

Akers Biosciences, Inc.  
Form 10-Q  
July 13, 2018

**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: **March 31, 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 (IRS Employer  
of incorporation)                      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 ☒ No ☐

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

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

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

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

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

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

As of July 13, 2018, there were 94,106,292 shares outstanding of the registrant's Common Stock.

## TABLE OF CONTENTS

### **PART I – FINANCIAL INFORMATION**

Item 1.	<u>Financial Statements</u>	3
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	32
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	45
Item 4.	<u>Controls and Procedures</u>	45

### **PART II – OTHER INFORMATION**

Item 1.	<u>Legal Proceedings</u>	46
Item 1A.	<u>Risk Factors</u>	47
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	50
Item 3.	<u>Defaults Upon Senior Securities</u>	50
Item 4.	<u>Mine Safety Disclosures</u>	50
Item 5.	<u>Other Information</u>	50
Item 6.	<u>Exhibits</u>	53
	<u>Signatures</u>	54

**PART I – FINANCIAL INFORMATION****Item 1. Financial Statements****AKERS BIOSCIENCES, INC. AND SUBSIDIARIES****Condensed Consolidated Balance Sheets****March 31, 2018 and December 31, 2017**

	March 31, 2018 (unaudited)	December 31, 2017 (audited) (restated)
<b>ASSETS</b>		
Current Assets		
Cash	\$647,267	\$438,432
Marketable Securities	8,679,010	5,011,607
Trade Receivables, net	416,898	964,671
Deposits and other receivables	29,495	16,590
Deposits and other receivables - Related Party	33,243	-
Inventories, net	973,947	947,612
Prepaid expenses	234,985	145,488
Prepaid expenses - Related Party	148,916	251,499
Total Current Assets	11,163,761	7,775,899
Non-Current Assets		
Prepaid expenses - Related Party	209,774	120,118
Property, Plant and Equipment, net	259,265	235,113
Intangible Assets, net	1,087,890	1,130,667
Other Assets	76,093	76,093
Total Non-Current Assets	1,633,022	1,561,991
Total Assets	\$12,796,783	\$9,337,890
<b>LIABILITIES</b>		
Current Liabilities		
Trade and Other Payables	\$1,360,533	\$1,745,216
Trade and Other Payables - Related Party	19,005	39,821
Total Current Liabilities	1,379,538	1,785,037

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

Total Liabilities	1,379,538	1,785,037
<b>SHAREHOLDERS' EQUITY</b>		
Convertible Preferred Stock, No par value, 50,000,000 shares authorized, 0 and 1,755 shares issued and outstanding as of March 31, 2018 and December 31, 2017	-	1,755,000
Common Stock, No par value, 500,000,000 shares authorized, 86,437,624 and 44,220,552 issued and outstanding as of March 31, 2018 and December 31, 2017	118,139,926	110,647,169
Deferred Compensation	-	(3,469 )
Comprehensive Loss	(16,843 )	-
Accumulated Deficit	(106,705,838)	(104,845,847)
Total Shareholders' Equity	11,417,245	7,552,853
Total Liabilities and Shareholders' Equity	\$12,796,783	\$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 months ended March 31, 2018 and 2017**

**(unaudited)**

	Three months ended March 31,	
	2018	2017
Revenues:		
Product Revenue	\$302,475	\$643,187
Product Revenue - Related party	-	24,063
Total Revenues	302,475	667,250
Cost of Sales:		
Product Cost of Sales	(297,500 )	(258,721 )
Gross Income	4,975	408,529
Administrative Expenses	915,533	790,529
Sales and Marketing Expenses	468,463	556,655
Sales and Marketing Expenses - Related Party	31,689	32,279
Research and Development Expenses	391,381	348,442
Research and Development Expenses – Related Party	48,589	-
Amortization of Non-Current Assets	42,777	42,777
Loss from Operations	(1,893,457 )	(1,362,153 )
Other (Income)/Expenses		
Foreign Currency Transaction (Gain)/Loss	2,875	(10,346 )
Interest and Dividend Income	(36,341 )	(2,537 )
Total Other Income	(33,466 )	(12,883 )
Loss Before Income Taxes	(1,859,991 )	(1,349,270 )
Income Tax Benefit	-	-
Net Loss Attributable to Common Shareholders	(1,859,991 )	(1,349,270 )
Other Comprehensive Income/(Loss)		
Net Unrealized Gain/(Loss) on Marketable Securities	(16,843 )	156
Total Other Comprehensive Income/(Loss)	(16,843 )	156
Comprehensive Loss	\$(1,876,834 )	\$(1,349,114 )

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

Basic and Diluted loss per common share	\$(0.03	) \$(0.19	)
Weighted average basic and diluted common shares outstanding	71,315,461	6,993,574	

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 three months ended March 31, 2018 and 2017**

	<b>Preferred Shares Issued and Outstanding</b>	<b>Preferred Stock</b>	<b>Common Shares Issued and Outstanding</b>	<b>Common Stock</b>	<b>Deferred Compensation</b>	<b>Accumulated Deficit</b>	<b>Accumulated Other Comprehensive Loss</b>	<b>Total Equity</b>
<b>Balance at December 31, 2017 (audited) (restated)</b>	1,755	\$ 1,755,000	44,220,552	\$ 110,647,169	\$(3,469)	\$(104,845,847)	\$-	\$7,552,853
Net loss	-	-	-	-	-	(1,859,991 )	-	(1,859,991 )
Exercise of warrants for common stock	-	-	30,492,070	5,717,325	-	-	-	5,717,325
Conversion of preferred stock to common stock	(1,755)	(1,755,000)	11,700,002	1,755,000				-
Amortization of deferred compensation	-	-	-	-	3,469	-	-	3,469
Issuance of stock grants to key employees			25,000	5,175				5,175
Issuance of non-qualified stock options to key employees	-	-	-	2,712	-	-	-	2,712
Issuance of restricted stock for services for non-employees	-	-	-	12,545	-	-	-	12,545
Net unrealized loss on marketable securities							(16,843)	(16,843 )
<b>Balance at March 31,</b>	-	\$-	86,437,624	\$ 118,139,926	\$-	\$(106,705,838)	\$(16,843)	\$11,417,245

**2018**  
**(unaudited)**

See accompanying notes to these condensed consolidated financial statements.

**AKERS BIOSCIENCES, INC. AND SUBSIDIARIES****Condensed Consolidated Statements of Cash Flows****For the three months ended March 31, 2018 and 2017****(unaudited)**

	<b>2018</b>	<b>2017</b>
<b>Cash flows from operating activities</b>		
Net loss	\$(1,859,991)	\$(1,349,270)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accrued income on marketable securities	(13,955 )	(326 )
Depreciation and amortization	56,452	60,718
Reserve and write-off for obsolete inventory	24,460	(32,333 )
Reserve for doubtful accounts	-	40,859
Amortization of deferred compensation	3,469	5,203
Share based compensation to employees - options	2,712	5,036
Share based compensation to employees - restricted stock	5,175	-
Share based compensation to non-employees - restricted stock	12,545	-
Changes in assets and liabilities:		
Decrease in trade receivables	547,773	43,351
Decrease in trade receivables - related party	-	7,458
(Increase)/decrease in deposits and other receivables	(12,905 )	10,692
Increase in deposit and other receivables - related party	(33,243 )	-
Increase in inventories	(50,795 )	(100,878 )
(Increase)/decrease in prepaid expenses	(89,497 )	69,930
Decrease in prepaid expenses - related party	12,927	16,140
Decrease in trade and other payables	(384,683 )	(200,059 )
Decrease in trade and other payables - related party	(20,816 )	(138,184 )
<b>Net cash used in operating activities</b>	<b>(1,800,372)</b>	<b>(1,561,663)</b>
<b>Cash flows from investing activities</b>		
Purchases of property, plant and equipment	(37,827 )	(16,774 )
Purchases of marketable securities	(3,972,386)	(1,202,210)
Proceeds from sale of marketable securities	302,095	1,095,218
<b>Net cash used in investing activities</b>	<b>(3,708,118)</b>	<b>(123,766 )</b>
<b>Cash flows from financing activities</b>		
Net proceeds from issuance of common stock	-	3,452,861
Net proceeds from exercise of warrants for common stock	5,717,325	244,950
<b>Net cash provided by financing activities</b>	<b>5,717,325</b>	<b>3,697,811</b>
Net increase in cash	208,835	2,012,382

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

Cash at beginning of period	438,432	72,700
Cash at end of period	\$647,267	\$2,085,082

**Supplemental Schedule of Non-Cash Financing and Investing Activities**

Net unrealized gains/(losses) on marketable securities	\$(16,843 )	\$156
Conversion of Series B Preferred Stock to common shares	\$1,755,000	\$-

See accompanying notes to these condensed consolidated financial statements.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

**Note 1 - Nature of Business**

**(a) Reporting Entity**

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

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

**(b) Nature of Business**

The Company’s primary focus is the development and sale of disposable diagnostic testing devices that can be performed in minutes, to facilitate time sensitive therapeutic decisions. The Company’s main products are a disposable breathalyzer test that measures the blood alcohol content of the user, a rapid test detecting the antibody causing an allergic reaction to Heparin and a disposable breathalyzer test that measures Free Radical activity in the human body.

**Note 2 - Basis of Presentation and Significant Accounting Policies**

**(a) Basis of Presentation**

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

Certain information and note disclosures normally included in the financial statements prepared in accordance with US GAAP have been condensed. As such, the information included in these financial statements should be read in conjunction with the audited financial statements as of and for the years ended December 31, 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 March 31, 2018 and its results of operations and cash flows for the three months ended March 31, 2018 and 2017. The results of operations for the three months ended March 31, 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.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

**(b) Use of Estimates and Judgments**

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

**(c) Functional and Presentation Currency**

These 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) Fair Value of Financial Instruments**

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



AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

**(g) Fair Value Measurement – Marketable Securities**

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

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

Level 2 Inputs to the valuation methodology include:

- quoted prices for similar assets or liabilities in active markets;
- quoted prices for identical or similar assets or liabilities in inactive markets;
- inputs other than quoted prices that are observable for the asset or liability;
- inputs that are derived principally from or corroborated by observable market data by correlation or other means

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

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

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

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

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

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

## AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

## Notes to Condensed Consolidated Financial Statements

As of March 31, 2018 and December 31, 2017, allowances for doubtful accounts for trade receivables were \$596,196. Bad debt expenses for trade receivables were \$- and \$42,361 for the three months ended March 31, 2018 and 2017.

As of March 31, 2018 and December 31, 2017, the aging of trade receivables was as follows:

Aging Period	March 31,		December 31,	
	2018	%	2017	%
			(restated)	
Current	\$237,066	24 %	\$1,181,335	76 %
01-30 Days	4,657	0 %	79,535	5 %
31-60 Days	1,428	0 %	20,154	1 %
61-90 Days	117	0 %	25,100	2 %
>90 Days	769,826	76 %	254,743	16 %
Subtotal	\$1,013,094		\$1,560,867	
Bad Debts Allowance	(596,196 )		(596,196 )	
Total	\$416,898		\$964,671	

The aging above represents the number of days that the account receivable balance exceeds the credit terms. Included in the current category is accounts receivable of \$- and \$470,000 as of March 31, 2018 and December 31, 2017 with payment terms extended to 180 days.

**(i) Concentration of Credit Risk**

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

All of the Company's cash is maintained with Fulton Bank of New Jersey, Bank of America, NA and PayPal. The funds are insured by the FDIC up to a maximum of \$250,000, but are otherwise unprotected. The Company placed \$631,099 and \$426,927 with Fulton Bank of New Jersey, \$12,578 and \$7,915 with Bank of America, NA and \$3,590 with PayPal as of March 31, 2018 and December 31, 2017. No losses have been incurred in these accounts.

Three customers accounted for 76% of trade receivables as of March 31, 2018. To limit such risks, the Company performs ongoing credit evaluations of its customers' financial condition.

**(j) Inventories**

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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

**(k) Property, Plant and Equipment**

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

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

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

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

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

**(l) Intangible Assets**

**(i) Patents and Trade Secrets**

The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person's breath, blood, urine and saliva. Propriety protection for the Company's products, technology and process is important to its competitive position. As of March 31, 2018, the Company has ten patents from the United States Patent Office in effect (9,383,368; 7,896,167; 8,097,171; 8,003,061; 8,425,859; 8,871,521; 8,808,639; D691,056; D691,057 and D691,058). Other patents are in effect in Australia through the Design Registry (348,310; 348,311 and 348,312), European Union Patents 1793906, 2684025, 002216895-0001; 002216895-0002 and 002216895-0003), in Hong Kong (HK11004006) and in Japan (1,515,170; 4,885,134; 4,931,821 5,775,790, and 6023096). Patents are in the national phase of prosecution in many Patent Cooperation Treaty participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the U.S., European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

**(ii) Patent Costs**

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

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

**(iii) Other Intangible Assets**

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

**(iv) Amortization**

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

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

**(m) Recoverability of Long Lived Assets**

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

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



**(n) Investments**

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

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

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

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

**(o) Revenue Recognition**

In accordance with FASB ASC 605, the Company recognizes revenue when (i) persuasive evidence of a customer or distributor arrangement exists, (ii) a retailer, distributor or wholesaler receives the goods and acceptance occurs, (iii) the price is fixed or determinable, and (iv) the collectability of the revenue is reasonably assured. Subject to these criteria, the Company recognizes revenue from product sales when title passes to the customer based on shipping terms. The Company typically does not accept returns nor offer charge backs or rebates except for certain distributors. Revenue recorded is net of any discount, rebate or sales return. The accrual for estimated sales returns was \$- as of March 31, 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 implemented a standard dealer cost model during the year ended December 31, 2016 which includes a provision for rebates to the distributors under limited circumstances. The Company established an accrual of \$57,725 and \$126,471 as of March 31, 2018 and December 31, 2017. Accounts receivable will be reduced when the rebates are applied by the customer. The Company recognized \$37,544 and \$102,824 during the three months ended March 31, 2018 and 2017 for rebates, which is included as a reduction of product revenue in the Condensed Consolidated Statement of Operations and Comprehensive Loss.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

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

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

**(p) Income Taxes**

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

**(q) Shipping and Handling Fees and Costs**

The Company charges actual shipping plus a handling fee to customers, which amounted to \$13,641 and \$18,420 for the three months ended March 31, 2018 and 2017. These fees are classified as part of product revenue in the Condensed Consolidated Statement of Operations and Comprehensive Loss. Shipping and other related delivery costs, including those for incoming raw materials are classified as part of the cost of net revenue, which amounted to \$26,944 and \$16,177 for the three months ended March 31, 2018 and 2017.

**(r) Research and Development Costs**

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

**(s) Stock-based Payments**

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

## AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

### Notes to Condensed Consolidated Financial Statements

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

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

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

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

#### **(u) Recently Adopted Accounting Pronouncements**

As of March 31, 2018 and for the three months then ended, there were no recently adopted accounting pronouncements that had a material effect on the Company's financial statements.

#### **(v) Recently Issued Accounting Pronouncements Not Yet Adopted**

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

In May 2014 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 interim reporting periods within annual reporting periods beginning after December 15, 2019. Early application is permitted as of annual reporting periods beginning after December 15, 2016 including interim reporting periods within that reporting period. The Company is currently evaluating the effect of the amendments but it does not anticipate a material impact of its financial statements. The Company expects to use the modified retrospective adoption method and will adopt this Update as of January 1, 2019.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

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

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

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

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





## AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

### Notes to Condensed Consolidated Financial Statements

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

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

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

### **Note 3 – Key Recent Events and Management Plans**

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 current 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.

The Company was not able to timely file this Quarterly Report on Form 10-Q due to delays in evaluating certain accounting and reporting matters. The Company's evaluation resulted in its filing a notification on June 18, 2018 on Form 8-K providing notice that investors should no longer rely upon the financial statements included within the Company's Quarterly Reports as of and for the periods ended June 30, 2017 and September 30, 2017, as well as the Company's Annual Report on Form 10-K for the year ended December 31, 2017. The Company has since prepared amended financial statements for such periods and the respective amended Quarterly and Annual financial reports have been filed contemporaneously with the filing of this Quarterly Report on Form 10-Q for the three months ended March 31, 2018.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

By way of a letter dated May 22, 2018, the Listing Qualifications Department of the NASDAQ Stock Market LLC (“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 Form 10-Q for the period ended March 31, 2018 (the “Quarterly Report”). 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. Upon acceptance of the Company’s compliance plan, NASDAQ is permitted to grant an extension of up to 180 calendar days from the Quarterly Report’s filing due date, or until November 19, 2018, for the Company to regain compliance with NASDAQ Listing Rule 5250(c)(1). The Company believes that its filing of this Quarterly Report and the Amended Quarterly and Annual Reports as discussed above have cured the potential default as to the Company meeting the requirements to continue its listing in good standing under NASDAQ.

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 400,000 to 800,000 shares and the second amendment, as approved by the Board on October 5, 2016, increased the number of shares under the 2013 Plan from 800,000 to 830,000 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 400,000 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.

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. Ultimately, there will be one class action complaint upon the appointment of a lead plaintiff and lead Counsel.

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.

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 three months ended March 31, 2018, the Company raised an additional \$5,717,325 from the exercise of warrants (Note 10). As of July 6, 2018, the Company had cash and marketable securities of approximately \$8.1 million and working capital of approximately \$8.8 million. The Company is not yet able to determine the impact of the key events during June and July of 2018 may have on the Company's ability to raise capital, nor the impact that these matters might have on its business operations.

Additionally, a former executive has threatened to sue the Company, Board members, and executives under the New Jersey Conscientious Employee Protection Act ("CEPA"), N.J. Stat. Ann. § 34-19.1 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 believes that its current working capital position will be sufficient to meet its obligations as they fall due within one year after the financial statements are issued.

## AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

## Notes to Condensed Consolidated Financial Statements

**Note 4 - Fair Value Measurement - Marketable Securities**

Following is a description of the valuation methodologies used for assets measured at fair value as of March 31, 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.

	As of March 31, 2018				
	Cost	Accrued Income	Unrealized Gains	Unrealized Losses	Fair Value
Level 2:					
Money market funds	\$26	\$5	\$ -	\$ -	\$31
Municipal securities	8,680,430	15,392	-	(16,843 )	8,678,979
Total Level 2:	8,680,456	15,397	-	(16,843 )	8,679,010
Total:	\$8,680,456	\$15,397	\$ -	\$ (16,843 )	\$8,679,010

	As of December 31, 2017				
	Cost	Accrued Income	Unrealized Gains	Unrealized Losses	Fair Value
Level 2:					
Money market funds	\$5,165	\$ 161	\$ -	\$ -	\$5,326
Municipal securities	5,005,000	1,281	-	-	5,006,281
Total Level 2:	5,010,165	1,442	-	-	5,011,607
Total:	\$5,010,165	\$ 1,442	\$ -	\$ -	\$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 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 unrealized loss of \$16,843 and unrealized gain of \$156 (net of effect of income tax expense of \$-) for the three months

ended March 31, 2018 and 2017.

Proceeds from the sale of marketable securities in the three months ended March 31, 2018 and 2017 were \$302,095 and \$1,095,218. Gross gains of \$- and \$1,051 resulted from these sales for the three months ended March 31, 2018 and 2017.

## AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

## Notes to Condensed Consolidated Financial Statements

**Note 5 - Inventories**

Inventories consists of the following categories:

	March 31, 2018	December 31, 2017 (restated)
Raw Materials	\$513,052	\$458,441
Sub-Assemblies	898,778	886,274
Finished Goods	774,725	815,505
Reserve for Obsolescence	(1,212,608)	(1,212,608)
	\$973,947	\$947,612

Obsolete inventory charged to cost of goods during the three months ended March 31, 2018 and 2017 totaled \$24,460 and a credit of \$32,333.

**Note 6 - Property, Plant and Equipment**

Property, plant and equipment consists of the following:

	<b>March 31, 2018</b>	<b>December 31, 2017</b>
Computer Equipment	\$114,771	\$114,771
Computer Software	40,681	40,681
Office Equipment	39,959	39,959
Furniture & Fixtures	38,356	38,356
Machinery & Equipment	1,153,960	1,138,134
Molds & Dies	890,571	868,570
Leasehold Improvements	222,593	222,593
	2,500,891	2,463,064
Less		



Accumulated Depreciation	2,241,626	2,227,951
	\$259,265	\$235,113

Depreciation expenses totaled \$13,675 and \$17,941 for the three months ended March 31, 2018 and 2017.

#### **Note 7 - Intangible Assets**

Intangible assets as of March 31, 2018 and December 31, 2017 and the movements for the periods then ended are as follows:

# AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

## Notes to Condensed Consolidated Financial Statements

	<b>Patents &amp; Trademarks</b>	<b>Distributor &amp; Customer Relationships</b>	<b>Totals</b>
<b><i>Cost or Deemed Cost</i></b>			
At December 31, 2017	\$ 2,626,996	\$ 1,270,639	\$ 3,897,635
Additions	-	-	-
Disposals	-	-	-
At March 31, 2018	\$ 2,626,996	\$ 1,270,639	\$ 3,897,635
<b><i>Accumulated Amortization</i></b>			
At December 31, 2017	\$ 1,496,329	\$ 1,270,639	\$ 2,766,968
Amortization Charge	42,777	-	42,777
Disposals	-	-	-
At March 31, 2018	\$ 1,539,106	\$ 1,270,639	\$ 2,809,745
<b><i>Net Book Value</i></b>			
At December 31, 2017	\$ 1,130,667	\$ -	\$ 1,130,667
At March 31, 2018	\$ 1,087,890	\$ -	\$ 1,087,890

Amortization expense totaled \$42,777 for the three months ended March 31, 2018 and 2017.

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

Period	Amount
2019	\$ 171,108
2020	149,298
2021	147,315
2022	147,315
2023	147,315

## Note 8 - Trade and Other Payables

Trade and other payables consists of the following:

	March 31, 2018	December 31, 2017 (restated)
Trade Payables	\$598,359	\$948,951
Accrued Expenses	702,424	736,515
Deferred Compensation	59,750	59,750
	\$1,360,533	\$1,745,216

# AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

## Notes to Condensed Consolidated Financial Statements

Trade and other payables – related party are as follows:

	March 31, 2018	<b>December 31, 2017</b>
Trade Payables	\$ 19,005	\$ 39,821
	\$ 19,005	\$ 39,821

As of March 31, 2018 the Company owed ChubeWorkx Guernsey Limited, previously a major shareholder, royalties of \$15,845 (Note 13) which was paid on April 23, 2018.

As of March 31, 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 \$2,490 as of March 31, 2018.

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

## Note 9 - Share-based Payments

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

On January 9, 2015, the Board of Directors of the Company approved, upon recommendation from the Compensation Committee of the Board, by unanimous written consent the Amended and Restated 2013 Incentive Stock and Award Plan (the “Amended Plan”), which increases the number of authorized shares of Common Stock subject to the Plan to 800,000 shares (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 830,000 shares. As of March 31, 2018, grants of restricted stock and options to purchase 255,000 shares of Common Stock have been issued, pursuant to the Amended Plan, and are unvested or unexercised and 7,292 shares of Common Stock remain available for grants under the Amended Plan.

On August 7, 2017, the Shareholders approved and the Company adopted the 2017 Equity Incentive Plan (the “Plan”) which will provide for the issuance of up to 1,350,000 shares. The purpose of the Plan is to provide additional incentive to those officers, employees, consultants and non-employee directors of the Company and its parents, subsidiaries and affiliates whose contributions are essential to the growth and success of the Company’s business. As of March 31, 2018, grants totaling 320,107 shares of restricted Common Stock have been issued pursuant to the Plan and 1,029,893 shares of Common Stock remain available for grants under the Plan.

## AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

## Notes to Condensed Consolidated Financial Statements

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

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

The Company did not issue any options or warrants under the above plan during the three months ended March 31, 2018.

The following table summarizes the option activities for the three months ended March 31, 2018:

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (years)</b>	<b>Aggregate Intrinsic Value</b>
<i>Balance at December 31, 2017</i>	255,000	\$ 4.25	2.02	\$ -
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
<b><i>Balance at March 31, 2018</i></b>	255,000	\$ 4.25	1.78	\$ -
<b><i>Exercisable as of March 31, 2018</i></b>	250,334	\$ 4.27	1.75	\$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$0.83 for our common shares on March 31, 2018.

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

A summary of the Company's non-vested shares as of March 31, 2018 and the changes during the three months then ended are as follows:

Non-Vested Shares	Shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2017	4,666	\$ 2.36
Granted	-	-
Vested	-	-
Forfeited	-	-
Non-vested at March 31, 2018	4,666	\$ 2.36

Unrecognized compensation cost related to non-vested employee stock options totaled \$4,219 as of March 31, 2018. The cost is to be recognized over a weighted average period of 0.38 years.

During the three months ended March 31, 2018 and 2017, the Company incurred stock option expenses totaling \$2,712 and \$5,036.

## AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

## Notes to Condensed Consolidated Financial Statements

The table below summarizes the warrant activity for the three months ended March 31, 2018:

	<b>Number of Warrants</b>	<b>Weighted Average Exercise Price</b>	<b>Average Remaining Contractual Term (years)</b>
<b><i>Balance at December 31, 2017</i></b>	49,490,571	\$ 0.22	4.95
Granted	-	-	-
Exercised	(30,492,070)	0.19	-
Forfeited	-	-	-
Canceled/Expired	-	-	-
<b><i>Balance at March 31, 2018</i></b>	18,998,501	\$ 0.28	4.68
<b><i>Exercisable as of March 31, 2018</i></b>	18,998,501	\$ 0.28	4.68

**Note 10 - 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 June 8, 2016, the Company issued 27,500 restricted common shares to an officer in connection with his employment agreement. These shares vest 1/3 immediately on the date of the grant and the remaining 2/3 vests equally on March 1, 2017 and March 1, 2018. The fair value of these shares was \$54,725 and was based on the share price on the date of the grant. \$3,469 and \$5,203 was recorded during the three months ended March 31, 2018 and



2017 as administrative expense on the Condensed Consolidated Statement of Operations and Comprehensive Loss.

On April 11, 2017, the Company issued 10,000 restricted shares to a consultant for services to be rendered during the year ending December 31, 2017. These shares vested on the date of the grant. The fair value of these shares was \$18,000 and was based on the share price on the date of the grant. During the year ended December 31, 2017, \$5,455 was recognized as stock based compensation expense. The remaining \$12,545 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 25,000 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 \$0.2070 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 three months ended March 31, 2018.

During the three months ended March 31, 2018, 1,755 shares of the Company's Series B Preferred Stock, no par value, converted into 11,700,002 shares of Common Stock.

During the three months ended March 31, 2018, warrant holders from the December 21, 2017 public offering executed 30,492,070 warrants with an exercise price of \$0.1875 per common share, raising net proceeds of \$5,717,325.

#### **Note 11 - Loss per share**

The calculation of basic and diluted loss per share at March 31, 2018 and 2017 was based on the loss attributable to common shareholders of \$1,859,991 and \$1,349,270. The basic and diluted weighted average number of common shares outstanding at March 31, 2018 and 2017 was 71,315,461 and 6,993,574.

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

Potential common shares consist of options, warrants and unvested restricted stock. Diluted net loss per common share was the same as basic net loss per common share for the three months ended March 31, 2018 and 2017 since the effect of options and warrants would be anti-dilutive due to the net loss attributable to the common shareholders. Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were as follows: incentive and award stock options – 255,000 and 259,000; unvested restricted shares of Common Stock – - and 9,166; warrants – 18,998,501 and 1,455,650 as of March 31, 2018 and 2017.

#### **Note 12 - Income Tax Expense**

There is no income tax benefit for the losses for the three months ended March 31, 2018 and 2017 since management has determined that the realization of the net deferred tax asset is not assured and has created a valuation allowance for

the entire amount of such benefits.

The Company's policy is to record interest and penalties associated with unrecognized tax benefits as additional income taxes in the statement of operations. As of January 1, 2018, the Company had no unrecognized tax benefits, or any tax related interest or penalties. There were no changes in the Company's unrecognized tax benefits during the three months ended March 31, 2018 related to unrecognized tax benefits. With few exceptions, the U.S. and state income tax returns filed for the tax years ended on December 31, 2014 and thereafter are subject to examination by the relevant taxing authorities.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

**Note 13 - 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 a number of commercialized products including BreathScan® Alcohol Detector and BreathScan OxiChek™; and a number of products in development.



AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

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 \$31,689 and \$32,279 for the three months ended March 31, 2018 and 2017 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 March 31, 2018 and 2017, the Company recognized \$- for the BreathScan Breath Alcohol products acquired from the Settlement.

The Company began purchasing manufacturing molds, plastic components and the assembled BreathScan Lync™ device through Hainan and its related party during the year ended December 31, 2016 (Note 8). The Company purchased a total of \$23,805 and \$16,744 during the three months ended March 31, 2018 and 2017. As of March 31, 2018, the Company owed the Hainan and its related party \$3,160 which is included in trade and other payables – related party on the Condensed Consolidated Balance Sheet.

During the three months ended March 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 \$48,589 during the three months ended March 31, 2018 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.

Product revenue – related party for the three months ended March 31, 2018 and 2017 were \$- and \$24,063. The revenue was the result of sales to Hainan and its related party.

## AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

## Notes to Condensed Consolidated Financial Statements

**Note 14 – 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 March 31, 2018 and 2017 totaled \$42,218 and \$40,487, 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 \$6,495 and \$- for the three months ended March 31, 2018 and 2017. The Company posted a security deposit of \$4,330 which is included in other assets on the Condensed Consolidated Balance Sheet.

The Company entered into a 29-month lease for warehouse space located in Pitman, New Jersey (“Pitman Lease”) with annual rents of \$39,650. The lease took effect on August 1, 2017 and runs through December 31, 2019. Rent expenses for the Pitman Lease totaled \$9,913 and \$- for the three months ended March 31, 2018 and 2017. A security deposit of \$4,950 is included in other assets on the Condensed Consolidated Balance Sheet.

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

The schedule of lease commitments is as follows:

	Thorofare Lease	Ramsey Lease	Pitman Lease	Equipment Lease	Total
Next 12 Months	\$ 132,000	\$25,980	\$39,650	\$ 6,156	\$203,786
Next 13-24 Months	99,000	4,330	29,736	3,591	136,657



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

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

**Note 15 - Major Customers**

For the three months ended March 31, 2018, one customer generated 10% or more of the Company's revenue. Sales to this customer accounted for 79% of the Company's revenue. As of March 31, 2018, the amount due from this customer was \$175,881. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

For the three months ended March 31, 2017, two customers generated 10% or more of the Company's revenue. Sales to these customers accounted for 67% of the Company's revenue.

**Note 16 - Major Suppliers**

For the three months ended March 31, 2018, one supplier accounted for 10% or more of the Company's purchases. As of March 31, 2018, the amount due to the supplier was \$9,302.

For the three months ended March 31, 2017, two suppliers each accounted for more than 10% of the Company's purchases. In aggregate, these suppliers accounted for 23% of the Company's total purchases.

**Note 17 – 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.



## AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

### Notes to Condensed Consolidated Financial Statements

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

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

Pulse subsequently filed an Amended Complaint, in which Pulse seeks not less than \$500,000 in damages and, among other items, an injunction prohibiting the Company from manufacture, use and sale of the OxiChek product. The Company answered the Amended Complaint on May 11, 2017. Discovery concluded on January 22, 2018.

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. 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.

#### *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. Ultimately, there will be one class action complaint upon the appointment of a lead plaintiff and lead Counsel.

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 March 31, 2018. All legal fees were expensed as and when incurred.

## **Note 18 – Segment Information**

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

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

The total revenue by different product lines was as follows:

<b>Product Line</b>	<b>Three months ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
MicroParticle Catalyzed Biosensor (“MPC”)	\$ 18,950	\$ 85,659
Particle ImmunoFiltration Assay (“PIFA”)	259,983	560,921
Rapid Enzymatic Assay (“REA”)	9,900	-
Other	13,642	20,670
Product Revenue Total	\$ 302,475	\$ 667,250
License Fees	-	-
Total Revenue	\$ 302,475	\$ 667,250

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements

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

<b>Geographic Region</b>	<b>Three months ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
United States	\$294,733	\$617,691
People's Republic of China	-	21,030
Rest of World	7,742	28,529
Total Revenue	\$302,475	\$667,250

The Company had long-lived assets totaling \$74,339 and \$59,830 located in the People's Republic of China and \$1,272,816 and \$1,305,950 located in the United States as of March 31, 2018 and December 31, 2017, respectively.

**Note 19 - Subsequent Events**

During the period April 1, 2018 through July 6, 2018, the Company received \$1,437,875 from the exercise of 7,668,667 warrants. See also Note 3.

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

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

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

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

### Overview

Akers Bio develops, manufactures, and supplies rapid, point-of-care screening and testing products designed to bring health-related information directly to the patient or clinician in a 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 and pipeline products focus on delivering diagnostic assistance in a wide variety of healthcare fields/specialties, including diagnostic rapid manual point-of-care tests for the detection of allergic reactions to Heparin, metabolism/nutrition 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 disease states and medical conditions can be performed on single-patient specimens without sacrificing accuracy.

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

cost pressures/efficiency of healthcare delivery;

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

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

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.

### **Key Events, Management's Plans and Basis of Presentation**

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 current 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.

The Company was not able to timely file this Quarterly Report on Form 10-Q due to delays in evaluating certain accounting and reporting matters. The Company's evaluation resulted in its filing a notification on June 18, 2018 on Form 8-K providing notice that investors should no longer rely upon the financial statements included within the Company's Quarterly Reports as of and for the periods ended June 30, 2017 and September 30, 2017, as well as the Company's Annual Report on Form 10-K for the year ended December 31, 2017. The Company has since prepared amended financial statements for such periods and the respective amended Quarterly and Annual financial reports have been filed contemporaneously with the filing of this Quarterly Report on Form 10-Q for the three months ended March 31, 2018.

By way of a letter dated May 22, 2018, the Listing Qualifications Department of the 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. 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. Upon acceptance of the Company's compliance plan, NASDAQ is permitted to grant an extension of up to 180 calendar days from the Quarterly Report's filing due date, or until November 19, 2018, for the Company to regain compliance with NASDAQ Listing Rule 5250(c)(1). The Company believes that its filing of this Quarterly Report and the Amended Quarterly and Annual Reports as discussed above have cured the potential default as to the Company meeting the requirements to continue its listing in good standing under NASDAQ.

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 400,000 to 800,000 shares and the second amendment, as approved by the Board on October 5, 2016, increased the number of shares under the 2013 Plan from 800,000 to 830,000 shares.

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 400,000 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.

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. Ultimately, there will be one class action complaint upon the appointment of a lead plaintiff and lead Counsel.

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.

As of March 31, 2018, the Company has in large part relied on equity financing to fund its operations, raising \$29,279,506, 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 products, especially those that utilize MPC Biosensor, PIFA and seraSTAT technologies;

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

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

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

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

some of Akers' distribution partnerships (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 the commercialization and marketing activities for its existing product platforms and product development (research, clinical trials, regulatory tasks) costs;

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 March 31, 2018, Akers had cash of \$647,267, working capital of \$9,784,223, shareholders' equity of \$11,417,245 and an accumulated deficit of \$106,705,838. The Company believes that its current working capital position will be sufficient to meet its estimated cash needs for at least the next 12 months. The Company closely monitors its cash balances, cash needs and expense levels. The Company is not yet able to determine the impact of the key events during June and July of 2018 as discussed above may have on the Company's ability to raise capital, nor the impact that these matters might have on its business operations.

## **Summary of Statements of Operations for the Three Months Ended March 31, 2018 and 2017**

### **Revenue**

Akers' revenue for the three months ended March 31, 2018 totaled \$302,475, a 55% decrease from the same period in 2017. The table below summarizes revenue by product line for the three months ended March 31, 2018 and 2017 as

well as the percentage of change year-over-year:

Product Lines	3 Months Ended March 31, 2018	3 Months Ended March 31, 2017	Percent Change	
Particle ImmunoFiltration Assay (“PIFA”)	\$259,983	\$560,921	(54)	)%
MicroParticle Catalyzed Biosensor (“MPC”)	18,950	85,659	(78)	)%
Rapid Enzymatic Assay (“REA”)	9,900	-	-	%
Other	13,642	20,670	(34)	)%
Product Revenue Total	\$302,475	\$667,250	(55)	)%
License and Service Fees	-	-	-	%
Total Revenue	\$302,475	\$667,250	(55)	)%

Revenue from the Company’s PIFA Heparin/PF4 Rapid Assay products decreased 54% to \$259,983 (2017: \$560,921) during the three months ended March 31, 2018, over the same period of 2017. The Company is taking steps to improve its market presence including the use of specialized Independent Sales Representatives (“ISRs”) 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.

During the three months ended March 31, 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, resulting 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 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. The Company’s relationship-building initiative with our partners has delivered a measurable increase in product trials and adoptions. Domestic sales for the three months ended March 31, 2018, of our distributors, Cardinal Health and Thermo Fisher Scientific, accounted for \$209,471 of the total PIFA Heparin/PF4 Rapid Assay sales as compared to \$454,656 for the same period of 2017.

The Company’s MPC product sales decreased by 78% to \$18,950 (2017: \$85,659) during the three months ended March 31, 2018. Sales of the Company’s Metron and BreathScan Alcohol products accounted for the revenue.

The Company's REA products generated \$9,900 (2017: \$-) during the three months ended March 31, 2018. The Company's re-introduced Tri-Cholesterol product is produced with this technology.

Other operating revenue decreased to \$13,642 (2017: \$20,670) during the three months ended March 31, 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.

The table below summarizes our revenue by geographic region for the three months ended March 31, 2018 and 2017 as well as the percentage of change year-over-year:

<b>Geographic Region</b>	<b>3 months ended March 31, 2018</b>	<b>3 months ended March 31, 2017</b>	<b>Percent Change</b>
United States	\$294,733	\$617,691	(52 )%
People's Republic of China	-	21,030	(100 )%
Rest of World	7,742	28,529	(73 )%
Total Revenue	\$302,475	\$667,250	(55 )%

Domestic sales represent the most significant portion of the Company's revenue, contributing 97% (2016: 93%). The primary sales and marketing efforts are concentrated on expanding the Company's domestic market share in the rapid clinical diagnostic and health and wellness segments. The introduction of the Tri-Cholesterol test has allowed the Company to re-enter the retail market.



## **Gross Margin**

The Company's gross margin declined to 2% (2017: 61%) for the three months ended March 31, 2018. Increases in direct personnel costs (\$96,824 (2017: \$65,353)) and the transfer of raw materials and sub-assemblies from/to inventory for production (\$13,419 (2017: \$133,111)) were offset by a decrease in services provided by sub-contractors for material preparation, assembly and packaging to \$600 (2017: \$113,761).

During the three months ended March 31, 2018, low yields during antigen extraction processes and the addition of a production laboratory technician to the direct manufacturing staff in anticipation of increased demand for the PIFA and REA platform products significantly affected direct costs of production.

Cost of production also includes significant components that are fixed expenses which effectively reduces the gross margin when revenue declines. These expenses include the cost of personnel, manufacturing and warehousing space, depreciation of equipment and other similar items.

Cost of sales for the three months ended March 31, 2018 totaled \$297,500 (2017: \$258,721). Direct cost of sales increased to 44% of product revenue while other cost of sales increased to 54% for the three months ended March 31, 2018 as compared to 16% and 23% respectively for the same period in 2017.

Direct cost of sales for the three-month period ended March 31, 2018 were \$132,653 (2017: \$106,129). Other cost of sales for the three months ended March 31, 2018 were \$164,847 (2017: \$152,593).

## **General and Administrative Expenses**

General and administrative expenses for the three months ended March 31, 2018, totaled \$915,533, which was a 16% increase as compared to \$790,529 for the three months ended March 31, 2017.

The table below summarizes our general and administrative expenses for the three months ended March 31, 2018 and 2017 as well as the percentage of change year-over-year:

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

Description	3 Months	3 Months	Percent	
	Ended	Ended		
	March	March	Change	
	31, 2018	31, 2017		
Personnel Costs	\$306,936	\$334,527	(8	)%
Professional Service Costs	303,937	191,753	59	%
Stock Market & Investor Relations Costs	114,166	82,386	39	%
Other General and Administrative Costs	190,494	181,863	5	%
Total General and Administrative Expense	\$915,533	\$790,529	16	%

Personnel expenses decreased by 8% for the three months ended March 31, 2018 as compared to the same period of 2017. A reduction in bonuses included in salaries and wages to \$243,941 (2017: \$277,456) was offset by increases in auto allowance and employee benefit expenses of \$19,938 (2017: \$14,286).

Professional service costs increased 59% for the three months ended March 31, 2018 as compared to the same period of 2017. A significant increase in legal fees (\$278,277 (2017: \$138,688)) were offset partially by a decrease in engineering fees (\$6,475 (2017: \$30,090)) resulting in the change. The Company replaced its SEC attorneys in February 2018 and continues to incur legal expenses related to ongoing litigation (Part II, Item 1).

Investor relations totaled \$52,573 (2017: \$39,354) and transfer agent fees of \$21,402 (2017: \$7,369) were the major contributors to the 39% increase in stock market and investor relations costs for the three months ended March 31, 2018.

Other general and administrative expenses increased by 5%. This increase is the result of increases in building expenses of \$74,909 (2017: \$45,253) for the addition of the Ramsey, New Jersey satellite office and licenses, permits and fees of \$16,374 (2017: \$4,869).

### Sales and Marketing Expenses

Sales and marketing expenses for the three months ended March 31, 2018 totaled \$500,152 which was a 15% decrease compared to \$588,934 for the three months ended March 31, 2017.

The table below summarizes our sales and marketing expenses for the three months ended March 31, 2018 and 2017 as well as the percentage of change year-over-year:

Description	3 Months Ended March 31, 2018	3 Months Ended March 31, 2017	Percent Change
Personnel Costs	\$321,708	\$335,832	(4 )%
Professional Service Costs	71,559	65,046	10 %
Royalties and Outside Commission Costs	27,855	45,133	(38 )%
Other Sales and Marketing Costs	79,030	142,923	(45 )%
Total Sales and Marketing Expenses	\$500,152	\$588,934	(15 )%

The US market has been divided into two regional zones, each with a business director that is responsible for recruiting and supporting ISRs and independent manufacturing representatives (“IMRs”) 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 March 31, 2017 to 5 as of March 31, 2018.

Personnel costs decreased in the three months ended March 31, 2018 as compared to the same period of 2017. A reduction in compensation, bonuses and commissions to \$257,352 (2017: \$293,269) primarily due to changes in the bonus and compensation plan was offset by increases in auto allowance and employee benefit expenses of \$31,648

(2017: \$14,208).

The Company renegotiated or eliminated several consulting arrangements targeted at improving market penetration or identifying marketing or distribution partners during the first half of 2017. The result was a significant reduction of in professional services for the three months ended March 31, 2017. The Company continually monitors the effectiveness of the remaining agreements and a few have been expanded to provide additional services resulting in an increase in professional service costs during the three months ended March 31, 2018.

The legal settlement with ChubeWorkx Guernsey, Ltd (“ChubeWorkx”), signed on August 11, 2016, requires the Company to pay a 5% royalty on adjusted gross sales to ChubeWorkx on a quarterly basis. During the three months ended March 31, 2018, this royalty totaled \$31,689 (2017: \$32,279). The Company received a credit for an overpayment of commissions to an IMR for \$14,208 which contributed to the decline in royalty and outside commission costs during the three months ended March 31, 2018.

The Company recognized significant reductions in advertising expenses (\$12,167 (2017: \$54,700)) and trade show expenses (\$885 (2017: \$29,523)) plus smaller reductions in several other operating categories that resulted in a 45% reduction in other sales and marketing costs.

## Research and Development

Research and development expenses for the three months ended March 31, 2018 totaled \$439,970, which was a 26% increase as compared to \$348,442 for the three months ended March 31, 2017.

The table below summarizes our research and development expenses for the three months ended March 31, 2018 and 2017 as well as the percentage of change year-over-year:

Description	3 Months Ended March 31, 2018	3 Months Ended March 31, 2017	Percent Change	
Personnel Costs	\$299,212	\$284,949	5	%
Clinical Trial Costs	905	150	503	%
Professional Service Costs	89,276	29,124	207	%
Other Research and Development Costs	50,577	34,219	48	%
Total Research and Development Expenses	\$439,970	\$348,442	26	%

Personnel costs increased 5% during the three months ended March 31, 2018 as compared to the same period of 2017. The Company expanded the research and development staff by one position to assist with the development of the health and wellness products.

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 \$72,496 (2017: \$17,705), fees for the consulting medical director totaled \$9,000 (2017: \$6,000) and other regulatory consulting fees totaled \$5,280 (2017: \$-) in the three months ended March 31, 2018.

Increases in laboratory supplies (\$15,642 (2017: \$8,059)) and the utilization of internal resources (\$16,037 (2017: \$1,887)) resulted in an increase of 48% for other research and development costs during the three months ended March 31, 2018.

The following table illustrates research and development costs by project for the three months ended March 31, 2018 and 2017, respectively:

Project	2018	2017
Breath Alcohol	\$-	\$4,669
Chlamydia Trachomatis	32,690	51,709
Heparin/PF4	46,593	11,499
Ketone	-	1,707
KetoChek™ / OxiChek™	342,605	89,724
Metron	9,723	-
Other Projects	-	59,688
SeraSTAT	-	5,610
Tri-Cholesterol	8,359	123,244
VIVO	-	592
Total R&D Expenses:	\$439,970	\$348,442

### Other Income and Expense

Other income, net of expense for the three months ended March 31, 2018 totaled \$33,466, which was a 160% increase as compared to \$12,883 for the three months ended March 31, 2017.

The table below summarizes our other income and expenses for the three months ended March 31, 2018 and 2017 as well as the percentage of change year-over-year:

Description	3	3	Percent	
	Months	Months		
	Ended	Ended	Change	
	March	March		
	31,	31,		
	2018	2017		
Currency Translation Gain/(Loss)	\$(2,875 )	\$10,346	(128 )	%
Realized Gains on Investments	-	1,051	(100 )	%
Interest and Dividends	36,341	1,486	2,346	%
Total Other Income, Net of Expenses	\$33,466	\$12,883	160	%

Losses associated with foreign currency transactions totaled \$2,875 during the three months ended March 31, 2018 as compared to a gain of \$10,346 the same period of 2017, primarily a result of the increased strength of the British Pound as compared to the US Dollar.

Realized gains, interest and dividend income increased to \$36,341 (2017: \$2,537). 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 three months ended March 31, 2018 resulting in the increase in investment income.

## Income Taxes

As of March 31, 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 three months ended March 31, 2018 and 2017, the Company generated a net loss attributable to shareholders of \$1,859,991 and \$1,349,270, respectively. As of March 31, 2018 and December 31, 2017, the Company has an accumulated deficit of \$106,705,838 and \$104,845,847 and had cash and marketable securities totaling \$9,326,277 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 OxiChek, BreathScan Lync Readers, METRON, BreathScan Alcohol detection devices and the Tri-Cholesterol assay and development activities for PIFA PLUSS Chlamydia rapid assay and BreathScan KetoChek products.

We expect to continue to incur losses from operations for the near-term and these losses could be significant as we incur product development, clinical and regulatory activities, contract consulting and other product development and commercialization related expenses. We 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 expect that our primary expenditures will be to continue development of BreathScan KetoChek via the enrollment of patients in clinical trials to support performance claims and generate studies in peer-reviewed journals to support product marketing. We will also continue to support commercialization and marketing activities of in-line products PIFA Heparin/PF4 rapid assays, PIFA PLUSS® PF4, breath alcohol detectors, METRON BreathScan OxiChek and BreathScan Lync Readers globally. Based upon our experience, clinical trial and related regulatory expenses can be significant costs. Steps to achieve commercialization of emerging products will be an ongoing and evolving process with expected improvements and possible subsequent generations being evaluated for commercialized and emerging tests. Should we be unable to achieve FDA clearance for products that require such regulatory “approval”, develop performance characteristics for rapid tests that satisfy market needs, or generate sufficient revenue from commercialized products, we would need to rely on other business or product opportunities to generate revenue and costs that we have incurred for the patents may be deemed impaired.

Capital expenditures for the three months ended March 31, 2018 were \$37,827 (2017: \$16,774). Capital expenditures, primarily for production, laboratory and facility improvement costs for the year ending December 31, 2018 are expected to be approximately \$250,000. 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.

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

We lease our manufacturing facility which also contains our administrative offices. Our current lease was executed January 1, 2013 and is effective through December 31, 2019. The Company has leased this property from the current owner since 1997. The Company executed a lease for a satellite office in Ramsey, New Jersey on June 23, 2017 which 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.

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

The table below summarizes our cash flows for the three months ended March 31, 2018 and 2017 as well as the percentage of change year-over-year:

Description	3 Months Ended March 31, 2018	3 Months Ended March 31, 2017	Percent Change	
Cash at beginning of period	\$438,432	\$ 72,700	503	%
Loss from operations	(1,859,991 )	(1,349,270 )	38	%
Adjustments				
Non-Cash Activities	90,858	79,157	15	%
Cash Used in Operating Activities				
Cash Consumed by Operating Activities	(591,939 )	(439,121 )	35	%
Cash Contributed by Operating Activities	560,700	147,571	280	%
Net Cash Consumed by Operating Activities	\$(1,800,372)	\$(1,561,663)	15	%
Cash Flows from Investing Activities				
Cash Consumed by Investing Activities	(4,010,213 )	(1,218,984 )	229	%
Cash Contributed by Investing Activities	302,095	1,095,218	(72 )	)%
Cash Flows from Financing Activities				
Cash Contributed by Financing Activities	5,717,325	3,697,811	55	%
Cash at end of period	\$647,267	\$ 2,085,082	(69 )	)%

Our net cash consumed by operating activities totaled \$1,800,372 during the three months ended March 31, 2018. Cash was consumed by the loss of \$1,859,991 plus non-cash adjustments of \$56,452 for depreciation and amortization of non-current assets, \$3,469 for the amortization of deferred compensation, \$24,460 for the reserve and write-off for obsolete inventory, \$7,887 for share based compensation to employees and \$12,545 for share based compensation to non-employees less \$13,955 for accrued interest and dividends on marketable securities. For the three months ended March 31, 2018, decreases in trade receivables of \$547,773 and prepaid expenses – related party of \$12,927 provided cash, primarily related to routine changes in operating activities. A net increase in deposits and other receivables of \$12,905, deposits and other receivables – related party of \$33,243, inventory of \$50,795, prepaid expenses of \$89,497 and decreases in trade and other payables of \$384,683 and trade and other payables – related party of \$20,816 consumed cash from operating activities.

Our net cash consumed by operating activities totaled \$1,561,663 during the three months ended March 31, 2017. Cash was consumed by the loss of \$1,349,270 plus non-cash adjustments of \$60,718 for depreciation and amortization of non-current assets, \$5,203 for the fair value of restricted Common Stock issued for services and \$5,036 for share based compensation to employees less \$326 for accrued interest and dividends on marketable securities and \$32,333 for a reduction in the reserve for obsolete inventory. For the three months ended March 31, 2017, decreases in trade receivables of \$43,351, trade receivables – related parties of \$7,458, deposits and other receivables of \$10,692, prepaid expenses of \$69,930, and prepaid expenses – related party of \$16,140 provided cash, primarily related to routine changes in operating activities. A net increase in inventories of \$100,878 and decreases in trade and other payables of \$200,059 and trade and other payables – related party of \$138,184 consumed cash from operating activities.

## Investing and Financing Activities

The table below summarizes our cash flows from investing and financing activities for the three months ended March 31, 2018 and 2017 as well as the percentage of change year-over-year:

Description	3 months ended March 31, 2018	3 months ended March 31, 2017	Percent Change	
Cash Flows from Investing Activities				
Cash Consumed by Investing Activities	(4,010,213)	(1,218,984)	229	%
Cash Contributed by Investing Activities	302,095	1,095,218	(72)	)%
Cash Flows from Financing Activities				
Cash Contributed by Financing Activities	5,717,325	3,697,811	55	%

The Company's net cash provided by investing and financing activities totaled \$6,019,420 (2017: \$4,793,028) during the three months ended March 31, 2018. Cash of \$4,010,213 (2017: \$1,218,984) was consumed by capital expenditures and the purchase of marketable securities. Proceeds from the sale of marketable securities contributed

cash of \$302,095 (2017: \$1,095,218) 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 \$5,717,325 (2017: \$3,697,811) for the three months ended March 31, 2018.

## **Critical Accounting Policies**

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

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

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

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

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

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

#### **Fair Value Measurement – Marketable Securities**

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

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

Level 2 Inputs to the valuation methodology include:

quoted prices for similar assets or liabilities in active markets;

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

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

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

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

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

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

## Intangible Assets

Intangible assets primarily represent legal and filing costs associated with obtaining patents on the Company's new discoveries or acquiring patents for diagnostic technologies or tests that will enhance the Company's product portfolio. The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person's breath and blood. Propriety protection for the Company's products, technology and process is important to its competitive position. Patents are in the national phase of prosecution in many PCT participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the U.S., European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

Propriety protection for the Company's products, technology and process is important to its competitive position. As of March 31, 2018, the Company has ten patents from the United States Patent Office in effect (9,383,368; 7,896,167; 8,097,171; 8,003,061; 8,425,859; 8,871,521; 8,808,639; D691,056; D691,057 and D691,058). Other patents are in effect in Australia through the Design Registry (348,310; 348,311 and 348,312), European Union Patents 1793906, 2684025, 002216895-0001; 002216895-0002 and 002216895-0003), in Hong Kong (HK11004006) and in Japan (1,515,170; 4,885,134; 4,931,821 5,775,790, and 6023096). Patents are in the national phase of prosecution in many Patent Cooperation Treaty participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the US, European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

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

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

## Long-Lived Assets

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

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

## **Investments**

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

- a) Representation on the Board of Directors



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

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

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

### **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 \$87,510 and \$- as of March 31, 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 implemented a standard dealer cost model during the year ended December 31, 2016 which includes a provision for rebates to the distributors under limited circumstances. The Company established an accrual of \$57,725 and \$126,471, which is a reduction of revenue as of March 31, 2018 and December 31, 2017. Accounts receivable will be reduced when the rebates are applied by the customer. The Company recognized \$37,544 and \$102,824 during the three months ended March 31, 2018 and 2017 for rebates, which is included as a reduction of product revenue in the Condensed Consolidated Statement of Operations and Comprehensive Loss.

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

When the Company enters into arrangements that contain more than one deliverable, the Company allocates revenue to the separate elements under the arrangement based on their relative selling prices in accordance with FASB ASC 605-25. As of March 31, 2018 and December 31, 2017, the Company had deferred revenue of \$49,655 and \$- related to transactions with multiple deliverables.

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 interim reporting periods within annual reporting periods beginning after December 15, 2019. Early application is permitted as of annual reporting periods beginning after December 15, 2016 including interim reporting periods within that reporting period. The Company is currently evaluating the effect of the amendments but it does not anticipate a material impact of its financial statements. The Company expects to use the modified retrospective adoption method and will adopt this Update as of January 1, 2019.

## **Stock-based Compensation**

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

## **Recently Issued and Adopted Accounting Pronouncements**

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

## **Quantitative and Qualitative Disclosure About Market Risk**

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

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

## **Interest Rates**

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

## **Off-Balance Sheet Arrangements**

We have no significant known off balance sheet arrangements.

## **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

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

## **Item 4. Controls and Procedures.**

### ***(a) Evaluation of Disclosure Controls and Procedures***

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

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. Furthermore, on account of the time and resources required to assess these accounting matters, the Company was not able to timely file this Quarterly Report on Form 10-Q.

As of March 31, 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) hiring and/or engagement of additional qualified personnel, (ii) the implementation of new 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***

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

## **PART II - OTHER INFORMATION**

### **Item 1. Legal Proceedings**

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

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

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

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

Pulse subsequently filed an Amended Complaint, in which Pulse seeks not less than \$500,000 in damages and, among other items, an injunction prohibiting the Company from manufacture, use and sale of the OxiChek product. The Company answered the Amended Complaint on May 11, 2017. Discovery concluded on January 22, 2018.

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. 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.

*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. Ultimately, there will be one class action complaint upon the appointment of a lead plaintiff and lead Counsel.

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 March 31, 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 our Annual Report on Form 10-K/A, Amendment No. 1, filed with the SEC on July 13, 2018, please see additional risk factors provided below.

*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.

Moreover, by way of a letter dated May 22, 2018, the Listing Qualifications Department of the 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. NASDAQ had 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. Upon acceptance of the Company's compliance plan, NASDAQ is permitted to grant an extension of up to 180 calendar days from the Quarterly Report's filing due date, or until November 19, 2018, for the Company to regain compliance with NASDAQ Listing Rule 5250(c)(1). The Company believes that its filing of this Quarterly Report and the Amended Quarterly and Annual Reports as discussed above have cured the potential default as to the Company meeting the requirements to continue its listing in good standing under NASDAQ.

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 400,000 to 800,000 shares and the second amendment, as approved by the Board on October 5, 2016, increased the number of shares under the 2013 Plan from 800,000 to 830,000 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 400,000 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 (i) does not believe that the filing of this Quarterly Report and the Amended Quarterly and Annual Reports as discussed above have cured the potential default as to the Company meeting the requirements to continue its listing in good standing under NASDAQ, or (ii) 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. We are filing this Form 10-Q, which was delayed due to the restatement, concurrently with our aforementioned amended filings on Form 10-Q and Form 10-K.

Accordingly, this Form 10-Q includes to: (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 Relevant Periods, 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 three months ended March 31, 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, resulting 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.

***Negotiations are underway with multiple customers for the Company’s products and are anticipated to be completed in the near term, but a significant delay will impact revenue projections.***

In May 2018, after extensive review both internally and with the FDA, we withdrew our initial 510(k) application for the PIFA Chlamydia rapid assay. We are currently evaluating the feasibility and marketability of this product in order to determine when and if the 510(k) application will be resubmitted.

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

The Company's Board of Directors authorized the issuance of 25,000 shares of Common Stock to a key employee on January 16, 2018 under the Plan.

There were no other unregistered sales of the Company's equity securities during the quarter ended March 31, 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.**

In this section, Akers is providing additional information to provide updates regarding recent key events in its business.

We have updated our product pipeline to reflect products marketed and/or within our pipeline as follows:

<b>Product</b>	<b>Platform</b>	<b>Marketed/Pipeline</b>	<b>FDA Clearance Required Prescription</b>	<b>FDA Clearance Status Obtained/Needed</b>	<b>Description</b>
----------------	-----------------	--------------------------	--	---	--------------------



Use/OTC					
BreathScan <sup>TM</sup>	MPC	Marketed	OTC	Obtained	Disposable breath alcohol detector
BreathScan <sup>®</sup> PRO	MPC	Marketed	OTC	Obtained	Quantitative breath alcohol detection system
METRON <sup>®</sup>	MPC	Marketed	Health and wellness	n/a	Disposable breath ketone device to monitor ketosis
BreathScan Lync	MPC	Marketed	Health and wellness	n/a	Non-invasive, quantitative measurement of biological markers for health and wellness
PIFA <sup>®</sup> Heparin/PF4 & PIFA PLUSS <sup>®</sup> PF4	PIFA	Marketed	Prescription Use	Obtained	Rapid tests for Heparin/PF4 antibodies to detect an allergy to the widely used blood thinner, Heparin
PIFA PLUSS <sup>®</sup> Chlamydia	PIFA	Pipeline	Prescription Use	Required/withdrawn on May 29, 2018 *See explanation below.	Rapid tests for the most prevalent sexually transmitted disease
seraSTAT <sup>®</sup>	seraSTAT	Marketed	Prescription Use	Obtained	Rapid Blood Cell Separator, marketed under the brand name seraSTAT <sup>®</sup> , further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically.
Tri-Cholesterol "Check <sup>®</sup> "	REA	Marketed	OTC	Obtained	Rapid test for Total and high density lipoprotein cholesterol and estimates low density lipo protein
BreathScan OxiChek	MPC	Marketed	Health and wellness	n/a	Breath test for oxidative stress using the Lync reader and digital app
BreathScan KetoChek	MPC	Pipeline	Health and wellness	n/a	Breath test for ketosis using the Lync reader and digital app

The Company follows a disciplined and rigorous process to determine market needs and the commercial viability of potential new products within its development pipeline. In doing so, the Company has targeted products that are aligned with our served markets and core capabilities, to further support our quest of enhancing business profitability and shareholder value.

All of the Company's existing development projects and platforms are being subjected to this process which involves the re-evaluation of the scientific feasibility and potential marketability of the products and platforms. The new business development process ruled out the commercial viability of the following products: Breath Diabetic Ketoacidosis, Breath PulmoHealth "Check" products, and breath cardiac marker test (Troponin).

In May 2018, after extensive review both internally and with the FDA, we withdrew our initial 510(k) application for the PIFA Chlamydia rapid assay. We are currently evaluating the feasibility and marketability of this product in order to determine when and if the 510(k) application will be resubmitted.

Regulatory requirements vary across the globe. Our authorized distributors are tasked to meet local and regional regulatory requirements.

#### *Rapid Blood Cell Separation Technology*

In addition to the Company's testing platforms, Akers' patented Rapid Blood Cell Separation ("Separator") Technology, marketed under the brand name seraSTAT<sup>®</sup>, further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically. Conventional methods of blood cell separation are labor-intensive and time-consuming, typically involving blood collection and laboratory personnel, as well as electrically-powered centrifuges and other specialized equipment. We wanted to clarify that the separator device requires a small-volume of venous whole blood sample.

#### *Manufacturing and Suppliers*

We are a vertically integrated manufacturer, producing substantially all of our devices in-house. The vast majority of our products start out as high quality, medical grade polymers and exit our facilities as fully manufactured and packaged medical devices. As a result, we have a short supply line between our raw materials and finished goods which gives us greater control over our product quality. The downside of our in-house manufacturing is the requirements for facilities, power, and equipment. This approach also requires mid-to-long-term planning and the

ability to predict future needs. Many of our processes are unique to us, but the Company's flexible manufacturing capabilities and unused current capacity generally translate into relatively short production timelines. As demand for our products increase, additional capacities may be required to advance our evolving needs.

We use a diverse and broad range of raw materials in the manufacturing of our products. We purchase all of our raw materials and select items such as packaging from external suppliers. In addition, we purchase some supplies from single sources for reasons of proprietary know-how, quality assurance, sole source availability, or due to regulatory qualification requirements. U.S. medical device manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products are known as current good manufacturing practices ("cGMP's"). cGMP requirements for devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. To date, we have not experienced any significant difficulty locating and obtaining the materials necessary to fulfill our production requirements.

During the three months ended March 31, 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, resulting 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 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 following is an update of our distribution strategy*

We distribute our products through direct and indirect channels of distribution. We have well-developed indirect distribution channels in the U.S. with, among others, Cardinal Health, Thermo Fisher Healthcare, a Division of Fisher Scientific Company L.L.C. and Diagnostica Stago, SA (“Stago”) for the Company’s PIFA Heparin/PF4 assays. These relationships provide us with access to most U.S. hospitals.

Our dedicated sales force works in tandem with independent and distributor sales representatives to uncover opportunities in the clinical laboratory marketplace. The Company facilitates direct sales for hospitals that prefer to purchase direct from the manufacturer.

Since 2012, the Company has had a distribution relationship with Novotek Pharmaceuticals, Inc., a division of Yifan Pharmaceuticals (“Novotek”), a Beijing-based pharmaceutical and *in vitro* diagnostic business development corporation. Through a multi-year distribution agreement, NovoTek has exclusive sales and marketing rights to distribute Akers’ PIFA products in Mainland China and Poland. Prior to being able to distribute our products in these markets, NovoTek must first obtain product reimbursement approval from each of the Provincial (regional) jurisdictions. Through June 2018, NovoTek has not been able to obtain these approvals in any of these jurisdictions. We do not anticipate additional PIFA revenue from this region until these approvals are received.

With respect to the Company’s breath alcohol franchise, historically Akers focused its commercial attention within the on-the-job safety/human resources sector. Access was and currently is largely achieved through designated BreathScan<sup>®</sup> distributors and limited arrangements in which the Company serves in an OEM capacity.

In select European countries and Australia, we have distribution relationships with specialized sales and marketing organizations for some of our products. We do not have a strong presence in many emerging markets, but are seeking to enter into agreements to enable us to enter other international markets in the current fiscal year.

#### *Other Emerging MPC Platform Products*

The Company’s MPC Biosensor technology is being applied to the development of products that serve the nutraceutical, fitness, and weight loss marketplaces. As a category, these disposable screening tests are exempt from FDA 510(k) premarket clearances. Biomarkers related to various metabolic processes can be measured in breath condensate. As a result, Akers has used its proprietary, easy-to-use platform to design disposable breath devices that

measure ketone (acid) production associated with fat-burning (METRON<sup>®</sup> and KetoChek) and oxidative stress levels that relate to cellular damage and the development of many preventable diseases (OxiChek). The Company believes that personalized health and wellness – and eventually personalized medicine – will become an increasingly significant market. The Company is positioning its tests for fitness, weight loss and oxidative stress for this market by designing a more consumer-focused reagent device, and linking this device to an application for smartphones and tablets that can not only produce a result, but also track progress over time. Initial marketing activities have commenced for these products and the Company is preparing for commercialization. Since devices with claims related to weight loss or nutrition are exempt from FDA oversight, a clinical program to support a 510(k) submission is not required for any of these products. Given the non-medical intended use, the Company does not believe products will be required to hold a CE-mark prior to marketing in the EU.

*Health and Wellness Market Development (OxiChek)*

The Company is currently assessing distribution opportunities with companies specializing in weight loss and/or mass distribution through health-related multilevel marketing organizations. We had been engaged with a with a large network marketing firm to secure a multi-year contractual arrangement. We failed to produce a custom product that satisfactorily met customer expectations, and as a result we were not able to finalize this arrangement. The Company is pursuing alternative customer options within the Multi-Level Market segment.

During October 2016 the Company was served with a notice that Pulse Health, LLC (“Pulse”) filed a lawsuit against the Company. This litigation has been assigned to mediation and our intention is to resolve this issue in the third quarter. There is risk associated with the BreathScan OxiChek product related to this litigation and an adverse decision may affect our ability to market the product. The Company is aggressively defending our product intellectual property and market position.

*Update regarding the marketing of the BreathScan Breath Alcohol products acquired in settlement with ChubeWorkx*

The Company has been actively marketing, on a global basis, the BreathScan Breath Alcohol products that were produced for and/or acquired as part of the ChubeWorkx settlement agreement in August 2016. Unfortunately, we have not been successful in securing buyers in sufficient volumes.

An extensive analysis of the market opportunity has been performed and it was determined that the on-hand quantity of this group of products exceeded the expected near term demand for the product prior to its expiration. As such, the Company’s management elected to establish a reserve.

**Item 6. Exhibits.**

- 31.1 Certification by the Principal Executive Officer of Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Rule 13a-14(a) or Rule 15d-14(a)). \*
- 31.2 Certification by the Principal Financial Officer of Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Rule 13a-14(a) or Rule 15d-14(a)). \*
- 32.1 Certification by the Principal Executive Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. \*
- 32.2 Certification by the Principal Financial Officer pursuant to 18 U.S.C. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. \*
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase
- 101.DEF XBRL Taxonomy Extension Definition Linkbase
- 101.LAB XBRL Taxonomy Extension Label Linkbase
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase

\* Filed herewith

## SIGNATURES

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

### **AKERS BIOSCIENCES, INC.**

Date: July 13, 2018 By: */s/ John J. Gormally*  
Name: John J. Gormally  
Chief Executive Officer  
Title:  
(Principal Executive Officer)

Date: July 13, 2018 By: */s/ Gary M. Rauch*  
Name: Gary M. Rauch  
Vice President, Finance & Treasurer  
Title:  
(Principal Financial Officer)

