# 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: June 30, 2017

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_

Commission File No. 001-36268

# **AKERS BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

New Jersey

(State or other jurisdiction of incorporation)

22-2983783

(IRS Employer Identification No.)

201 Grove Road Thorofare, NJ 08086

(Address of principal executive offices)

(856) 848-2116

(Registrant's telephone number, including area code)

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

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

| Large accelerated filer | [] Accelerated | ed filer        | []  |
|-------------------------|----------------|-----------------|-----|
| Non-accelerated filer   | [] Smaller rep | porting company | [X] |
|                         | Emerging g     | growth company  | [X] |

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

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

As of August 14, 2017, there were 8,901,245 shares outstanding of the registrant's common stock.

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# PART I – FINANCIAL INFORMATION

# Item 1. Financial Statements

# AKERS BIOSCIENCES, INC. AND SUBSIDIARIES Condensed Consolidated Balance Sheets June 30, 2017 and December 31, 2016

|   | 2017 |              | 2016 |             |  |
|---|------|--------------|------|-------------|--|
| + 0.05000   | (    | unaudited)   |      | (audited)   |  |
| ASSETS  |      |              |      |             |  |
| Current Assets  | ¢    | 107 175      | ¢    | 72 700      |  |
| Cash  | \$   | 197,175      | \$   | 72,700      |  |
| Marketable Securities   |      | 1,011,625    |      | 50,001      |  |
| Trade Receivables, net  |      | 927,534      |      | 601,271     |  |
| Trade Receivables - Related Party, net  |      | 125,001      |      | 31,892      |  |
| Deposits and other receivables  |      | 13,090       |      | 23,782      |  |
| Inventories, net  |      | 2,166,699    |      | 2,036,521   |  |
| Prepaid expenses  |      | 147,526      |      | 168,277     |  |
| Prepaid expenses - Related Party  |      | 317,439      |      | 202,500     |  |
| Total Current Assets  |      | 4,906,089    |      | 3,186,944   |  |
| Non-Current Assets  |      |              |      |             |  |
| Prepaid expenses - Related Party  |      | 108,353      |      | 270,183     |  |
| Property, Plant and Equipment, net  |      | 260,756      |      | 259,392     |  |
| Intangible Assets, net  |      | 1,216,221    |      | 1,301,775   |  |
| Other Assets  |      | 71,143       |      | 66,813      |  |
| Total Non-Current Assets  |      | 1,656,473    |      | 1,898,163   |  |
|   |      | 1,000,475    |      | 1,070,105   |  |
| Total Assets  | \$   | 6,562,562    | \$   | 5,085,107   |  |
|   |      |              |      |             |  |
| LIABILITIES   |      |              |      |             |  |
| Current Liabilities   |      |              |      |             |  |
| Trade and Other Payables  | \$   | 1,413,141    | \$   | 1,463,363   |  |
| Trade and Other Payables - Related Party  |      | 33,911       |      | 234,067     |  |
| Total Current Liabilities   |      | 1,447,052    |      | 1,697,430   |  |
| Total Liabilities   |      | 1,447,052    |      | 1,697,430   |  |
| STOCKHOLDERS' EOUITY  |      |              |      |             |  |
| Convertible Preferred Stock, No par value, 50,000,000 shares authorized, no shares issued and outstanding as of June 30, 2017 and December 31, 2016 |      |              |      |             |  |
| Common Stock, No par value, 500,000,000 shares authorized, 8,901,245 and 5,452,545 issued and   |      | -            |      | -           |  |
| outstanding as of June 30, 2017 and December 31, 2016   |      | 104,624,119  |      | 100,891,786 |  |
| Deferred Compensation   |      | (14,163)     |      | (24,572     |  |
| Accumulated Deficit   |      | (99,495,455) |      | (97,479,537 |  |
| Accumulated Other Comprehensive Income  |      | 1,009        |      | (97,479,537 |  |
| Total Stockholders' Equity  |      | 5 115 510    |      | 2 297 (77   |  |
| I UTAL STUCKHUIUCIS EQUILY  |      | 5,115,510    |      | 3,387,677   |  |
| Total Liabilities and Stockholders' Equity  |      | 6,562,562    | \$   | 5,085,107   |  |

See accompanying notes to these condensed consolidated financial statements.

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

|  | Three months ended<br>June 30, |           |    |   | Six mont<br>June |             | ed |             |
|--|--------------------------------|-----------|----|---|------------------|-------------|----|-------------|
|  |                                | 2017      | ,  | 2016                                    |                  | 2017        | ,  | 2016        |
| Revenues:  |                                |           |    |   |                  |             |    |             |
| Product Revenue  | \$                             | 1,097,295 | \$ | 956,486                                 | \$               | 1,740,481   | \$ | 1,694,510   |
| Product Revenue - Related party                              |                                | 100,567   |    | -                                       |                  | 124,631     |    | -           |
| Total Revenues   |                                | 1,197,862 |    | 956,486                                 |                  | 1,865,112   |    | 1,694,510   |
| Cost of Sales:   |                                | 1,177,002 |    | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |                  | 1,000,112   |    | 1,05 1,010  |
| Product Cost of Sales  |                                | (264,231) |    | (276,848)                               |                  | (522,952)   |    | (476,876)   |
|  |                                | (201,201) |    | (270,010)                               |                  | (022,002)   |    | (110,010)   |
| Gross Income   |                                | 933,631   |    | 679,638                                 |                  | 1,342,160   |    | 1,217,634   |
| Administrative Expenses                                      |                                | 829,929   |    | 816,244                                 |                  | 1,620,457   |    | 1,739,806   |
| Sales and Marketing Expenses                                 |                                | 354,889   |    | 513,430                                 |                  | 911,545     |    | 1,238,754   |
| Sales and Marketing Expenses - Related Party                 |                                | 61,502    |    | -                                       |                  | 93,781      |    | -           |
| Research and Development Expenses                            |                                | 290,841   |    | 321,989                                 |                  | 639,283     |    | 685,280     |
| Research and Development Expenses - Related Party            |                                | 22,994    |    | -                                       |                  | 22,994      |    | -           |
| Amortization of Non-Current Assets                           |                                | 42,777    |    | 42,777                                  |                  | 85,554      |    | 85,554      |
| Loss from Operations   |                                | (669,301) |    | (1,014,802)                             |                  | (2,031,454) |    | (2,531,760) |
| Other (Income)/Expenses                                      |                                |           |    |   |                  |             |    |             |
| Foreign Currency Transaction (Gain)/Loss                     |                                | 978       |    | 2,562                                   |                  | (9,367)     |    | 4,817       |
| Interest and Dividend Income                                 |                                | (3,632)   |    | (8,432)                                 |                  | (6,169)     |    | (18,716)    |
| Other Income   |                                | -<br>-    |    | - · ·                                   |                  |             |    | - ·         |
| Total Other Income   |                                | (2,654)   |    | (5,870)                                 |                  | (15,536)    |    | (13,899)    |
| Loss Before Income Taxes                                     |                                | (666,647) |    | (1,008,932)                             |                  | (2,015,918) |    | (2,517,861) |
| Income Tax Benefit   |                                | -         |    | -                                       |                  | -           |    | -           |
|  |                                |           |    |   |                  |             |    |             |
| Net Loss   |                                | (666,647) |    | (1,008,932)                             |                  | (2,015,918) |    | (2,517,861) |
| Other Comprehensive Income/(Loss)                            |                                |           |    |   |                  |             |    |             |
| Net Unrealized Gain/(Loss) on Marketable Securities          |                                | 852       |    | (2,006)                                 |                  | 1,009       |    | 6,528       |
| Total Other Comprehensive Income/(Loss)                      |                                | 852       |    | (2,006)                                 |                  | 1,009       |    | 6,528       |
| Comprehensive Loss   | \$                             | (665,795) | \$ | (1,010,938)                             | \$               | (2,014,909) | \$ | (2,511,333) |
| Basic and diluted loss per common share                      | \$                             | (0.08)    | \$ | (0.19)                                  | \$               | (0.25)      | \$ | (0.46)      |
| Waighted everyon basis and diluted common shares sutter dire |                                | 8,882,326 |    | 5,427,261                               |                  | 7,943,168   |    | 5,426,153   |
| Weighted average basic and diluted common shares outstanding |                                | 0,002,020 |    | 3,427,201                               | _                | /,943,108   | _  | 3,420,133   |

See accompanying notes to these condensed consolidated financial statements.

# AKERS BIOSCIENCES, INC. AND SUBSIDIARIES Condensed Consolidated Statement of Changes in Stockholder's Equity For the six months ended June 30, 2017

|   | Common<br>Shares<br>Issued and<br>Outstanding |    | Common<br>Stock        |    | Deferred<br>mpensation | A  | Accumulated<br>Deficit | Accumula<br>Other<br>Comprehen<br>Income/(Lo | sive      |    | Total<br>Equity        |
|---|---|----|------------------------|----|------------------------|----|------------------------|--|-----------|----|------------------------|
| Balance at December 31, 2016 (audited)  | 5,452,545                                     | \$ | 100,891,786            | \$ | (24,572)               | \$ | (97,479,537)           | \$   | -         | \$ | 3,387,677              |
| Net loss  | -   |    | -                      |    | -                      |    | (2,015,918)            |  | -         |    | (2,015,918)            |
| Public offering of common stock, net of offering costs of \$494,406<br>Private offering of common stock, net of offering costs of \$267,443 | 1,789,500<br>1,448,400                        |    | 1,652,994<br>1,760,317 |    | -                      |    | -                      |  | -         |    | 1,652,994<br>1,760,317 |
| Exercise of warrants for common stock<br>Amortization of deferred compensation  | 200,800                                       |    | 301,200                |    | - 10,409               |    | -                      |  | -         |    | 301,200<br>10,409      |
| Issuance of non-qualified stock options to key employees<br>Issuance of non-qualified stock options for services to non-employees           | -   |    | 10,184<br>2,183        |    | -                      |    | -                      |  | -         |    | 10,184<br>2,183        |
| Issuance of restricted stock for services to non-employees<br>Net uncelized gain on marketable securities                                   | 10,000  |    | 5,455                  |    | -                      |    | -                      | 1  | -<br>.009 |    | 5,455<br>1,009         |
| Ŭ   |   | _  |                        | _  | -                      | _  | -                      |  |           | _  |                        |
| Balance at June 30 2017 (unaudited)   | 8,901,245                                     | \$ | 104,624,119            | \$ | (14,163)               | \$ | (99,495,455)           | \$ 1   | ,009      | \$ | 5,115,510              |

See accompanying notes to these condensed consolidated financial statements.

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

|  |    | 2017        |          | 2016        |  |  |
|--|----|-------------|----------|-------------|--|--|
| Cash flows from operating activities   |    |             |          |             |  |  |
| Net loss for the year  | \$ | (2,015,918) | \$       | (2,517,861) |  |  |
| Adjustments to reconcile net loss to net cash used in operating activities:  |    |             |          |             |  |  |
| Accrued income on marketable securities  |    | (1,001)     |          | 8,927       |  |  |
| Depreciation and amortization  |    | 121,381     |          | 113,906     |  |  |
| Reserve and write-off for obsolete inventory   |    | 21,542      |          | -           |  |  |
| Allowance for doubtful accounts  |    | 46,239      |          | 146,196     |  |  |
| Fair value of restricted common stock issued for services  |    | 15,864      |          | 18,243      |  |  |
| Share based compensation to employees - options  |    | 10,184      |          | -           |  |  |
| Share based compensation to non-employees - options  |    | 2,183       |          | 8,241       |  |  |
| Changes in assets and liabilities:   |    |             |          |             |  |  |
| Increase in trade receivables  |    | (372,502)   |          | (79,906)    |  |  |
| Increase in trade receivables - related party  |    | (93,109)    |          | -           |  |  |
| Decrease in deposits and other receivables   |    | 10,692      |          | 31,196      |  |  |
| Increase in inventories  |    | (151,720)   |          | (85,588)    |  |  |
| Decrease in prepaid expenses   |    | 20,752      |          | 43,933      |  |  |
| Decrease in prepaid expenses - related party   |    | 46,890      |          | -           |  |  |
| Increase in other assets   |    | (4,330)     |          | -           |  |  |
| Decrease in trade and other payables   |    | (50,222)    |          | (103,029)   |  |  |
| Decrease in trade and other payables - related party   |    | (200,156)   |          | -           |  |  |
| Net cash used in operating activities  |    | (2,593,231) |          | (2,415,742) |  |  |
| Cash flows from investing activities   |    |             |          |             |  |  |
| Purchases of property, plant and equipment   |    | (37,191)    |          | (81,462)    |  |  |
| Purchases of marketable securities   |    | (2,705,168) |          | (27,643)    |  |  |
| Proceeds from sale of marketable securities  |    | 1,745,554   |          | 2,502,319   |  |  |
| Net cash (used in)/provided by investing activities  |    | (996,805)   |          | 2,393,214   |  |  |
| Cash flows from financing activities   |    |             |          |             |  |  |
| Net proceeds from issuance of common stock   |    | 3,413,311   |          | -           |  |  |
| Net proceeds from exercise of warrants for common stock  |    | 301,200     |          | -           |  |  |
| Net cash provided by financing activities  |    | 3,714,511   |          | -           |  |  |
| Net increase/(decrease) in cash  |    | 124,475     |          | (22,528)    |  |  |
| Cash at beginning of period  |    | 72,700      |          | 402,059     |  |  |
| Cash at end of period  | \$ | 197,175     | \$       | 379,531     |  |  |
| Complemental Calculate of New Coale Financing and Jacobian Astroitics  |    |             |          |             |  |  |
| Supplemental Schedule of Non-Cash Financing and Investing Activities<br>Issuance of a restricted common stock grant for services | \$ | 5,455       | \$       | -           |  |  |
| Issuance of a restricted common stock grant to an officer  | \$ | 5,155       | \$       | 54.725      |  |  |
| ç  | ·  | 1.000       | <u> </u> |             |  |  |
| Net unrealized gains on marketable securities  | \$ | 1,009       | \$       | 6,528       |  |  |

See accompanying notes to these condensed consolidated financial statements.

Notes to Condensed Consolidated Financial Statements

#### Note 1 - Nature of Business

# (a) Reporting Entity

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

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

#### (b) Nature of Business

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

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

#### (a) Basis of Presentation

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

Certain information and note disclosures normally included in the financial statements prepared in accordance with US GAAP have been condensed. As such, the information included in these financial statements should be read in conjunction with the audited financial statements as of and for the years ended December 31, 2016 and 2015 included in the Company's 2016 Form 10-K. In the opinion of the management, these consolidated financial statements include all adjustments, consisting of only normal recurring nature, necessary for a fair statement of the financial position of the Company as of June 30, 2017 and its results of operations and cash flows for the three and six months ended June 30, 2017 and 2016. The results of operations for the three and six months ended June 30, 2017 and 2017.

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

#### (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.

| 1 |   | 7 |  |
|---|---|---|--|
|   |   |   |  |
|   | 1 |   |  |

Notes to Condensed Consolidated Financial Statements

# (c) Functional and Presentation Currency

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

#### (d) Comprehensive Income (Loss)

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

# (e) Cash and Cash Equivalents

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

# (f) Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, receivables and trade and other payables. The carrying value of cash and cash equivalents, receivables and trade and other payables approximate their fair value because of their short maturities. The fair value of marketable securities is described in Note 3(c).

# (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:

Notes to Condensed Consolidated Financial Statements

- 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.

As of June 30, 2017 and December 31, 2016, allowances for doubtful accounts for trade receivables were \$192,435 and \$1,010,196. Bad debt expenses for trade receivables were \$5,380 and \$47,741 for the three month and six months ended June 30, 2017 and \$146,196 for the three and six months ended June 30, 2016.

Notes to Condensed Consolidated Financial Statements

# (j) 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 \$182,913 and \$67,865 with Fulton Bank of New Jersey, \$10,222 and \$795 with Bank of America, NA and \$4,040 and \$4,040 with PayPal as of June 30, 2017 and December 31, 2016. No losses have been incurred in these accounts.

Concentration of credit risk with respect to trade receivables exists as approximately 68% of the Company's product revenue is generated by three customers. These customers accounted for 62% of trade receivables as of June 30, 2017. In order to limit such risks, the Company performs ongoing credit evaluations of its customers' financial condition.

# (k) Inventories

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

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

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

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

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



Notes to Condensed Consolidated Financial Statements

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

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

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

### (m) 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 June 30, 2017, the Company has eleven patents from the United States Patent Office in effect (9,383,368; 7,896,167; 8,097,171; 8,003,061; 8,425,859; 8,871,521; 8,808,639; D691,056; D691,057; D691,057; D691,058 and D786,872). Other patents are in effect in Australia through the Design Registry (348,310; 348,311 and 348,312), European Union Patents 1793906, 2684025, 002216895-0001; 002216895-0002; 002216895-0003; 3459700-0001 and 3459395-001), United Kingdom and France (2684025), Germany (602012021524.0), Spain (E1275523), China (2016305495829), in Hong Kong (HK11004006) and in Japan (1,515,170; 4,885,134; 4,931,821 5,775,790, and 6023096). Patents are in the national phase of prosecution in many Patent Cooperation Treaty participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the U.S., European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

#### (ii) Patent Costs

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

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

### (iii) Other Intangible Assets

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



Notes to Condensed Consolidated Financial Statements

### (iv) Amortization

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

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

### (n) 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.

#### (o) 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 valuate these investments using the cost method.



Notes to Condensed Consolidated Financial Statements

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

# (p) 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 June 30, 2017 and December 31, 2016.

The Company implemented a standard dealer cost model during the year ended December 31, 2016 which includes a provision for rebates to the distributors under limited circumstances. The Company established an accrual of \$24,294 and \$41,120, which is a reduction of revenue as of June 30, 2017 and December 31, 2016. Accounts receivable will be reduced when the rebates are applied by the customer. The Company recognized \$67,855 and \$170,678 during the three and six months ended June 30, 2017 and \$115,685 and \$215,653 for the three and six months ended June 30, 2016 for rebates, which is included as a reduction of product revenue in the Condensed Consolidated Statement of Operations and Comprehensive Loss.

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

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

## (q) 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.

Notes to Condensed Consolidated Financial Statements

# (r) Shipping and Handling Fees and Costs

The Company charges actual shipping plus a handling fee to customers, which amounted to \$15,049 and \$14,387 for the three months ended June 30, 2017 and 2016 and to \$33,469 and \$30,432 for the six months ended June 30, 2017 and 2016. These fees are classified as part of product revenue in the Condensed Consolidated Statement of Operations and Comprehensive Loss. Shipping and other related delivery costs, including those for incoming raw materials are classified as part of the cost of net revenue, which amounted to \$31,393 and \$47,570 for the three and six months ended June 30, 2017 and to \$47,018 and \$68,732 for the three and six months ended June 30, 2016.

#### (s) Research and Development Costs

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

# (t) Stock-based Payments

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

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

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

Notes to Condensed Consolidated Financial Statements

### (u) 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.

#### (v) Reclassifications

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

#### (w) Recently Adopted Accounting Pronouncements

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

#### (x) Recently Issued Accounting Pronouncements Not Yet Adopted

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

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

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740), Balance Sheet Classification of Deferred Taxes.* The amendments in this Update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. For nonpublic entities, 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.

Notes to Condensed Consolidated Financial Statements

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments – Overall (Subtopic 825-10), Recognition and Measurement of Financial Assets and Financial Liabilities.* The amendments in this Update require all equity investments to be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under the equity method of accounting or those that result in consolidation of the investee). The amendments in this Update 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): Deferral of the Effective Date, which deferred the effective date to annual reporting periods beginning after December 15, 2018. The Company is currently evaluating the effect the amendments in this Update will have on its financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which simplifies several aspects of the accounting for share-based payment award transactions, including: (1) income tax consequences; (2) classification of awards as either equity or liabilities, and (3) classification on the statement of cash flows. The amendments in this ASU are effective for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 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.

Notes to Condensed Consolidated Financial Statements

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

# Note 3 – Management Plan

Historically, the Company has relied upon public offerings and private placements of common stock to raise operating capital. During the three months ending March 31, 2017, the Company raised approximately \$1.7 million in a public offering and an additional \$1.8 million from a private placement of common stock (Note 11). As of August 10, 2017, the Company had cash and marketable securities of approximately \$734,000 and working capital of approximately \$3.25 million.

The 2017-19 Strategic Business Plan ("Strat Plan") was presented to and approved by the Board of Directors on December 12, 2016. The plan outlines the Company's business objectives for the next three years and sets measurable targets for new product releases, sales and marketing programs to increase market penetration for the Company's products and operational expense management.

Implementation of the Strat Plan began in January 2017 and management remains confident that the objectives are achievable. The Company anticipates achievement of a cash-flow positive position during the next twelve months based upon the revenue targets as outlined in the Strat Plan, the results of the private placement offering in March 2017 and the backing of a shareholder, if required. In Addition, the Company has initiated discussions with our primary financial institution to establish a line of credit to manage short-term cash fluctuations.

During the year ended December 31, 2016, the Company significantly reduced operating expenses through a systematic review of operations throughout the organization. As a result, the Company achieved a reduction in <u>its</u> weekly operating cash requirements of approximately 19% to \$80,253 (2015: \$98,699). The Strat Plan assumes the weekly cash requirement will <u>decline</u> through the year ending December 31, 2017.

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



Notes to Condensed Consolidated Financial Statements

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

During the six months ended June 30, 2017, the Company's average weekly operating cash requirement was \$99,740 (2016: \$89,472). Payments to vendors and sub-contractors included in the December 31, 2016 accounts payable balance, a significant royalty payment that had been deferred in 2016 as part of a legal settlement and other payments for contractual obligations has resulted in a higher than expected rate as compared to the year ended December 31, 2016. Many of these items are one-time events and the Company anticipates the cash requirements to revert to \$80,000 to \$85,000 per week by the end of 2017.

Barring any unforeseen circumstances, the Company believes that it is probable that it will be able to meet its obligations as they fall due within one year after the financial statements are issued.

# Note 4 - Fair Value Measurement - Marketable Securities

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

Money Market Funds 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 June 30, 2    | 017               |              |
|----------------------|-----------|-------------------|---------------------|-------------------|--------------|
|                      | Cost      | Accrued<br>Income | Unrealized<br>Gains | Unrealized Losses | Fair Value   |
| Level 2:             |           |                   |                     |                   |              |
| Money market funds   | \$        | 228 \$            | - \$ -              | \$-               | \$ 228       |
| Municipal securities | 1,009,    | 356 1,030         | ) 1,009             | -                 | 1,011,395    |
| Total Level 2:       | 1,009,    | 584 1,030         | 1,009               | -                 | 1,011,623    |
|                      |           |                   |                     |                   |              |
| Total:               | \$ 1,009, | 584 \$ 1,030      | \$ 1,009            | <u>\$</u>         | \$ 1,011,623 |
|                      |           |                   | As of December 31,  | 2016              |              |
|                      | Cost      | Accrued<br>Income | Unrealized Gains    | Unrealized Losses | Fair Value   |
| Level 2:             |           |                   |                     |                   |              |
| Money market funds   | \$ 29,657 | 7 \$ 15           | \$ -                | \$ -              | \$ 29,672    |
| Municipal securities | 20,314    | 15                | -                   | -                 | 20,329       |
| Total Level 2:       | 49,971    | 30                | -                   | -                 | 50,001       |
| Total:               | \$ 49,971 | \$ 30             | \$ -                | \$ -              | 50,001       |

Marketable securities include money market funds and municipal securities which are classified as available for sale. The securities are valued at fair market value. Maturities of the securities are less than one year. Unrealized gains relating to the available for sale investment securities were recorded in the Condensed Consolidated Statement of Changes in Stockholders' Equity as comprehensive income. These amounts were \$852 and \$1,009 (net of effect of income tax expense of \$-) for the three and six months ended June 30, 2017 and an unrealized loss of \$2,006 and unrealized gain of \$6,528 for the three and six months ended June 30, 2017.



Notes to Condensed Consolidated Financial Statements

Proceeds from the sale of marketable securities in the three and six months ended June 30, 2017 and 2016 were \$650,661 and \$1,745,554 and \$900,863 and \$2,502,319 for the three and six months ended June 30, 2016. Gross gains, resulting from these sales, amounted to \$605 and \$1,844 for the three months ended June 30, 2017 and 2016 and \$1,656 and \$2,152 for the six months ended June 30, 2017 and 2016.

### Note 5 - Trade Receivables - Related Party

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

# Note 6 - Inventories

Inventories consists of the following categories:

|                          | <br>June 30, 2017 | <br>December 31, 2016 |  |  |  |
|--------------------------|-------------------|-----------------------|--|--|--|
| Raw Materials            | \$<br>487,218     | \$<br>440,316         |  |  |  |
| Sub-Assemblies           | 912,627           | 907,989               |  |  |  |
| Finished Goods           | 810,381           | 749,488               |  |  |  |
| Reserve for Obsolescence | (43,527)          | <br>(61,272)          |  |  |  |
|                          | \$<br>2,166,699   | \$<br>2,036,521       |  |  |  |

Obsolete inventory charged to cost of goods during the three and six months ended June 30, 2017 totaled \$21,542 and \$21,542 and \$- and \$2,968 was charged for the three and six months ended June 30, 2016.

# Note 7 - Property, Plant and Equipment

Property, plant and equipment consists of the following:

|                          | June 30, 2017 |           | Dece | mber 31, 2016 |
|--------------------------|---------------|-----------|------|---------------|
| Computer Equipment       | \$            | 114,771   | \$   | 114,771       |
| Computer Software        | Ŷ             | 40,681    | Ŷ    | 40,681        |
| Office Equipment         |               | 39,959    |      | 39,959        |
| Furniture & Fixtures     |               | 38,356    |      | 29,939        |
| Machinery & Equipment    |               | 1,138,134 |      | 1,126,134     |
| Molds & Dies             |               | 851,254   |      | 834,480       |
| Leasehold Improvements   |               | 222,593   |      | 222,593       |
|                          |               | 2,445,748 |      | 2,408,557     |
| Less                     |               |           |      |               |
| Accumulated Depreciation |               | 2,184,992 |      | 2,149,165     |
|                          |               |           |      |               |
|                          | \$            | 260,756   | \$   | 259,392       |

Depreciation expenses totaled \$17,885 and \$35,827 for the three and six months ended June 30, 2017 and \$14,650 and \$28,352 for the three and six months ended June 30, 2016.



Notes to Condensed Consolidated Financial Statements

# Note 8 - Intangible Assets

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

|                 | Distributor &<br>Customer<br>Relationships                               |   |  | Totals   |  |
|-----------------|--|---|--|--|--|
|                 |  |   |  |  |  |
| \$<br>2,626,996 | \$   | 1,270,639   | \$   | 3,897,635  |  |
| -               |  | -   |  | -  |  |
| -               |  | -   |  | -  |  |
| \$<br>2,626,996 | \$   | 1,270,639   | \$   | 3,897,635  |  |
|                 |  |   |  |  |  |
| \$<br>1,325,221 | \$   | 1,270,639   | \$   | 2,595,860  |  |
| 85,554          |  | -   |  | 85,554   |  |
| -               |  | -   |  | -  |  |
| \$<br>1,410,775 | \$   | 1,270,639   | \$   | 2,681,414  |  |
|                 |  |   |  |  |  |
| \$<br>1,301,775 | \$   | -   | \$   | 1,301,775  |  |
| \$<br>1,216,221 | \$   | -   | \$   | 1,216,221  |  |
|                 | \$ 2,626,996<br>\$ 1,325,221<br>\$ 5,554<br>\$ 1,410,775<br>\$ 1,301,775 | Patents &<br>Trademarks   Ref     \$ 2,626,996   \$     \$ 2,626,996   \$     \$ 2,626,996   \$     \$ 2,626,996   \$     \$ 1,325,221   \$     \$ 1,325,221   \$     \$ 1,325,221   \$     \$ 1,325,221   \$     \$ 1,325,221   \$     \$ 1,301,775   \$ | Patents &<br>Trademarks   Customer<br>Relationships     \$ 2,626,996   \$ 1,270,639     \$ 2,626,996   \$ 1,270,639     \$ 2,626,996   \$ 1,270,639     \$ 2,626,996   \$ 1,270,639     \$ 1,325,221   \$ 1,270,639     \$ 1,325,554   -     \$ 1,410,775   \$ 1,270,639     \$ 1,301,775   \$ - | Patents &<br>Trademarks   Customer<br>Relationships     \$ 2,626,996   \$ 1,270,639   \$     \$ 2,626,996   \$ 1,270,639   \$     \$ 2,626,996   \$ 1,270,639   \$     \$ 1,325,221   \$ 1,270,639   \$     \$ 1,325,221   \$ 1,270,639   \$     \$ 1,325,221   \$ 1,270,639   \$     \$ 1,301,775   \$ 1,270,639   \$ |  |

Amortization expense totaled \$42,777 and \$85,554 during the three and six months ended June 30, 2017 and \$42,777 and \$85,554 for the three and six months ended June 30, 2016.

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

| Period | <br>Amount    |
|--------|---------------|
| 2017   | \$<br>171,108 |
| 2018   | \$<br>171,108 |
| 2019   | \$<br>171,108 |
| 2020   | \$<br>171,108 |
| 2021   | \$<br>171,108 |

# Note 9 - Trade and Other Payables

Trade and other payables consists of the following:

|                       | J  | une 30, 2017 | Dec | ember 31, 2016 |
|-----------------------|----|--------------|-----|----------------|
| Trade Payables        | \$ | 821,581      | \$  | 923,311        |
| Accrued Expenses      |    | 531,810      |     | 480,302        |
| Deferred Compensation |    | 59,750       |     | 59,750         |
| -                     | \$ | 1,413,141    | \$  | 1,463,363      |

Notes to Condensed Consolidated Financial Statements

Trade and other payables - related party are as follows:

|                  | June | June 30, 2017 |    |         |
|------------------|------|---------------|----|---------|
| Trade Payables   | \$   | 33,911        | \$ | 182,001 |
| Accrued Expenses |      | -             |    | 52,066  |
|                  | \$   | 33,911        | \$ | 234,067 |

As of June 30, 2017, the Company owed ChubeWorkx Guernsey Limited, a major shareholder, a royalty of \$30,751 (Note 14) which was paid on July 20, 2017.

As of June 30, 2017, the Company owed Hainan \$670. Senior management at Hainan are actively involved in two other companies, Shenzhen Savy-Akers Biosciences ("Shenzhen") and Dong Guan Senming E&P ("Senming") which are therefore being included as related parties. The Company owed these two companies \$2,490 as of June 30, 2017.

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

# Note 10 - Share-based Payments

On January 23, 2014, upon effectiveness of the registration statement filed with the SEC, the Company adopted the 2013 Stock Incentive Plan (the "Plan") which provides 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 increased the number of authorized shares of common stock subject to the Plan to 800,000 shares.

On September 30, 2016, the Board of Directors increased the number of authorized shares of common stock subject to the Amended Plan to 830,000 shares. As of June 30, 2017, under the 2013 Amended Plan, grants of restricted stock and options to purchase 268,166 shares of common stock have been issued and are unvested or unexercised and 3,292 shares of common stock remain available for grants.

The Amended 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.

Notes to Condensed Consolidated Financial Statements

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

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

The following table summarizes the option activities for the six months ended June 30, 2017:

|                                 | Number of<br>Shares | Weighted<br>Average<br>Exercise Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (years) | <br>Aggregate<br>Intrinsic<br>Value |
|---------------------------------|---------------------|---------------------------------------|---|-------------------------------------|
| Balance at December 31, 2016    | 259,000             | \$<br>4.23                            | 3.05  | \$<br>20,100                        |
| Granted                         | -                   | -                                     | -   | -                                   |
| Exercised                       | -                   | -                                     | -   | -                                   |
| Forfeited                       | -                   | -                                     | -   | -                                   |
| Canceled/Expired                | -                   | -                                     | -   | -                                   |
| Balance at June 30, 2017        | 259,000             | \$<br>4.23                            | 2.55  | \$<br>600                           |
| Exercisable as of June 30, 2017 | 241,667             | \$<br>4.30                            | 2.44  | \$<br>600                           |

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of \$1.25 for our common shares on June 30, 2017.

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

|         | Weighte<br>Average G | rant                                       |
|---------|----------------------|--|
| Shares  | Date Fair V          | alue                                       |
| 19,834  | \$                   | 2.36                                       |
| -       |                      | -  |
| (2,500) |                      | 1.05                                       |
|         |                      | -  |
| 17,334  | \$                   | 2.36                                       |
|         | 19,834<br>(2,500)    | Average G<br>Shares Date Fair V<br>(2,500) |

Unrecognized compensation cost related to non-vested employee stock options totaled \$23,167 as of June 30, 2017. The cost is to be recognized over a weighted average period of 1.13 years.

During the three and six months ended June 30, 2017, the Company incurred stock option expenses totaling \$7,275 and \$12,367. No stock option expenses were incurred in the three and six months ended June 30, 2016.

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

Notes to Condensed Consolidated Financial Statements

|                                 | Number of<br>Warrants | Weighted<br>Average<br>Exercise Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (years) |
|---------------------------------|-----------------------|---------------------------------------|---|
| Balance at December 31, 2016    | -                     | \$ -                                  | -   |
| Granted                         | 1,691,370             | 1.88                                  | -   |
| Exercised                       | (200, 800)            | 1.50                                  | -   |
| Forfeited                       | -                     | -                                     | -   |
| Canceled/Expired                |                       |                                       | -   |
| Balance at June 30, 2017        | 1,490,570             | \$ 1.73                               | 4.65  |
| Exercisable as of June 30, 2017 | 693,950               | \$ 1.47                               | 4.54  |

### Note 11 - Equity

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

A restricted stock award is an award of common shares that are subject to certain restrictions during a specified period. Restricted stock awards are independent of option grants and are generally subject to forfeiture if employment terminates prior to the release of the restrictions. The grantee cannot transfer the shares before the restricted shares vest. Shares on non-vested restricted stock have the same voting rights as common stock, are entitled to receive dividends and other distributions thereon and are considered to be currently issued and outstanding. The Company's restricted stock awards vest of a period of one to three years. The Company expenses the cost of the restrictions layer. For these purposes, the fair market value of the shares at the date of grant, straight-line over the period during which the restrictions layer. 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. \$5,206 was recorded during the three months ended June 30, 2017 as administrative expense on the Condensed Consolidated Statement of Operations and Comprehensive Loss and the remaining \$14,163 is reported as deferred compensation, a contra equity account, on the Condensed Consolidated Balance Sheet as of June 30, 2017.

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

Notes to Condensed Consolidated Financial Statements

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

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

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

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

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

Notes to Condensed Consolidated Financial Statements

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

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

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

# Note 12 - Loss per share

The calculation of basic and diluted loss per share at June 30, 2017 and 2016 was based on the net loss of \$2,015,918 and \$2,517,861. The basic and diluted weighted average number of common shares outstanding as of June 30, 2017 and 2016 was 7,943,168 and 5,426,153.

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

Notes to Condensed Consolidated Financial Statements

Potential common shares consist of options and warrants. Diluted net loss per common share was the same as basic net loss per common share for the six months ended June 30, 2017 and 2016 since the effect of options and warrants would be anti-dilutive due to the net loss. Instruments excluded from dilutive earnings per share, because their inclusion would be anti-dilutive, were as follows: incentive and award stock options – 259,000 (2016: 203,000); unvested restricted shares of common stock – 9,166 (2016: 18,333); warrants – 1,490,570 (2016: -) as of June 30, 2017.

### Note 13 - Income Tax Expense

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

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

# Note 14 - Related Party Transactions

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

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

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

Under the terms of the Settlement Agreement, the Company will recover the full outstanding principal amount in the year of the settlement in the form of \$750,000 of BreathScan® Alcohol Detector inventory – which the Company intends to subsequently sell – and the balance of \$549,609 as prepaid royalty. Akers' established an allowance for this doubtful note in the Company's financial statements for the year ended December 31, 2015. As a result of the Settlement Agreement, the Company reversed the allowance for doubtful note in the amount of \$1,299,609 which was included in the 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<sup>TM</sup>; and a number of products in development.

In return for the Company regaining the full rights to sell breath technology products, under the terms of the Settlement Agreement, ChubeWorkx is entitled to receive a royalty of 5% of the Company's gross revenues (the "ChubeWorkx Royalty") until ChubeWorkx has earned an aggregate \$5,000,000, after which point ChubeWorkx will no longer be entitled to receive any royalties from the Company and the Company shall have no further obligation to ChubeWorkx. The Settlement Agreement further allows the Company to retain 50% of the ChubeWorkx Royalty until the full \$549,609 cash component of the monies owed by ChubeWorkx to the Company as described above has been satisfied. The Company recorded royalty expenses of \$61,502 and \$93,781 for the three and six months ended June 30, 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, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment 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 (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.



Notes to Condensed Consolidated Financial Statements

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

The Company began purchasing manufacturing molds, plastic components and the assembled BreathScan Lync<sup>™</sup> device through Hainan and its related parties during the year ended December 31, 2016 (Note 9). The Company purchased a total of \$- and \$30,043 during the three months ended June 30, 2017 and 2016 and \$16,774 and \$30,043 for the six months ended June 30, 2017 and 2016 from this related party. As of June 30, 2017, the Company owed the three companies \$3,160 which is included in trade and other payables – related party on the Condensed Consolidated Balance Sheet.

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

Product revenue – related party for the three months ended June 30, 2017 and 2016 were \$100,567 and \$- and total \$124,631 and \$- for the six months then ended. The revenue was the result of sales to Hainan and its related parties.

#### Note 15 - Commitments

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

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

Rent expense for the Thorofare Lease, including related CAM charges for the three months ended June 30, 2017 and 2016 totaled \$40,440 and \$40,290, respectively. Rent expenses for the Thorofare Lease, including related CAM charges totaled \$80,927 and \$80,580 for the six months ended June 30, 2017 and 2016.

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

Rent expenses for the Ramsey Lease for the three and six months ended June 30, 2017 totaled \$2,165. 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 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<br>Lease<br>\$ | Ramsey<br>Lease<br>\$ | Equipment<br>Lease<br>\$ | Total<br>\$ |
|-------------------|--------------------------|-----------------------|--------------------------|-------------|
| Next 12 Months    | 132,000                  | 25,980                | 6,156                    | 164,136     |
| Next 13-24 Months | 132,000                  | 23,815                | 6,156                    | 161,971     |
| Next 25-36 Months | 66,000                   | -                     | 2,052                    | 68,052      |

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

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

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

# Note 16 - Major Customers

For the three months ended June 30, 2017, two customers generated 10% or more of the Company's revenue. Sales to these customers accounted for 66% of the Company's revenue. As of June 30, 2017, the amount due from these customers was \$701,826 of which \$500,000 has an extended term of 180 days. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

For the six months ended June 30, 2017, three customers generated 10% or more of the Company's revenue. Sales to these customers accounted for 68% of the Company's revenue. As of June 30, 2017, the amount due from these customers was \$768,306 of which \$500,000 has an extended term of 180 days. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

For the three months ended June 30, 2016, two customers each generated more than 10% of the Company's product revenue. In aggregate, sales to these customers accounted for 79% of the Company's product revenue. As of June 30, 2016, the amount due from these two customers was \$96,390.

For the six months ended June 30, 2016, three customers each generated more than 10% of the Company's product revenue. In aggregate, sales to these customers accounted for 82% of the Company's product revenue. As of June 30, 2016, the amount due from these three customers was \$488,456. This concentration makes the Company vulnerable to a near-term severe impact should the relationships be terminated.

Notes to Condensed Consolidated Financial Statements

#### Note 17 - Major Suppliers

For the three months ended June 30, 2017, two suppliers accounted for 10% or more of the Company's purchases. These suppliers accounted for 30% of the Company's total purchases. As of June 30, 2017, the amount due to these suppliers was \$42,742.

For the six months ended June 30, 2017, one supplier accounted for 10% or more of the Company's purchases. This supplier accounted for 14% of the Company's total purchases. As of June 30, 2017, the amount due to this supplier was \$-.

For the three months ended June 30, 2016, two suppliers each accounted for more than 10% of the Company's purchases. In aggregate, these suppliers accounted for 32% of the Company's total purchases. As of June 30, 2016, the amount due to the suppliers was \$20,445.

For the six months ended June 30, 2016, no suppliers accounted for more than 10% of the Company's purchases.

# Note 18 – Contingencies

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

Pulse subsequently filed an Amended Complaint, in which Pulse seeks not less than \$500,000 in damages and, among other items, an injunction prohibiting the Company from manufacture, use and sale of the OxiChek product. The Company answered the Amended Complaint on May 30, 2017. Discovery has commenced and is scheduled to conclude on October 2, 2017. The Court has set the trial date for July 17, 2018.

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

Notes to Condensed Consolidated Financial Statements

# Note 19 – Segment Information

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

The total revenue by different product lines was as follows:

|  | <br>Three mo<br>Jun | nths en<br>e 30, | ded     |      | Six mont<br>Jun | ths end<br>e 30, | ed        |
|--|---------------------|------------------|---------|------|-----------------|------------------|-----------|
| Product Line                                 | <br>2017 2016       |                  |         | 2017 |                 | 2016             |           |
| MicroParticle Catalyzed Biosensor<br>("MPC") | \$<br>191,816       | \$               | 44,918  | \$   | 277,475         | \$               | 109,702   |
| Particle ImmunoFiltration Assay ("PIFA")     | 426,747             |                  | 879,081 |      | 987,668         |                  | 1,514,256 |
| Other  | 579,299             |                  | 32,487  |      | 599,969         |                  | 70,552    |
| Total Revenue                                | \$<br>1,197,862     | \$               | 956,486 | \$   | 1,865,112       | \$               | 1,694,510 |

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

|                            | _  | Three moi<br>Jun |    |         |    |           |    |           |  |  |
|----------------------------|----|------------------|----|---------|----|-----------|----|-----------|--|--|
| Geographic Region          |    | 2017             |    | 2016    |    | 2017      |    | 2016      |  |  |
| United States              | \$ | 512,395          | \$ | 452,756 | \$ | 1,129,619 | \$ | 1,118,961 |  |  |
| People's Republic of China |    | 603,068          |    | 473,853 |    | 627,132   |    | 506,398   |  |  |
| Rest of World              |    | 82,399           |    | 29,877  |    | 108,361   |    | 69,151    |  |  |
| Total Revenue              | \$ | 1,197,862        | \$ | 956,486 | \$ | 1,865,112 | \$ | 1,694,510 |  |  |

The Company had long-lived assets totaling \$62,954 and \$61,081 located in the People's Republic of China and \$1,414,023 and \$1,500,086 located in the United States as of June 30, 2017 and December 31, 2016, respectively.

# Note 20 - Subsequent Events

On August 7, 2017, the Company's shareholders approved the 2017 Equity Incentive Plan ("Plan") which provides 1,350,000 common shares to encourage and enable the officers, employees, directors, consultants and other key persons of the Company, upon whose judgment, initiative and efforts the Company largely depends for the successful conduct of its business, to acquire a proprietary interest in the Company.

On August 7, 2017, the Shareholders elected Bill J. White, Richard C. Tarbox III and Christopher C. Schreiber to serve as non-executive directors and reelected Raymond F. Akers and elected John J. Gormally as executive directors for the Company.



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

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

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

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

#### Overview

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

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

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

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

- cost pressures/efficiency of healthcare delivery;
- need for affordable mass screening tests for key infectious diseases, cardiac conditions, and metabolic markers;
- need for easy to use, accurate at-home tests for individuals to monitor their personal health and wellness; and
- public health needs in developing countries lacking basic health infrastructure.

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

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

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

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

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

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

At June 30, 2017, Akers had cash of \$197,175, working capital of \$3,459,037, stockholders' equity of \$5,115,510 and an accumulated deficit of \$99,495,455. The Company believes that its current working capital position will be sufficient to meet its estimated cash needs for at least the next 12 months. The Company closely monitors its cash balances, cash needs and expense levels.

# Summary of Statements of Operations for the Three Months Ended June 30, 2017 and 2016

### Revenue

Akers' revenue for the three months ended June 30, 2017 totaled \$1,197,862, a 25% increase from the same period in 2016. The tables below summarize our revenue by product line and geographic region for the three months ended June 30, 2017 and 2016 as well as the percentage of change year-over-year:

| Product Lines                             | 3 Months<br>Ended<br>June 30, 2017 | 3 Months<br>Ended<br>une 30, 2016 | Percent Change |
|---|------------------------------------|-----------------------------------|----------------|
| Particle ImmunoFiltration Assay ("PIFA")  | \$<br>426,747                      | \$<br>879,081                     | (51)%          |
| MicroParticle Catalyzed Biosensor ("MPC") | 191,816                            | 44,918                            | 327%           |
| Other                                     | 579,299                            | 32,487                            | 1,683%         |
| Total Revenue                             | \$<br>1,197,862                    | \$<br>956,486                     | 25%            |

| Geographic Region          | 3 Months<br>Ended<br>June 30, 2017 | 3 Months<br>Ended<br>June 30, 2016 | Percent Change |
|----------------------------|------------------------------------|------------------------------------|----------------|
| United States              | \$<br>512,395                      | \$<br>452,756                      | 13%            |
| People's Republic of China | 603,068                            | 473,853                            | 27%            |
| Rest of World              | 82,399                             | 29,877                             | 176%           |
| Total Revenue              | \$<br>1,197,862                    | \$<br>956,486                      | 25%            |

Revenue from the Company's PIFA Heparin/PF4 Rapid Assay products decreased 51% during the three months ended June 30, 2017 over the same period of 2016. During the three months ended June 30, 2016 the Company recognized approximately \$474,000 (2017: \$-) in PIFA revenue from the Company's distribution partner in the People's Republic of China ("PRC"). The distributor continues to work with the various provincial governments in the PRC to finalize reimbursement rates for the providers. Once these rates are established, the distributor expects strong demand for the PIFA products. Revenue from PIFA related components, totaling \$500,000, during the three months ended June 30, 2017 is included in other revenue.

Total unit sales volumes for PIFA Classic and PIFA PLUSS in the United States remained steady, however; the ratio of each product sold changed slightly year-over-year. The Company experienced renewed interest in Western Europe and the Far East for the products after reviving the Conformité Européene Mark ("CE Mark"). The PIFA Classic product is being actively marketed in Great Britain and a clinical trial is scheduled in Italy.

MPC revenue increased 327% during the three months ended June 30, 2017 over the same period of 2016. Domestic and International sales of the BreathScan Breath Alcohol tests which accounted for the majority of the improvement.

The Company signed an amendment to the exclusive distribution agreement for the PIFA Heparin/PF4 products with NovoTek Pharmaceuticals Limited ("NovoTek") to expand their geographic region to include Poland, include other PIFA Heparin/PF4 products and allow NovoTek to assemble the products at its facilities in the PRC or Poland from components acquired from the Company.

Other revenue increased 1,683% during the three months ended June 30, 2017 as compared to the same period of 2016. The significant increase resulted from an initial order for manufacturing components from NovoTek totaling \$500,000. NovoTek will utilize these components along with additional materials to be purchased in a future period to assemble PIFA Heparin/PF4 products in either the PRC or Poland.

The Company's gross margin improved to 78% (2016: 71%) for the three months ended June 30, 2017. Generally, costs associated with production declined across the board; however, the Company was able to sell a large quantity of raw materials associated with a previously discontinued product that had been removed from inventory and, as such, had no book value. The Company expects the gross margin to return to the 65% to 68% range in the near-term.

Cost of sales for the three months ended June 30, 2017 totaled \$264,231 (2016: \$276,848). Direct cost of sales decreased to 10% of revenue while other cost of sales decreased to 12% for the three months ended June 30, 2017 as compared to 14% and 15% respectively for the same period in 2016.

Direct cost of sales for the three-month period ended June 30, 2017 were \$117,184 (2016: \$135,298). Other cost of sales for the three months ended June 30, 2017 were \$147,047 (2016: \$141,550).

# General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2017, totaled \$829,929, which was a 2% increase as compared to \$816,244 for the three months ended June 30, 2016.

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

| Description                              | onths Ended<br>e 30, 2017 | Ended<br>e 30, 2016 | Percent Change |  |
|--|---------------------------|---------------------|----------------|--|
| Personnel Costs                          | \$<br>223,944             | \$<br>165,021       | 36%            |  |
| Professional Service Costs               | 354.570                   | 227,246             | 56%            |  |
| Stock Market & Investor Relations Costs  | 117,253                   | 116,962             | -%             |  |
| Other General and Administrative Costs   | 134,162                   | 307,015             | (56)%          |  |
| Total General and Administrative Expense | \$<br>829,929             | \$<br>816,244       | 2%             |  |

3 Months

Personnel expenses increased by 36% for the three months ended June 30, 2017 as compared to the same period of 2016. The increase is related to the creation of the Controller's position in the Finance department and salary adjustments for executive management.

Professional service costs increased by 56% for the three months ended June 30, 2017 as compared to the same period of 2016. A significant increase in accounting and audit fees (\$104,000 (2016: \$20,600)), personnel recruitment (\$22,355 (2016: (\$25))), engineering (\$26,704 (2016: \$7,847)) and general consulting services (\$30,000 (2016: \$847)) accounted for the change.

The Company established a reserve for an uncollectable account during the three months ended June 30, 2016 for \$146,196 (2017: \$5,380) which accounted for the decline of 56% in other general and administrative expenses for the three months ended June 30, 2017. Travel restrictions, put in place earlier in the year, also contributed to the decline, totaling \$16,638 (2016: \$34,276).

# Sales and Marketing Expenses

Sales and marketing expenses for the three months ended June 30, 2017 totaled \$416,391 which was a 19% decrease as compared to \$513,430 for the three months ended June 30, 2016.

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

| Description                            | 3 Months<br>Ended<br>June 30, 2017 |    | 3 Months<br>Ended<br>June 30, 2016 | Percent Change |  |
|--|------------------------------------|----|------------------------------------|----------------|--|
| Personnel Costs                        | \$<br>181,653                      | \$ | 295,108                            | (38)%          |  |
| Professional Service Costs             | 72,079                             |    | 113,916                            | (37)%          |  |
| Royalties and Outside Commission Costs | 103,702                            |    | 30,302                             | 242%           |  |
| Other Sales and Marketing Costs        | 58,957                             |    | 74,104                             | (20)%          |  |
| Total Sales and Marketing Expenses     | \$<br>416,391                      | \$ | 513,430                            | (19)%          |  |

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

The Company renegotiated or eliminated several consulting arrangements targeted at improving market penetration or identifying marketing or distribution partners during the first half of 2016. The result is a reduction of 37% in professional service costs with general consulting services (\$68,092 (2016: \$104,958)) accounting for the majority of the savings for the three months ended June 30, 2017.

The legal settlement with ChubeWorkx Guernsey, Ltd ("ChubeWorkx"), signed on August 11, 2016, requires the Company to pay a 5% royalty on adjusted gross sales to ChubeWorkx on a quarterly basis. During the three months ended June 30, 2017, this royalty totaled \$61,502 (2016: \$-).

A significant decline in travel expenses (\$21,065 (2016: \$50,435)) and small decreases in other expenses were partially offset by an increase in technology expenses (\$21,099 (2016: \$147)) which resulted in an overall decline of 20% in other sales and marketing costs.

# **Research and Development**

Research and development expenses for the three months ended June 30, 2017 totaled \$313,835, which was a 3% decrease as compared to \$321,989 for the three months ended June 30, 2016.

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

|   | 3 Months<br>Ended |               | 3 Months<br>Ended |               |                |
|---|-------------------|---------------|-------------------|---------------|----------------|
| Description                             |                   | June 30, 2017 |                   | June 30, 2016 | Percent Change |
| Personnel Costs                         | \$                | 227,887       | \$                | 219,530       | 4%             |
| Clinical Trial Costs                    |                   | 150           |                   | 44,265        | (100)%         |
| Professional Service Costs              |                   | 18,588        |                   | 18,579        | -%             |
| Other Research and Development Costs    |                   | 67,210        |                   | 39,615        | 70%            |
| Total Research and Development Expenses | \$                | 313,835       | \$                | 321,989       | (3)%           |

Employee benefit expenses (\$22,683 (2016: \$14,050)) accounted for the majority of the 4% increase in personnel expenses during the three months ended June 30, 2017.

Clinical trial costs decreased 100% during the three months ended June 30, 2017 as compared to the same period of 2016. The Company continued to perform two clinical trials during the three months ended June 30, 2016, one to test the effectiveness of the PIFA Chlamydia assay and one for the KetoChek<sup>TM</sup> health and wellness product. Both studies were completed during 2016 and no significant expense was incurred during the three months ended June 30, 2017.

Significant increases in internal resource utilization (\$11,852 (2016: \$853)) and supplies expense (\$34,124 (2016 \$10,637)) were offset by small declines in several expense categories to account for the 70% increase in other research and development expenses.

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

| Project  | 2017 |         | <br>2016      |
|--|------|---------|---------------|
| Breath Alcohol                                 | \$   | 502     | \$<br>-       |
| Chlamydia Trachomatis                          |      | 98,325  | 5,345         |
| Heparin/PF4                                    |      | 26,425  | 16,228        |
| Ketone   |      | 1,757   | 708           |
| KetoChek <sup>TM</sup> / OxiChek <sup>TM</sup> |      | 124,499 | 181,281       |
| Metron   |      | 1,098   | -             |
| Other Projects                                 |      | -       | 33,358        |
| Pulmo Health                                   |      | 11,361  | 3,220         |
| SeraSTAT                                       |      | -       | -             |
| Tri-Cholesterol                                |      | 49,868  | 76,633        |
| VIVO   |      | -       | 5,216         |
| Total R&D Expenses:                            | \$   | 313,835 | \$<br>321,989 |

### Other Income and Expense

Other income, net of expense for the three months ended June 30, 2017 totaled \$2,653, which was a 55% decrease as compared to \$5,870 for the three months ended June 30, 2016.

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

| Description                         | E  | Months<br>Inded<br>30, 2017 | ]  | Months<br>Ended<br>e 30, 2016 | Percent Change |
|-------------------------------------|----|-----------------------------|----|-------------------------------|----------------|
| Currency Translation Loss           | \$ | (978)                       | \$ | (2,562)                       | 62%            |
| Realized Gains on Investments       |    | 605                         |    | 6,587                         | (91)%          |
| Interest and Dividends              |    | 3,026                       |    | 1,845                         | 64%            |
| Other Income                        |    |                             |    | -                             | -%             |
| Total Other Income, Net of Expenses | \$ | 2,653                       | \$ | 5,870                         | (55)%          |

Gains and losses associated with foreign currency transactions improved by 62% during the three months ended June 30, 2017 as compared to the same period of 2016, primarily a result of the increased strength of the US Dollar compared to the British Pound.

Realized gains, interest and dividend income declined to \$3,631 (2016: \$8,432). The Company's available capital for investment activities was limited during the three months ended June 30, 2017 resulting in the decline in investment income.

# Summary of Statements of Operations for the Six Months Ended June 30, 2017 and 2016

# Revenue

Akers' revenue for the six months ended June 30, 2017 totaled \$1,865,112, a 10% increase from the same period in 2016. The tables below summarize our revenue by product line and by geographic region for the six months ended June 30, 2017 and 2016 as well as the percentage of change year-over-year:

| Product Lines                             |    | 6 Months<br>Ended<br>June 30, 2017 |                                    | 6 Months<br>Ended<br>June 30, 2016 | Percent Change |  |
|---|----|------------------------------------|------------------------------------|------------------------------------|----------------|--|
| Particle ImmunoFiltration Assay ("PIFA")  | \$ | 987,668                            | \$                                 | 1,514,255                          | (35)%          |  |
| MicroParticle Catalyzed Biosensor ("MPC") |    | 277,475                            |                                    | 109,703                            | 153%           |  |
| Other                                     |    | 599,969                            |                                    | 70,552                             | 750%           |  |
| Total Revenue                             | \$ | 1,865,112                          | \$                                 | 1,694,510                          | 10%            |  |
| Geographic Region                         |    | 6 Months<br>Ended<br>June 30, 2017 | 6 Months<br>Ended<br>June 30, 2016 |                                    | Percent Change |  |
| United States                             | \$ | 1,129,619                          | \$                                 | 1,118,961                          | 1%             |  |
| People's Republic of China                |    | 627,132                            |                                    | 506,398                            | 24%            |  |
| Rest of World                             |    | 108,361                            |                                    | 69,151                             | 57%            |  |
| Total Revenue                             | \$ | 1,865,112                          | \$                                 | 1,694,510                          | 10%            |  |
| 33  | 5  |                                    |                                    |                                    |                |  |

Revenue from the Company's PIFA Heparin/PF4 Rapid Assay products decreased 35% during the six months ended June 30, 2017 over the same period of 2016. During the six months ended June 30, 2016 the Company recognized approximately \$474,000 (2017: \$-) in PIFA revenue from the Company's distribution partner in the People's Republic of China ("PRC"). The distributor continues to work with the various provincial governments in the PRC to finalize reimbursement rates for the providers. Once these rates are established, the distributor expects strong demand for the PIFA products. Revenue from PIFA related components, totaling \$500,000, during the six months ended June 30, 2017 is included in other revenue.

Total unit sales volumes for PIFA Classic and PIFA PLUSS in the United States remained steady, however; the sales mix changed slightly year-over-year. The Company experienced renewed interest in Western Europe and the Far East for the products after reviving the Conformité Européene Mark ("CE Mark"). The PIFA Classic products have shipped to Great Britain and India and is being actively marketed in the European Union and a clinical trial is scheduled in Italy.

MPC revenue increased 153% during the six months ended June 30, 2017 over the same period of 2016. Domestic and International sales of the BreathScan Breath Alcohol tests and domestic sales of the BreathScan Lync<sup>TM</sup> and OxiChek<sup>TM</sup> products accounted for the majority of the improvement.

The Company signed an amendment to the exclusive distribution agreement for the PIFA Heparin/PF4 products with NovoTek Pharmaceuticals Limited ("NovoTek") to expand their geographic region to include Poland, include other PIFA Heparin/PF4 products and allow NovoTek to assemble the products at its facilities in the PRC or Poland from components acquired from the Company.

Other revenue increased 750% during the six months ended June 30, 2017 as compared to the same period of 2016. The significant increase resulted from an initial order for manufacturing components from NovoTek totaling \$500,000. NovoTek will utilize these components along with additional materials to be purchased in a future period to assemble PIFA Heparin/PF4 products in either the PRC or Poland.

The Company's gross margin was 72% (2016: 72%) for the six months ended June 30, 2017. The Company's use of sub-contractors for assembly and packaging services increased to \$119,072 (2016: \$10,506) and increases in warehousing costs (\$39,770 (2016: \$7,662)) were offset by smaller declines in several expense categories. Additionally, the Company was able to sell its stock of raw materials associated with a previously discontinued product that had been removed from inventory and, as such, had no book value. The Company expects the gross margin to return to the 65% to 68% range in the near-term.

Cost of sales for the six months ended June 30, 2017 totaled \$522,952 (2016: \$476,876). Direct cost of sales decreased to 12% of revenue while other cost of sales increased to 16% for the six months ended June 30, 2017 as compared to 13% and 15% respectively for the same period in 2016.

Direct cost of sales for the six months ended June 30, 2017 were \$223,313 (2016: \$216,087). Other cost of sales for the six months ended June 30, 2017 were \$299,639 (2016: \$260,789).

# **General and Administrative Expenses**

General and administrative expenses for the six months ended June 30, 2017, totaled \$1,620,457, which was a 7% decrease as compared to \$1,739,806 for the six months ended June 30, 2016.

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

| Description                              | <br>onths Ended<br>e 30, 2017 | 6 Months<br>Ended<br>June 30, 2016 |           | Percent Change |  |
|--|-------------------------------|------------------------------------|-----------|----------------|--|
| Personnel Costs                          | \$<br>558,471                 | \$                                 | 543,770   | 3%             |  |
| Professional Service Costs               | 546,322                       |                                    | 477,094   | 15%            |  |
| Stock Market & Investor Relations Costs  | 199,639                       |                                    | 234,003   | (15)%          |  |
| Other General and Administrative Costs   | 316,025                       |                                    | 484,939   | (35)%          |  |
| Total General and Administrative Expense | \$<br>1,620,457               | \$                                 | 1,739,806 | (7)%           |  |

Personnel expenses increased by 3% for the six months ended June 30, 2017 as compared to the same period of 2016. The increase is related to the creation of the Controller's position in the Finance department and salary adjustments for executive management.

Professional service costs increased by 15% for the six months ended June 30, 2017 as compared to the same period of 2016. A significant increase in accounting and audit (\$104,000 (2016: \$60,896)), personnel recruitment (\$22,355 (2016: \$409)), engineering (\$56,794 (2016: \$24,605)) and general consulting services (\$52,975 (2016: \$3,388)) were offset by a decrease in legal fees (\$310,198 (2016: \$386,146)) which accounted for the change.

Decreases in consulting (\$47,185 (2016: \$61,127)) and investor relation services (\$106,687 (2016: \$130,436)) accounted for the 15% decrease in stock market & investor relations expenses.

The Company established a reserve for an uncollectable account during the <u>six</u> months ended June 30, 2016 for \$146,196 (2017:<u>\$47,741</u>) which accounted for the decline of 35% in other general and administrative expenses for the six months ended June 30, 2017. Travel restrictions, put in place earlier in the year, also contributed to the decline, totaling \$26,205 (2016: \$96,219).

### Sales and Marketing Expenses

Sales and marketing expenses for the six months ended June 30, 2017 totaled \$1,005,326 which was a 19% decrease as compared to \$1,238,754 for the six months ended June 30, 2016.

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

|  | 6 Months<br>Ended |    | 6 Months<br>Ended |                |
|--|-------------------|----|-------------------|----------------|
| Description                            | <br>June 30, 2017 |    | June 30, 2016     | Percent Change |
| Personnel Costs                        | \$<br>517,485     | \$ | 714,796           | (28)%          |
| Professional Service Costs             | 137,126           |    | 307,020           | (55)%          |
| Royalties and Outside Commission Costs | 148,836           |    | 50,045            | 197%           |
| Other Sales and Marketing Costs        | 201,879           |    | 166,893           | 21%            |
| Total Sales and Marketing Expenses     | \$<br>1,005,326   | \$ | 1,238,754         | (19)%          |

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

The Company renegotiated or eliminated several consulting arrangements targeted at improving market penetration or identifying marketing or distribution partners during the first half of 2016. The result is a reduction of 55% in professional service fees for general consulting services (\$136,714 (2016: \$220,289)) and marketing services (\$-(2016: \$51,246)) for the six months ended June 30, 2017.

The legal settlement with ChubeWorkx Guernsey, Ltd ("ChubeWorkx"), signed on August 11, 2016, requires the Company to pay a 5% royalty on adjusted gross sales to ChubeWorkx on a quarterly basis. During the six months ended June 30, 2017, this royalty totaled \$93,781 (2016: \$-).

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

## **Research and Development**

Research and development expenses for the six months ended June 30, 2017 totaled \$662,277, which was a 3% decrease as compared to \$685,280 for the six months ended June 30, 2016.

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

|   |    | 6 Months     |       |               |                |
|---|----|--------------|-------|---------------|----------------|
|   |    | Ended        | 6     | Months        |                |
| Description                             | Jı | une 30, 2017 | Ended | June 30, 2016 | Percent Change |
| Personnel Costs                         | \$ | 512,837      | \$    | 378,553       | 35%            |
| Clinical Trial Costs                    |    | 300          |       | 141,342       | (100)%         |
| Professional Service Costs              |    | 47,711       |       | 57,147        | (17)%          |
| Other Research and Development Costs    |    | 101,429      |       | 108,238       | (6)%           |
| Total Research and Development Expenses | \$ | 662,277      | \$    | 685,280       | (3)%           |

Personnel costs increased 35% during the six months ended June 30, 2017 as compared to the same period of 2016. This increase was a result of the transfer of Dr. Akers' salary and benefits from the General and Administrative department to Research and Development as he assumed his new responsibilities as Chief Scientific Director for the Company. In addition, employee benefit expenses (\$41,636 (2016: \$31,221)) also contributed to the increase.

Clinical trial costs decreased 100% during the six months ended June 30, 2017 as compared to the same period of 2016. The Company performed two clinical trials during the six months ended June 30, 2016, one to test the effectiveness of the PIFA Chlamydia assay and one for the KetoChek<sup>™</sup> health and wellness product. Both studies were completed during 2016 and no significant expense was incurred during the six months ended June 30, 2017.

A reduction in general consulting services (\$21,503 (2016: \$31,619)) for the six months ended June 30, 2017 was responsible for the 17% decline in professional service fees.

Moderate decreases in several expense categories were offset by increases in internal resource utilization (\$13,739 (2016: \$2,937)) and travel expenses (\$19,593 (2016 \$11,047)) to account for the 6% decrease in other research and development expenses.

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

| Project  | 2017 |         | <br>2016      |
|--|------|---------|---------------|
| Breath Alcohol                                 | \$   | 5,171   | \$<br>1,381   |
| Chlamydia Trachomatis                          |      | 150,033 | 10,685        |
| Heparin/PF4                                    |      | 37,923  | 72,575        |
| Ketone   |      | 3,465   | 2,125         |
| KetoChek <sup>TM</sup> / OxiChek <sup>TM</sup> |      | 214,224 | 365,178       |
| Metron   |      | 1,098   | 2,507         |
| Other Projects                                 |      | 59,688  | 101,584       |
| Pulmo Health                                   |      | 11,361  | 6,126         |
| SeraSTAT                                       |      | 5,610   | -             |
| Tri-Cholesterol                                |      | 173,112 | 117,903       |
| VIVO   |      | 592     | <br>5,216     |
| Total R&D Expenses:                            | \$   | 662,277 | \$<br>685,280 |

### **Other Income and Expense**

Other income, net of expense for the six months ended June 30, 2017 totaled \$15,536, which was a 12% increase as compared to \$13,899 for the six months ended June 30, 2016.

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

| Description                         | I  | Months<br>Ended<br>2 30, 2017 | 1  | Months<br>Ended<br>2 30, 2016 | Percent Change |
|-------------------------------------|----|-------------------------------|----|-------------------------------|----------------|
| Currency Translation Gain/(Loss)    | \$ | 9,367                         | \$ | (4,817)                       | 294%           |
| Realized Gains on Investments       |    | 1,656                         |    | 2,152                         | (23)%          |
| Interest and Dividends              |    | 4,513                         |    | 16,564                        | (73)%          |
| Other Income                        |    |                               |    |                               | -%             |
| Total Other Income, Net of Expenses | \$ | 15,536                        | \$ | 13,899                        | 12%            |

Gains and losses associated with foreign currency transactions improved by 294% during the six months ended June 30, 2017 as compared to the same period of 2016, primarily a result of the increased strength of the US Dollar compared to the British Pound and Euro.

Realized gains, interest and dividend income declined to \$6,169 (2016: \$18,716). The Company's available capital for investment activities was limited during the six months ended June 30, 2017 resulting in the decline in investment income.

## **Income Taxes**

As of June 30, 2017, 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 six months ended June 30, 2017 and 2016, the Company generated a net loss of \$2,015,918 and \$2,517,861, respectively. As of June 30, 2017 and December 31, 2016, the Company has an accumulated deficit of \$99,495,455 and \$97,479,537 and had cash and marketable securities totaling \$1,208,800 and \$122,701, respectively.

During the six months ended June 30, 2017, the Company raised \$1,652,994 in net proceeds from a public offering of 1,789,500 shares of common stock, \$1,760,317 in net proceeds from a private placement of 1,448,400 shares of common stock and \$301,200 from the exercise of warrants for 200,800 shares of common stock.

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

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

Capital expenditures for the six months ended June 30, 2017 were \$37,191 (2016: \$81,462). Capital expenditures, primarily for production, laboratory and facility improvement costs for the year ending December 31, 2017 are expected to be approximately \$65,000. As per the Company's lease agreement, the owner of the facility will be handling the majority of facility upgrades, and we anticipate financing any production and laboratory capital expenditures through working capital.

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

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

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

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

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

| Description                              |    | 6 Months<br>Ended<br>June 30, 2017 | 6 Months<br>Ended<br>June 30, 2016 | Percent<br>Change |
|--|----|------------------------------------|------------------------------------|-------------------|
| Cash at beginning of period              | \$ | 72,700                             | \$<br>402,059                      | (82)%             |
| Loss from operations                     |    | (2,015,918)                        | (2,517,861)                        | 20%               |
| Adjustments                              |    |                                    |                                    |                   |
| Non-Cash Activities                      |    | 216,392                            | 295,513                            | (40)%             |
| Cash Used in Operating Activities        |    |                                    |                                    |                   |
| Cash Consumed by Operating Activities    |    | (872,039)                          | (268,523)                          | (210)%            |
| Cash Contributed by Operating Activities |    | 78,334                             | 75,129                             | 4%                |
| Cash Flows from Investing Activities     |    |                                    |                                    |                   |
| Cash Consumed by Investing Activities    |    | (2,742,359)                        | (109,105)                          | (2,414)%          |
| Cash Contributed by Investing Activities |    | 1,745,554                          | 2,502,319                          | 30%               |
| Cash Flows from Financing Activities     |    |                                    |                                    |                   |
| Cash Consumed by Financing Activities    |    | -                                  | -                                  | -%                |
| Cash Contributed by Financing Activities | _  | 3,714,511                          | <br>                               | 100%              |
| Cash at end of period                    | \$ | 197,175                            | \$<br>379,531                      | (48)%             |

The Company's net cash consumed by investing activities totaled \$2,742,359 during the six months ended June 30, 2017. Cash of \$37,191 was consumed by capital expenditures and \$2,705,168 for the purchase of marketable securities. Proceeds from the sale of marketable securities contributed cash of \$1,745,554 for the period ended June 30, 2017.

The Company's net cash provided by investing and financing activities totaled \$2,393,214 during the six months ended June 30, 2016. Cash of \$109,105 was consumed by capital expenditures and the purchase of marketable securities. Proceeds from the sale of marketable securities contributed cash of \$2,502,319 for the period ended June 30, 2016.

Our net cash consumed by operating activities totaled \$2,593,231 during the six months ended June 30, 2017. Cash was consumed by the loss of \$2,015,918 plus non-cash adjustments of \$121,381 for depreciation and amortization of non-current assets, \$21,542 for the write-off and reserve for obsolete inventory, \$15,864 for the fair value of restricted common stock issued for services and \$12,367 for share based compensation less \$1,001 for accrued interest and dividends on marketable securities. For the six months ended June 30, 2017, decreases in deposits and other receivables of \$10,692, prepaid expenses of \$20,752, and prepaid expenses – related party of \$46,890 provided cash, primarily related to routine changes in operating activities. A net increase in trade receivables of \$372,502, trade receivables – related parties of \$93,109, inventories of \$151,720 and other assets of \$4,330 and decreases in trade and other payables of \$19,471, trade and other payables – related party of \$230,907 consumed cash from operating activities.

Our net cash consumed by operating activities totaled \$2,415,742 during the six months ended June 30, 2016. Cash was consumed by the loss of \$2,517,861 plus non-cash adjustments of \$113,906 for depreciation and amortization of non-current assets, \$146,196 for allowances for doubtful accounts, \$18,243 for share based compensation, \$8,241 for options issued for services and \$8,927 for accrued income on marketable securities. For the six months ended June 30, 2016, decreases in deposits and other receivables of \$31,196 and prepaid expenses of \$43,933 provided cash, primarily related to routine changes in operating activities. A net increase in trade receivables of \$79,906 and inventories of \$85,588 and a decrease in trade and other payables of \$103,029 consumed cash from operating activities.

### **Critical Accounting Policies**

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

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

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

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

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

The normal credit terms extended to customers ranges between 30 and 90 days. 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.

### Fair Value Measurement - Marketable Securities

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

- Level 1 Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company has the Ability to access.
- Level 2 Inputs to the valuation methodology include
  - quoted prices for similar assets or liabilities in active markets;
  - quoted prices for identical or similar assets or liabilities in inactive markets;
  - inputs other than quoted prices that are observable for the asset or liability;
  - inputs that are derived principally from or corroborated by observable market data by correlation or other means.

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

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

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

### **Intangible Assets**

The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person's breath, blood, urine and saliva. Propriety protection for the Company's products, technology and process is important to its competitive position. As of June 30, 2017, the Company has eleven patents from the United States Patent Office in effect (9,383,368; 7,896,167; 8,097,171; 8,003,061; 8,425,859; 8,871,521; 8,808,639; D691,056; D691,057; D691,058 and D786,872). Other patents are in effect in Australia through the Design Registry (348,310; 348,311 and 348,312), European Union Patents 1793906, 2684025, 002216895-0001; 002216895-0002; 002216895-0003; 3459700-0001 and 3459395-001), United Kingdom and France (2684025), Germany (602012021524.0), Spain (E12755523), China (2016305495829), in Hong Kong (HK11004006) and in Japan (1,515,170; 4,885,134; 4,931,821 5,775,790, and 6023096). Patents are in the national phase of prosecution in many Patent Cooperation Treaty participating countries. Additional proprietary technology consists of numerous different inventions. The Company intends to file additional patent applications, where appropriate, relating to new products, technologies and their use in the US, European and Asian markets. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

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

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

### Long-Lived Assets

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

#### Investments

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

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

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

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

### **Revenue Recognition**

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

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

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

### **Stock-based Compensation**

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

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

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

## Quantitative and Qualitative Disclosure About Market Risk

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

### **Interest Rates**

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



### **Off-Balance Sheet Arrangements**

We have no significant known off balance sheet arrangements.

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

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

## Item 4. Controls and Procedures.

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

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

As of June 30, 2017 and based upon that evaluation, the Company's PEO and PFO concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act, are recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Company's PEO and PFO, as appropriate, to allow timely decisions regarding required disclosure.

# (b) Changes in Internal Control over Financial Reporting.

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

# PART II - OTHER INFORMATION

# Item 1. Legal Proceedings.

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

On August 17, 2016, the Company entered into a Settlement Deed (the "Settlement Agreement") by and among the Company, ChubeWorkx Guernsey Limited ("Chube"), Thirty Six Strategies, LLC ("36S"), Gavin Moran ("Mr. Moran") and Frank Runge ("Mr. Runge") (each, a "Party" and, collectively, the "Parties") to resolve disputes related to (i) the Company's claims brought against Chube in United States District Court, District of New Jersey for outstanding amounts due to the Company pursuant to that certain promissory note (the "Note") issued in favor of Chube on December 31, 2014 ("Dispute 1"); (ii) various claims brought by Chube against the Company brought in The High Court of Justice, Queen's Bench Division Commercial Court, Royal Courts of Justice, United Kingdom arising out that certain Licensing and Supply Agreement, as amended (the "License Agreement"), pursuant to which Chube was granted a worldwide, exclusive license to import, offer for sale, sell, distribute, use, promote or label certain products using the Company's intellectual property ("Dispute 2") and (iii) various claims brought by the Company against 36S, Mr. Moran and Mr. Runge in the United States District Court, District of New Jersey, related to that certain Distribution Agreement entered into by and between the Company and 36S on October 5, 2015 ("Dispute 3" and, together with Dispute 1 and Dispute 2, the "Disputes").

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

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

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

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

Pulse subsequently filed an Amended Complaint, in which Pulse seeks not less than \$500,000 in damages and, among other items, an injunction prohibiting the Company from manufacture, use and sale of the OxiChek product. The Company answered the Amended Complaint on May 30, 2017. Discovery commenced in April 2017 and is scheduled to conclude on October 2, 2017. The Court has set the trial date for July 17, 2018.

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

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

## Item 1A. Risk Factors.

We believe there are no changes that constitute material changes from the risk factors previously disclosed in our Annual Report on Form 10-K, filed with the SEC on April 11, 2017.



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

There were no unregistered sales of the Company's equity securities during the quarter ended June 30, 2017, other than those previously reported in a Current Report on Form 8-K.

## Item 3. Defaults Upon Senior Securities.

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

## Item 4. Mine Safety Disclosures.

Not applicable.

## Item 5. Other Information.

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

## Item 6. Exhibits.

| 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 herewi | lh   |
|                |  |

# 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: August 14, 2017 | By: /s/ John J. Gormally   Name: John J. Gormally   Title: Chief Executive Officer   (Principal Executive Officer)         |
| Date: August 14, 2017 | By: /s/ Gary M. Rauch   Name: Gary M. Rauch   Title: Vice President, Finance and Treasurer   (Principal Financial Officer) |
|                       | 48   |

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

I, John J. Gormally, certify that:

- 1. I have reviewed this Form 10-Q of Akers Biosciences, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2017

By: /s/ John J. Gormally

John J. Gormally Principal Executive Officer Akers Biosciences, Inc.

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

I, Gary M. Rauch, certify that:

- 1. I have reviewed this Form 10-Q of Akers Biosciences, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2017

By: /s/ Gary M. Rauch

Gary M. Rauch Principal Financial Officer Akers Biosciences, Inc.

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

In connection with this Quarterly Report of Akers Biosciences, Inc. (the "Company"), on Form 10-Q for the period ended June 30, 2017, as filed with the U.S. Securities and Exchange Commission on the date hereof, I, John J. Gormally, Principal Executive Officer of the Company, certify to the best of my knowledge, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) Such Quarterly Report on Form 10-Q for the period ended June 30, 2017, fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in such Quarterly Report on Form 10-Q for the period ended June 30, 2017, fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2017

By: /s/ John J. Gormally

John J. Gormally Principal Executive Officer Akers Biosciences, Inc.

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

In connection with this Quarterly Report of Akers Biosciences, Inc. (the "Company"), on Form 10-Q for the period ended June 30, 2017, as filed with the U.S. Securities and Exchange Commission on the date hereof, I, Gary M. Rauch, Principal Financial Officer of the Company, certify to the best of my knowledge, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) Such Quarterly Report on Form 10-Q for the period ended June 30, 2017, fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in such Quarterly Report on Form 10-Q for the period ended June 30, 2017, fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2017

By: /s/ Gary M. Rauch

Gary M. Rauch Principal Financial Officer Akers Biosciences, Inc.