certificate of Amendment") to its Amended and Restated Certificate of Incorporation with the Secretary of State of the State of New Jersey to effect a reverse stock split of its common stock at a ratio of eight-for-one (8-for-1). As a result of the reverse stock split, there are approximately 12,474,028 shares of common stock outstanding. The reverse stock split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity, except to the extent that the reverse stock split would have resulted in a stockholder owning a fractional share. Fractional shares have not been issued as a result of the reverse stock split; instead, the board of directors of the Company determined to effect an issuance of shares to holders that would otherwise have been entitled to a fractional share such that any fractional shares were rounded up to the nearest whole number.

On November 7, 2018, the announced that the Board of Directors has initiated a process to evaluate strategic alternatives to maximize shareholder value. This process will consider a range of potential strategic alternatives including, but not limited to, business combinations, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities. The Company does not plan to disclose or comment on developments regarding the strategic review process until it is complete or further disclosure is deemed appropriate. There can be no assurance that the exploration of strategic alternatives will result in any transaction or other alternative.

Through September 30, 2018, the Company has in large part relied on equity financing to fund its operations, raising $30,717,381, net of expenses, in various public and private offering on the NASDAQ Capital Market and through the exercise of warrants associated with the offerings. 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 Particle Immuno-Filtration Assay (PIFA®) Technology platform;
- continuing to strengthen and forge domestic and international relationships with well-established sales organizations with strong distribution channels in specific target markets;
- evaluating strategic alternatives to maximize shareholder value, including the consideration of a range of potential strategic alternatives including, but not limited to, business combinations, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities; 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 (Diagnostica Stago) 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 marketing activities for its existing product platforms;
- 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, 2018, Akers had cash (including restricted cash of $500,000) of $1,801,418, working capital of $5,608,785, shareholders' equity of $7,719,236 and an accumulated deficit of $111,857,241. The Company believes that its current working capital position, including funds raised on November 2, 2018, will be sufficient to meet its estimated cash needs for at least the next 12 months. The Company closely monitors its cash balances, cash needs and expense levels.

Summary of Statements of Operations for the Three Months Ended September 30, 2018 and 2017

Revenue

Akers' revenue for the three months ended September 30, 2018 totaled $557,089, an 18% decrease from the same period in 2017. The table below summarizes our revenue by product line for the three months ended September 30, 2018 and 2017 as well as the percentage of change year-over-year:

	For the Three Months Ended September 30,		
Product Lines	2018	2017	Percent Change
Particle ImmunoFiltration Assay ("PIFA")	$ 567,262	$ 490,058	16%
MicroParticle Catalyzed Biosensor ("MPC")	(18,798)	104,094	(118)%
Rapid Enzymatic Assay ("REA")	-	27,500	(100)%
Other	8,625	16,679	(48)%
Product Revenue Total	557,089	638,331	(13)%
License Fees	-	37,500	(100)%
Total Revenue	$ 557,089	$ 675,831	(18)%

Revenue from the Company's PIFA Heparin/PF4 Rapid Assay products increased 16% to $567,262 (2017: $490,058) during the three months ended September 30, 2018, over the same period of 2017, with the increase principally on account of filling open backorders.

During the six months ended June 30, 2018, we experienced lower yields in the process of extracting antigen from the platelets used to produce our PIFA Heparin product. At these yield levels, our production of this product was under target levels, resulting in backorders. During the three months ended September 30, 2018, our antigen yields improved, and we were able to fill all of our backorders. Our engineers and representatives from our supplier continue to work together to adjust our processes in order to restore the yield to appropriate levels, the results of which are not yet determined.

Furthermore, we are evaluating and testing a resolution that may involve one or more alternative antigen suppliers and processes that may provide a path to restoring yield levels for this product. For each of these potential solutions, we will be conducting production validation and stability testing.

The Company's dedicated technical sales account executives are supporting over 300 sales representatives of Akers' U.S. distribution partners, Cardinal Health, Thermo Fisher Scientific and Diagnostica Stago, and the Company's ISRs. Domestic sales for the three months ended September 30, 2018, of our distributors, Cardinal Health, Thermo Fisher Scientific and Diagnostica Stago, accounted for $529,860 of the total PIFA Heparin/PF4 Rapid Assay related product sales as compared to $441,676 for the same period of 2017.

The Company's MPC product sales decreased by 118% to $(18,798) (2017: $104,094) during the three months ended September 30, 2018. On account of our settlement with Pulse (as discussed in Note 10 of the footnotes within this Quarterly Report), we repurchased from our U.S. distributor their remaining inventory in the amount of $33,600 for the OxiChek products. In addition, we saw a decline in sales of the Breath Alcohol products.

The Company's REA products generated $0 (2017: $27,500) during the three months ended September 30, 2018.

Other revenue decreased to $8,625 (2017: $16,679) during the three months ended September 30, 2018 primarily due to a decline in shipping/handling revenue. The category is made up of the sales of miscellaneous raw material components, sub-assembled products and fees billed for shipping and handling charges.

Gross Margin

The Company's gross margin declined to 14% (2017: 52%) for the three months ended September 30, 2018, principally on account of the Pulse litigation settlement which resulted in a write off of OxiChek products in the aggregate amount of $218,799. Fixed costs within product cost of sales consisted principally of direct personnel costs, manufacturing and warehousing space and depreciation of equipment. Within these fixed costs, direct personnel costs decreased during the period to $76,254 (2017: $88,903). This decrease was a result of fewer personnel being utilized in production related activities.

Cost of sales for the three months ended September 30, 2018 increased to $476,453 (2017: $323,526). The increase was principally attributable to the write off of $218,799 of OxiChek product. Direct cost of sales decreased to 22% of product revenue while other cost of sales increased to 64% for the three months ended September 30, 2018 as compared to 31% and 20% respectively for the same period in 2017 as described above.

Direct cost of sales for the three months ended September 30, 2018 were $122,545 (2017: $196,866). Other cost of sales for the three months ended September 30, 2018 were $353,908 (2017: $126,660).

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2018, totaled $2,636,651, which was a 222% increase as compared to $819,565 for the three months ended September 30, 2017.

The table below summarizes our general and administrative expenses for the three months ended September 30, 2018 and 2017 as well as the percentage of change year-over-year:

Description	For the Three Months Ended September 30, 2018	2017	Percent Change
Personnel Costs	$ 287,054	$ 223,361	29%
Professional Service Costs	727,069	320,081	127%
Stock Market & Investor Relations Costs	122,214	120,807	1%
Other General and Administrative Costs	1,500,314	155,316	866%
Total General and Administrative Expense	$ 2,636,651	$ 819,565	222%

Personnel expenses increased by 29% for the three months ended September 30, 2018 as compared to the same period of 2017. An increase in salaries, wages and bonuses to $249,445 (2017: $172,587) was offset by a decline in employee benefit expenses of $14,723 (2017: $22,857).

Professional service costs increased 127% for the three months ended September 30, 2018 as compared to the same period of 2017. A significant increase in legal fees ($394,067 (2017: $258,026)) and accounting and audit expenses ($206,374 (2017: $36,130)) resulted in the change. The increase in the legal and accounting fees were principally in connection with our Board's recent investigation and the resulting restatement of our previously issued financials, as well as in connection with litigation matters. Configuration and implementation expenses for the planned NetSuite Financial System also contributed to the increased accounting service costs.

Stock market and investor fees increased 1% for the three months ended September 30, 2018. The fees included costs associated with the Company's nominated advisor, stock transfer agents, investor relations team and stock exchange fees.

Other general and administrative expenses increased by 866%. During the three months ended September 30, 2018, the Company made a lump sum compensation payment of $100,000 to each of the independent directors. In addition, the Board approved the settlement of the Pulse Litigation which resulted in a one-time charge of $930,000. Increases in other general and administrative expenses were also attributable to business insurance costs, totaled $137,256 (2017: $39,902) and computer expenses $58,502 (2017: $7,688) related to the licensing and implementation of the NetSuite Financial System impacted the higher costs.

Sales and Marketing Expenses

Sales and marketing expenses for the three months ended September 30, 2018 totaled $364,641 which was a 3% decrease compared to $377,091 for the three months ended September 30, 2017.

The table below summarizes our sales and marketing expenses for the three months ended September 30, 2018 and 2017 as well as the percentage of change year-over-year:

Description	For the Three Months Ended September 30, 2018	2017	Percent Change
Personnel Costs	$ 209,029	$ 184,835	13%
Professional Service Costs	41,147	67,111	(39)%
Royalties and Outside Commission Costs	68,017	43,635	56%
Other Sales and Marketing Costs	46,448	81,510	(43)%
Total Sales and Marketing Expenses	$ 364,641	$ 377,091	(3)%

The U.S. market has been divided into two regional zones, each with a business director that is responsible for recruiting and supporting Independent Sales Representatives ("ISRs") to target large integrated delivery networks and individual facilities. This strategy requires more experienced and technically knowledgeable sales personnel to interact with surgeons, executive management, laboratory and medical directors. The Company has increased its sales and marketing staff from 4 members on September 30, 2017 to 5 as of September 30, 2018.

Personnel costs increased in the three months ended September 30, 2018 as compared to the same period of 2017, the results of an increase in compensation, commissions and benefit costs to $175,296 (2017: $155,488).

The Company has terminated relationships with several of its professional service providers.

Commissions paid to ISRs totaled $85,370 in the three months ended September 30, 2018 (2017: $9,307) which were offset by an adjustment to the royalties due to ChubeWorkx Guernsey, Ltd ("ChubeWorkx").

The Company recognized reductions in computer and travel expenses in the three months ended September 30, 2018 ($5,230 (2017: $12,854) and ($26,651 (2017: $37,405), respectively) plus smaller reductions in several other operating categories that resulted in a 43% decrease in other sales and marketing costs.

Research and Development

Research and development expenses for the three months ended September 30, 2018 totaled $160,867, which was a 45% decrease as compared to $290,447 for the three months ended September 30, 2017.

The table below summarizes our research and development expenses for the three months ended September 30, 2018 and 2017 as well as the percentage of change year-over-year:

	For the Three Months Ended September 30,		
Description	2018	2017	Percent Change
Personnel Costs	$ 95,896	$ 214,369	(55)%
Clinical Trial Costs	-	2,153	(100)%
Professional Service Costs	15,554	41,829	(63)%
Other Research and Development Costs	49,417	32,096	54%
Total Research and Development Expenses	$ 160,867	$ 290,447	(45)%

Personnel costs decreased 55% during the three months ended September 30, 2018 as compared to the same period of 2017. The Company's termination of Dr. Akers in April combined with additional reductions in the number of staff in the department resulted in the decline in personnel costs.

Professional services consisted of fees paid to engineering consultants to address production mold designs, specialized tooling and manufacturing process development, regulatory consultants to assist with governmental filings and facility certifications and the medical director. Engineering service costs decreased to $8,545 (2017: $32,830) and other general and regulatory consulting fees totaled $7,009 (2017: $9,000) in the three months ended September 30, 2018.

Increases in laboratory supplies ($14,948 (2017: $9,325)) and seminar and conference fees ($15,213 (2017: $0)) resulted in an increase of 54% for other research and development costs during the three months ended September 30, 2018.

Other Income and Expense

Other income, net of expense, for the three months ended September 30, 2018 totaled $40,351 as compared to an expense of $68 for the three months ended September 30, 2017.

The table below summarizes our other income and expenses for the three months ended September 30, 2018 and 2017 as well as the percentage of change year-over-year:

	For the Three Months Ended September 30,		
Description	2018	2017	Percent Change
Currency Translation (Gain)/Loss	$ (634)	$ 3,195	(120)%
Interest and Dividend Income	(35,545)	(3,127)	1,036%
Other Income	(4,172)	-	N/A
Total Other Income, Net of Expenses	$ (40,351)	$ 68	(59,440)%

Realized gains, interest and dividend income increased to $35,545 (2017: $3,127). The Company's available capital for investment activities increased significantly due to the capital raise in December 2017 and the subsequent exercises of warrants during the nine months ended September 30, 2018 resulting in the increase in investment income.

Summary of Statements of Operations for the Nine Months Ended September 30, 2018 and 2017

Revenue

Akers' revenue for the nine months ended September 30, 2018 totaled $1,386,165, a 43% decrease from the same period in 2017. The table below summarizes our revenue by product line for the nine months ended September 30, 2018 and 2017 as well as the percentage of change year-over-year:

	For the Nine Months Ended September 30,		
Product Lines	2018	2017	Percent Change
Particle ImmunoFiltration Assay ("PIFA")	$ 1,183,327	$ 1,477,726	(20)%
MicroParticle Catalyzed Biosensor ("MPC")	106,832	259,601	(59)%
Rapid Enzymatic Assay ("REA")	55,000	27,500	100%
Other	41,006	613,614	(93)%
Product Revenue Total	1,386,165	2,378,441	(42)%
License Fees	-	37,500	(100)%
Total Revenue	$ 1,386,165	$ 2,415,941	(43)%

Revenue from the Company's PIFA Heparin/PF4 Rapid Assay products decreased 20% to $1,183,327 (2017: $1,477,726) during the nine months ended September 30, 2018, over the same period of 2017. The decline in revenues was principally on account of the aforementioned yield matters and the resulting and customer backorders, but our antigen yields improved, and we were able to fill all our backorders from June 30, 2018.

Domestic sales for the nine months ended September 30, 2018, of our distributors, Cardinal Health, Thermo Fisher Scientific and Diagnostica Stago accounted for $1,067,018 of the total PIFA Heparin/PF4 Rapid Assay related product sales as compared to $1,207,372 for the same period of 2017.

The Company's MPC product sales decreased by 59% to $106,832 (2017: $259,601) during the nine months ended September 30, 2018.

The Company's REA products generated $55,000 (2017: $27,500) during the nine months ended September 30, 2018.

Other revenue decreased to $41,006 (2017: $613,614) during the nine months ended September 30, 2018. The category is made up of the sales of miscellaneous raw material components, sub-assembled products and fees billed for shipping and handling charges. During the nine months ended September 30, 2017, the Company received an order for manufacturing components totaling $500,000.

Gross Margin

The Company's gross margin declined to 22% (2017: 64%) for the nine months ended September 30, 2018 principally on account of the decline in revenue against a base of certain fixed costs within product cost of sales. These fixed costs within product cost of sales consisted principally of direct personnel costs, manufacturing and warehousing space, depreciation of equipment. Within these fixed costs, direct personnel costs increased during the period to $283,707 (2017: $213,867).

Cost of sales for the nine months ended September 30, 2018 increased to $1,076,779 (2017: $872,847). Direct cost of sales increased to 30% of product revenue while other cost of sales increased to 47% for the nine months ended September 30, 2018 as compared to 19% and 18% respectively for the same period in 2017 as described above. The increase was principally attributable to the write off of $218,799 of the OxiChek products.

Direct cost of sales for the nine month period ended September 30, 2018 were $419,910 (2017: $446,549). Other cost of sales for the nine months ended September 30, 2018 were $656,869 (2017: $426,299).

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2018, totaled $5,117,786, which was a 110% increase as compared to $2,440,023 for the nine months ended September 30, 2017.

The table below summarizes our general and administrative expenses for the nine months ended September 30, 2018 and 2017 as well as the percentage of change year-over-year:

	For the Nine Months Ended September 30,		
Description	2018	2017	Percent Change
Personnel Costs	$ 786,781	$ 781,833	1%
Professional Service Costs	1,958,819	866,403	126%
Stock Market & Investor Relations Costs	382,151	320,446	19%
Other General and Administrative Costs	1,990,035	471,341	322%
Total General and Administrative Expense	$ 5,117,786	$ 2,440,023	110%

Personnel expenses increased by 1% for the nine months ended September 30, 2018 as compared to the same period of 2017.

Professional service costs increased by 126% for the nine months ended September 30, 2018 as compared to the same period of 2017. A significant increase in legal fees ($1,277,518 (2017: $568,225)), accounting and audit services ($442,416 (2017: $140,130)) and general consulting services of $134,567 (2017: $52,975) were offset partially by a decrease in engineering fees $28,883 (2017: $82,718). The increase in the legal and accounting fees were principally in connection with our Board's recent investigation and the resulting restatement of our previously issued financials, as well in connection with litigation matters. Configuration and implementation expenses for the planned NetSuite Financial System also contributed to the increased accounting and general consulting service costs.

Stock market and investor fees increased 19% for the nine months ended September 30, 2018. The fees included costs associated with the Company's nominated advisor, stock transfer agents, investor relations team and stock exchange fees. Investor relations fees of $181,548 (2017: $167,245) and stock exchange fees of $71,669 (2017: $37,631) contributed to the increase.

Other general and administrative expenses increased by 322%. During September of 2018, the Company made a lump sum compensation payment of $100,000 to each of the independent directors. The Board approved the settlement of the Pulse Litigation which resulted in a one-time charge of $930,000. Other categories that increased during the nine months ended September 30, 2018 included bad debt expenses $125,000 (2017: $47,471), business insurance costs totaled $233,008 (2017: $116,482) and computer expenses $87,278 (2017: $32,406) related to the licensing and implementation of the NetSuite Financial System impacted the higher costs.

Sales and Marketing Expenses

Sales and marketing expenses for the nine months ended September 30, 2018 totaled $1,334,262 which was a 3% decrease compared to $1,382,416 for the nine months ended September 30, 2017.

The table below summarizes our sales and marketing expenses for the nine months ended September 30, 2018 and 2017 as well as the percentage of change year-over-year:

	For the Nine Months Ended September 30,		
Description	2018	2017	Percent Change
Personnel Costs	$ 797,627	$ 702,319	14%
Professional Service Costs	181,770	204,237	(11)%
Royalties and Outside Commission Costs	165,855	192,470	(14)%
Other Sales and Marketing Costs	189,010	283,390	(33)%
Total Sales and Marketing Expenses	$ 1,334,262	$ 1,382,416	(3)%

Personnel costs increased in the nine months ended September 30, 2018 as compared to the same period of 2017. This was due to an increase in compensation, bonuses, commissions and severance payments to $651,402 (2017: $602,029) and employee benefit expenses of $37,891 (2017: $23,454).

During the nine months ended September 30, 2018, the ChubeWorkx royalty totaled $41,418 (2017: $128,109) and was partially off-set by an increase in commissions to ISRs, which were $124,437 (2017: $64,362), which contributed to the decline in royalty and outside commission costs during the nine months ended September 30, 2018.

The Company recognized significant reductions in advertising expenses ($12,167 (2017: $60,568)) due to a television commercial that was produced in 2017 and a reduction in trade show expenses ($950 (2017: $33,199)) plus smaller reductions in several other operating categories that resulted in a 33% reduction in other sales and marketing costs.

Research and Development

Research and development expenses for the nine months ended September 30, 2018 totaled $859,961, which was a 10% decrease as compared to $952,724 for the nine months ended September 30, 2017.

The table below summarizes our research and development expenses for the nine months ended September 30, 2018 and 2017 as well as the percentage of change year-over-year:

Description	For the Nine Months Ended September 30, 2018	2017	Percent Change
Personnel Costs	$ 571,311	$ 727,206	(21)%
Clinical Trial Costs	1,480	2,453	(40)%
Professional Service Costs	153,450	89,541	71%
Other Research and Development Costs	133,720	133,524	0%
Total Research and Development Expenses	$ 859,961	$ 952,724	(10)%

Personnel costs decreased 21% during the nine months ended September 30, 2018 as compared to the same period of 2017. The Company's termination of Dr. Akers in April combined with additional reductions in the number of staff in the department resulted in the decline in personnel costs.

Professional services consisted of fees paid to engineering consultants to address production mold designs, specialized tooling and manufacturing process development, regulatory consultants to assist with governmental filings and facility certifications and the medical director. Engineering service costs increased to $106,345 (2017: $56,164), fees for the other general and regulatory consulting fees totaled $47,105 (2017: $33,377) in the nine months ended September 30, 2018.

Other Income and Expense

Other income, net of expense for the nine months ended September 30, 2018 totaled $119,560, which was a 673% increase as compared to $15,468 for the nine months ended September 30, 2017.

The table below summarizes our other income and expenses for the nine months ended September 30, 2018 and 2017 as well as the percentage of change year-over-year:

Description	For the Nine Months Ended September 30, 2018	2017	Percent Change
Currency Translation (Gain)/Loss	$ 5,271	$ (6,172)	(185)%
Interest and Dividend Income	(120,659)	(9,296)	1,198%
Other Income	(4,172)	-	N/A
Total Other Income, Net of Expenses	$ (119,560)	$ (15,468)	673%

Realized gains, interest and dividend income increased to $120,659 (2017: $9,296). The Company's available capital for investment activities increased significantly due to the capital raise in December 2017 and the subsequent exercises of warrants during the nine months ended September 30, 2018 resulting in the increase in investment income.

Income Taxes

As of September 30, 2018, the Company does not believe any uncertain tax positions exist that would result in the Company having a liability to the taxing authorities. The Company's policy is to classify interest and penalties related to unrecognized tax benefits, if and when required, as part of interest expense and general and administrative expense, respectively in the consolidated statement of operations.

Liquidity and Capital Resources

For the nine months ended September 30, 2018 and 2017, the Company generated a net loss attributable to shareholders of $7,011,394 and $3,344,932, respectively. As of September 30, 2018 and December 31, 2017, the Company has an accumulated deficit of $111,857,241 and $104,845,847 and had cash (excluding restricted cash) and marketable securities totaling $6,167,451 and $5,450,039, respectively.

Our primary focus is to expand the global distribution of our PIFA Heparin PF/4 rapid assays. The Company continues commercialization of its BreathScan Alcohol detection devices and the Tri-Cholesterol assay.

We expect to continue to incur losses from operations for the near-term and these losses could be significant as we incur regulatory and commercialization related expenses. We expect that our current working capital position will be sufficient to meet our estimated cash needs for at least the next twelve months. We are closely monitoring our cash balances, cash needs and expense levels. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might result in the possible inability of the Company to continue as a going concern.

We will also continue to support marketing activities of in-line products PIFA Heparin/PF4 rapid assays, PIFA PLUSS® PF4, breath alcohol detectors, METRON breath ketone tests and Tri-Cholesterol products, globally.

Capital expenditures for the nine months ended September 30, 2018 were $68,214 (2017: $37,191). As per the Company's lease agreement, the owner of the facility will be handling most of the facility upgrades, and we anticipate financing any production and laboratory capital expenditures through working capital.

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 expires May 31, 2019. The satellite office supports members of executive management and the sales and marketing team with convenient access to resources in the greater New York City area.

Our net cash consumed by operating activities totaled $5,874,664 during the nine months ended September 30, 2018. Cash was consumed by the loss of $7,011,394 plus non-cash adjustments of $173,047 for depreciation and amortization of non-current assets, $3,469 for the amortization of deferred compensation, $218,799 for the charge for obsolescence, $97,000 for the allowance of doubtful accounts, $12,106 for share based compensation to employees and $12,545 for share based compensation to non-employees less $10,633 for accrued interest and dividends on marketable securities. For the nine months ended September 30, 2018, decreases in trade receivables of $584,443, prepaid expenses – related party of $20,706 and increases in trade and other payables – related party of $7,366 and trade and other payables of $508,983 provided cash, primarily related to routine changes in operating activities. A net increase in deposits and other receivables of $13,836, deposits and other receivables – related party of $30,243, inventory of $79,162, and prepaid expenses of $367,860 consumed cash from operating activities.

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 $3,344,932 plus non-cash adjustments of $182,866 for depreciation and amortization of non-current assets, $46,239 for the reserve and write-off of doubtful accounts, $15,784 for the fair value of restricted common stock issued for services and $14,502 for share-based compensation less $148 for accrued interest and dividends on marketable securities. For the nine months ended September 30, 2017, decreases in deposits and other receivables of $2,034, trade receivables – related parties of $31,892, prepaid expenses of $68,797, prepaid expenses – related party of $38,438, and an increase in trade and other payables of $174,185 provided cash, primarily related to routine changes in operating activities. A net increase in trade receivables of $570,065, inventories of $111,486 and other assets of $9,280 and a decrease in trade and other payables – related party of $213,822 consumed cash from operating activities.

Investing and Financing Activities

The Company's net cash provided by investing and financing activities totaled $7,237,650 (2017: $3,717,291) during the nine months ended September 30, 2018. Cash of $5,378,212 (2017: $2,746,339) was consumed by capital expenditures and the purchase of marketable securities. Proceeds from the sale of marketable securities contributed cash of $5,460,662 (2017: $2,749,119) and net proceeds from the public and private placements of common and Series B preferred stock and the exercise of warrants for Common Stock contributed $7,155,200 (2017: $3,714,511) for the nine months ended September 30, 2018.

On November 2, 2018, the Company, entered into a securities purchase agreement with certain investors (the "Purchase Agreement") pursuant to which the Company agreed to sell an aggregate of 694,445 shares of common stock and warrants to purchase approximately 694,445 shares of common stock (the "Warrants"). The combined purchase price for one share of common stock and each Warrant will be priced at $2.88 (the "Offering"). The Purchase Agreement contains customary representations, warranties, and covenants by the Company.

Each Warrant has an initial exercise price of $3.76 per share, will be exercisable immediately after the date of issuance and will expire five years from the date it becomes exercisable. Subject to limited exceptions, a holder of the Warrants will not have the right to exercise any portion of such securities if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after the exercise. The exercise price of the Warrants, and in some cases the number of shares of common stock issuable upon exercise of the Warrants, will be subject to adjustment in the event of stock splits, stock dividends, combinations, rights offerings and similar events affecting the common stock.

In addition, the Warrants provide that, in the event of a fundamental transaction (as such term is described in the Warrant), the holder of such Warrant, at the holder's option, may receive, for each warrant share (as such term is described in the Warrant) that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock for which the Warrant is exercisable immediately prior to such fundamental transaction. If holders of common stock are given any choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the alternate consideration it receives upon any exercise of the Warrant following such fundamental transaction. The Company shall cause any successor entity (as such term is described in the Warrant), at the option of the holder, to deliver to the holder in exchange for the Warrant a security of the successor entity evidenced by a written instrument substantially similar in form and substance to the Warrant which is exercisable for a corresponding number of shares of capital stock of such successor entity (or its parent entity) equivalent to the shares of common stock acquirable and receivable upon exercise of the Warrant (without regard to any limitations on the exercise of this Warrant) prior to such fundamental transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock.

The Offering was made pursuant to a shelf registration statement on Form S-3 (File No. 333-214214), previously filed with the Securities and Exchange Commission on October 24, 2016 and declared effective on November 16, 2016. Such securities are being offered only by means of a prospectus.

Critical Accounting Policies

See accounting policies in Note 2 of the condensed consolidated financial statements included in Part I, Item 1 of this report.

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.

Subsequent to the filing of the Company's Form 10-K for the year ended December 31, 2017, the Company determined that there were material errors within its Quarterly Reports on Form 10-Q for the periods ended June 30, 2017 and September 30, 2017 and in its Annual Report on Form 10-K for the year ended December 31, 2017. Specifically, the Company determined that certain revenue transactions did not qualify for revenue recognition under generally accepted accounting principles, that certain obligations were not recorded as expenses on a timely basis and that the Company did not properly value its inventory. The Company concluded that the impact of applying corrections for these errors was materially different from its previously reported results under its historical practice.

As of September 30, 2018 and based upon that evaluation, and in light of the restatement discussion above, the Company's PEO and PFO concluded that the Company's disclosure controls and procedures were not 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.

Management is actively engaged in the planning for and implementation of remediation efforts to address the material weakness identified above. The remediation plan includes (i) the engaging of additional experienced financial resources, (ii) the development and implementation of enhanced controls designed to evaluate the appropriateness of revenue recognition policies and procedures, (iii) the implementation of review and monitoring of transactions to ensure compliance with the new policies and procedures, and (iv) the training of personnel responsible for revenue and inventory.

(b) Changes in Internal Control over Financial Reporting

The Company has implemented additional controls around sales transactions to (i) further validate shipping terms including, the date for which risk of ownership transfers to the purchaser and (ii) that shipped product met purchasers' specifications. In connection with the preparation of the condensed consolidated financial statements for the quarter ended September 30, 2018, the Company engaged a third party consultant to assist in the review of financial statements and to address complex accounting matters. There have been no other changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rules 13a-15 or 15d-15 under the Exchange Act that occurred during the fiscal quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. On October 5, 2018, the Company hired Mr. Howard Yeaton as its CEO and interim Chief Financial Officer. Mr. Yeaton replaced the former CEO, Mr. John Gormally who resigned on October 5, 2018.

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 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.

The Company filed a Motion for Summary Judgment on January 24, 2018. On June 21, 2018, the Court ruled in favor of the Company on some issues and determined that other issues warranted a trial. As part of its ruling on the Motion for Summary Judgment, the Court held "While it seems likely that Plaintiff did suffer some amount of damages, Plaintiff has so far failed to provide a sufficient evidentiary foundation from which the trier of fact could reasonably calculate the value of its injury." The Court stated that it was "reasonably certain that Plaintiff suffered some damage" and found that Pulse Health "may be entitled to nominal damages." The Court further determined that equitable relief, such as an injunction, "may be warranted." Following such rulings, the Company discovered certain deficiencies in its discovery responses and is taking the appropriate steps to supplement the record and correct these deficiencies. In addition, the Court has ordered a settlement conference in front of a U.S. magistrate to be held on August 31, 2018. Trial has been set for November 13, 2018 in Portland, Oregon.

On or about June 15, 2018, certain parties brought certain class action lawsuits against the Company.

On September 17, 2018, the Company and Pulse entered into a settlement. Pursuant to the settlement reached between the Plaintiff and the Company, on October 9, 2018 the Company paid $930,000 to the Plaintiff. The Company has also agreed to a permanent injunction and will not make, use, sell or offer to sell the BreathScan OxiChek™ product, any product that detects aldehydes or oxidative stress in exhaled human breath or breath condensate using either basic fuchsin or sodium metabisulfite or any form, analog or equivalent thereof, and the BreathScan Lync device, or any equivalent thereof, as part of a test for aldehydes or oxidative stress in human exhaled breath or breath condensate. The Company does not anticipate a material impact on revenues as a result of the withdrawal of the BreathScan OxiChek™ product from sale. The Settlement Agreement does not contain any admission of liability, wrongdoing, or responsibility by any of the parties.

Faulkner v. Akers Biosciences, Inc., No. 2:18-cv-10521 (D.N.J.)

On June 13, 2018, Plaintiff Tim Faulkner filed a class action complaint alleging securities violations against Akers Biosciences, Inc. ("Akers"), John J. Gormally, and Gary M. Rauch ("Individual Defendants") (together with Akers, "Defendants") on behalf of all persons and entities who purchased publicly traded Akers securities from May 15, 2017 through June 5, 2018. The complaint alleges violations of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants, and violations of Section 20(a) of the Exchange Act against the Individual Defendants. In particular, the complaint alleges that Defendants made false and/or misleading statements and/or failed to disclose in its first, second, and third quarter 2017 10-Qs and its 2017 10-K that: (1) Akers was improperly recognizing revenue for the fiscal year ended December 31, 2017; and, (2) Akers had downplayed weaknesses in its internal controls over financial reporting and failed to disclose the true extent of those weaknesses. On July 10, 2018, Plaintiff and Defendants entered into a stipulation that Defendants are not required to respond to the complaint until the court appoints a lead plaintiff and lead counsel for the class, and then after the lead plaintiff chooses whether to file an amended complaint or whether to designate the complaint as the operative complaint.

Gleason v. Akers Biosciences, Inc., No. 2:18-cv-10805 (D.N.J.)

On June 20, 2018, Plaintiff David Gleason filed a class action complaint alleging securities violations against Akers Biosciences, Inc. ("Akers"), John J. Gormally, and Gary M. Rauch ("Individual Defendants") (together with Akers, "Defendants") on behalf of all persons and entities who purchased publicly traded Akers securities from May 15, 2017 through June 5, 2018. The complaint alleges violations of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants, and violations of Section 20(a) of the Exchange Act against the Individual Defendants. In particular, the complaint alleges that Defendants made false and/or misleading statements and/or failed to disclose in its first, second, and third quarter 2017 10-Qs and its 2017 10-K that: (1) Akers was improperly recognizing revenue for the fiscal year ended December 31, 2017; and, (2) Akers had downplayed weaknesses in its internal controls over financial reporting and failed to disclose the true extent of those weaknesses. No Defendant has been served yet, and no response is due at this time.

Other class action lawsuits have been threatened against the Company and may be filed shortly. Although there are currently two separate actions pending, we anticipate that the two actions will be consolidated into one action.

The Company maintains D&O liability insurance coverage, insuring both the Company and the Directors and Officers for covered defense and indemnification, and has noticed these matters thereunder.

Additionally, a former executive has threatened to sue the Company, Board members, and executives under CEPA over the termination of his employment. That statute prohibits any retaliatory action against an employee who discloses, or threatens to disclose to a supervisor or to a public entity any activity, policy or practice of the employer that is a violation of a law, or a rule or regulation. Remedies may include a counter claim for back pay, reinstatement, compensatory and punitive damages and attorneys' fees if appropriate. The Company will vigorously defend any litigation brought by this former executive.

The Company intends to establish a rigorous defense of all claims. The Company is unable to assess the potential outcome, so no accrual for losses was made as of September 30, 2018. 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

In addition to the risk factors in this quarterly report, please see the additional risk factors in our Annual Report on Form 10-K/A, Amendment No. 1, filed with the SEC on July 13, 2018, our Quarterly Report on Form 10-Q, filed with the SEC on July 13, 2018, and our Quarterly Report on Form 10-Q, filed with the SEC on August 14, 2018.

The market price of our common stock is likely to be volatile and could subject us to litigation.

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

- variations in our revenue and operating expenses;
- actual or anticipated changes in the estimates of our operating results or changes in stock market analyst recommendations regarding our ordinary shares, other comparable companies or our industry generally;
- market conditions in our industry and the economy as a whole;
- developments in the financial markets and worldwide or regional economies;
- announcements of innovations or new products or services by us or our competitors;
- announcements by the government relating to regulations that govern our industry;
- sales of our common stock or other securities by us or in the open market;
- recruitment or departure of key personnel;
- any actions taken against the Company by former executives;
- Potential delisting from the NASDAQ Stock Market;
- any class action lawsuits brought against the Company; and
- changes in the market valuations of other comparable companies

In addition, if the market for biotech stocks or the stock market in general experiences loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition or operating results. The trading price of our shares might also decline in reaction to events that affect other companies in our industry, even if these events do not directly affect us. Each of these factors, among others, could harm the value of your investment in our common stock. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, operating results and financial condition. Specifically, on or about June 15, 2018, certain parties have brought certain class action lawsuits against the Company, and a former executive has threatened to sue the Company, Board members, and executives under the New Jersey CEPA, N.J. Stat. Ann. § 34-19.1 over the termination of his employment. Both, the class action lawsuits brought against the Company and CEPA action threatened by a former executive could result in substantial costs and diversion of management's attention and resources, which could harm the value of your investment in our common stock and materially and adversely affect our business, operating results and financial condition.

A robust public market for our common stock may not develop or be sustained, which could affect your ability to sell our common stock or depress the market price of our common stock.

Our common stock is listed on NASDAQ, but we cannot assure you that our common stock will continue to trade on this market or another national securities exchange. In addition, we are unable to predict whether an active trading market for our common stock will develop or will be sustained.

On June 11, 2018, the Company received a letter from the Listing Qualifications Department NASDAQ notifying the Company that it has determined that the Company violated the shareholder approval requirements of Listing Rule 5635(c). Listing Rule 5635(c) requires shareholder approval prior to the issuance of securities when a stock option or purchase plan is to be established or materially amended or other equity compensation arrangement made or materially amended, pursuant to which stock may be acquired by officers, directors, employees or consultants.

Prior to the Company's public offering and listing on NASDAQ, the Company's 2013 Plan was approved by its Board NASDAQ has concluded that the 2013 Plan was materially amended on two occasions after the Company's public offering and listing on NASDAQ. The first amendment, as approved by the Board on January 9, 2015, increased the number of shares available under the 2013 Plan from 50,000 to 100,000 shares and the second amendment, as approved by the Board on October 5, 2016, increased the number of shares under the 2013 Plan from 100,000 to 103,750 shares. The Company has until December 10, 2018, to regain compliance with Listing Rule 5635.

During the first quarter of 2018 the Company promptly notified NASDAQ, as required by Listing Rule 5625, when it became aware of its potential non-compliance with Listing Rule 5635(c). On May 4, 2018, the Staff requested additional information from the Company with respect to such non-compliance and on May 31, 2018, the Company responded. On June 25, 2018, the Company submitted the 5635 Compliance Plan to NASDAQ to remediate this matter. The 5635 Compliance Plan included that a proposal for shareholders of the Company to ratify the 2013 Plan Amendments be included in the proxy statement for the Company's 2018 annual meeting of the shareholders of the Company and that the Company shall suspend the trading of each share granted, and each share granted upon the exercise of any option granted, in excess of 50,000 shares under the 2013 Plan (the number of shares properly approved pursuant to the 2013 Plan prior to the 2013 Plan Amendments). The 5635 Compliance Plan also proposes to prevent the exercise of any option granted under the 2013 Plan.

If NASDAQ does not find that the 5635 Compliance Plan acceptable to cure the Company's violation of Listing Rule 5635(c), then we cannot assure you that our common stock will continue to trade on this market or another national securities exchange.

The restatement of our previously issued financial statements contained in our Forms 10-Q for the periods ended June 30, 2017 and September 30, 2017 and the Form 10-K for the year ended December 31, 2017 may lead to additional risks and uncertainties, including regulatory, stockholder or other actions, loss of investor confidence and negative impacts on our stock price.

Our Audit Committee, after consultation with management and discussing with outside counsel, external auditors and third-party consultants, concluded that our previously issued consolidated financial statements for the quarterly periods ended June 30, 2017 and September 30, 2017 and for the year ended December 31, 2017 should be restated. The Company determined that certain revenue transactions did not qualify for revenue recognition under generally accepted accounting principles, that certain obligations were not recorded as expenses on a timely basis and that the Company did not properly value its inventory. The Company concluded that the impact of applying corrections for these errors was materially different from its previously reported results under its historical practice. As a result, the Company restated its consolidated financial statements for the periods impacted, as more fully described within each of the respective amended reports, as filed on July 13, 2018. Financial information included in our previously filed Form 10-K and our Quarterly Reports on Form 10-Q and all earnings press releases and similar communications issued by us, for such periods, should not be relied upon and are superseded in their entirety by the above described amended Quarterly and Annual reports.

Accordingly, this Form 10-Q reflects: (1) changes to our Condensed Consolidated Balance Sheet and our Condensed Consolidated Statements of Shareholders' Equity as of December 31, 2017; (2) expanded risk factor disclosures within Part II, Item 1A, and (3) additional disclosures and conclusions regarding Controls and Procedures in Part II, Item 4.

As a result of the 2017 restatements and associated non-reliance on previously issued financial information, we have become subject to a number of additional costs and risks, including unanticipated costs for accounting and legal fees in connection with or related to the restatement and the remediation of our ineffective disclosure controls and procedures and material weakness in internal control over financial reporting. Likewise, the attention of our management team has been diverted by these efforts. In addition, we could also be subject to additional shareholder, governmental, regulatory or other actions or demands in connection with the restatement or other matters. Any such proceedings will, regardless of the outcome, consume a significant amount of management's time and attention and may result in additional legal, accounting, insurance and other costs. If we do not prevail in any such proceedings, we could be required to pay damages or settlement costs. In addition, the restatement and related matters could impair our reputation or could cause our customers, shareholders, or other counterparties to lose confidence in us. Any of these occurrences could have a material adverse effect on our business, results of operations, financial condition and stock price.

In connection with the restatement of our financial statements for the quarterly periods ended June 30, 2017 and September 30, 2017 and for the year ended December 31, 2017, our management identified material weaknesses in our internal control over financial reporting, as described in Item 9A, "Control and Procedures" of this Form 10-K. A material weakness is a deficiency, or combination of deficiencies in internal controls over financial reporting that results in a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Further, management determined that control deficiencies existed with respect to certain aspects of our historical financial reporting and, accordingly, management has concluded that management's reports related to the effectiveness of internal and disclosure controls may not have been correct.

A deterioration of global economic conditions may adversely affect our industry, business and results of operations.

Disruptions in the global credit and financial markets and in economic conditions generally may include diminished liquidity and credit availability, a decline in consumer confidence, a decline in economic growth, an increased unemployment rate and uncertainty about economic stability. Such disruptions may affect businesses such as ours in a number of ways, making it difficult to accurately forecast and plan our future business activities. Any adverse global economic conditions and tightening of credit in financial markets may lead consumers to postpone spending, which may cause our customers to cancel, decrease or delay their existing and future orders with us. In addition, financial difficulties experienced by our suppliers, manufacturers, distributors or customers could result in product delays, increased accounts receivable defaults and inventory challenges. We are unable to predict the likely duration and severity of disruptions in the credit and financial markets and adverse global economic conditions.

Our ability to grow and compete in the future will be adversely affected if adequate capital is not available to us or not available on terms favorable to us.

Historically, our cash generated from operations has not been sufficient to meet our expenses. We have financed our operations principally through the raising of equity capital, debt and through trade credit with our vendors. Our ability to continue our operations and to pay our obligations when they become due is contingent upon obtaining additional financing. If we are unable to obtain sufficient amounts of additional capital, we may be required to reduce the scope of our planned market development activities, and/or consider reductions in personnel costs or other operating costs. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

Obligations associated with being a public company require significant company resources and management attention, which may have a material adverse effect on our financial condition and results of operations.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the "Exchange Act," and the other rules and regulations of the SEC, including the Sarbanes-Oxley Act. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition and the Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. These reporting and other obligations place significant demands on our management, administrative, operational and accounting resources, make certain activities more time-consuming and cause us to incur significant legal, accounting and other expenses. In order to comply with these obligations, we may need to upgrade our systems or create new systems, implement additional financial and management controls, reporting systems and procedures, expand or outsource our internal audit function, and hire additional accounting and finance staff. Because our resources are limited compared to many public companies, these requirement may impose a disproportionate financial burden on us. Furthermore, our limited management resources may exacerbate the difficulties in complying with these reporting and other requirements and prevent us from focusing on executing our business strategy. In addition, if we are unable to comply with the financial reporting requirements and other rules that apply to reporting companies, the market price of our common stock could be adversely affected.

As an “emerging growth company” and a “smaller reporting company” we intend to continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” or “smaller reporting companies,” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and other scaled disclosure requirements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In general, we will remain an “emerging growth company” until December 31, 2020, although a variety of circumstances could cause us to lose that status earlier, and will remain a “smaller reporting company” for each fiscal year where our public float remains below $75 million as of the last day of the second fiscal quarter of the prior fiscal year. We intend to take advantage of some or all of these exemptions and reduced reporting requirements until we are no longer an “emerging growth company” and/or a “smaller reporting company,” at which time, we expect to incur significant additional expenses and devote substantial management effort toward ensuring compliance with these additional requirements.

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

We use a diverse and broad range of raw materials in the manufacturing of our products. We purchase all of our raw materials and select items, such as packaging, from external suppliers. In addition, we purchase some supplies from single sources for reasons of proprietary know-how, quality assurance, sole source availability, or due to regulatory qualification requirements and disruption of these sources could have, at a minimum, a temporary adverse effect on shipments and the financial results of the Company. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. Any prolonged inability to obtain certain materials or components could have an adverse effect on the Company’s financial condition or results of operations and could result in damage to its relationships with its customers and, accordingly, adversely affect the Company’s business.

During the nine months ended September 30, 2018, we experienced lower yields in the process of extracting antigen from the supplier provided platelets used to produce our PIFA Heparin product. At these yield levels, our production of this product was under target levels, which had resulted in backorders. Our engineers and representatives from our supplier have been working together to adjust our processes in order to restore the yield to appropriate levels, the results of which are not yet determined. Furthermore, we are evaluating and testing a solution that may involve one or more alternative antigen suppliers and processes that may provide a path to restoring yield levels for this product.

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, 2018, 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.

Not applicable.

Item 6. Exhibits.

31.1	Certification by the Principal Executive Officer and 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 and Principal Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

* Filed herewith

SIGNATURES

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

AKERS BIOSCIENCES, INC.

Date: November 14, 2018

By: */s/ Howard Yeaton*
Name: Howard Yeaton
Title: Chief Executive Officer and Interim Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Howard Yeaton, certify that:

1. I have reviewed this Form 10-Q of Akers Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2018

By: */s/ Howard Yeaton*
Howard Yeaton
Chief Executive Officer and Interim Chief Financial Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)
Akers Biosciences, Inc.

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF
THE SARBANES-OXLEY ACT OF 2002

In connection with this Quarterly Report of Akers Biosciences, Inc. (the "Company"), on Form 10-Q for the period ended September 30, 2018, as filed with the U.S. Securities and Exchange Commission on the date hereof, the undersigned, in the capacity and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: November 14, 2018

By: */s/ Howard Yeaton*
Howard Yeaton
Chief Executive Officer and Interim Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)
Akers Biosciences, Inc.