

RespireRx Pharmaceuticals Inc.  
Form 10-Q  
November 16, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2018**

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

**Commission file number: 1-16467**

**RESPIRERX PHARMACEUTICALS INC.**

(Exact name of registrant as specified in its charter)

**Delaware** **33-0303583**  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification Number)

**126 Valley Road, Suite C**

**Glen Rock, New Jersey 07452**

(Address of principal executive offices)

**(201) 444-4947**

(Registrant's telephone number, including area code)

Not applicable

(Former name, former address and former fiscal year, if changed since last report)

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 preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes  No

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of November 8, 2018 the Company had 3,588,433 shares of common stock, \$0.001 par value, issued and outstanding.

**RESPIRERX PHARMACEUTICALS INC.**

**AND SUBSIDIARY**

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### Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q of RespireRx Pharmaceuticals Inc. (“RespireRx” or the “Company”) contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Company intends that such forward-looking statements be subject to the safe harbor created thereby. These might include statements regarding the Company’s future plans, targets, estimates, assumptions, financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about research and development efforts, including, but not limited to, preclinical and clinical research design, execution, timing, costs and results, future product demand, supply, manufacturing, costs, marketing and pricing factors.

In some cases, forward-looking statements may be identified by words including “anticipates,” “believes,” “intends,” “estimates,” “expects,” “plans,” “contemplates,” “targets,” “continues,” “budgets,” “may,” and similar expressions and such statements may include, but are not limited to, statements regarding (i) future research plans, expenditures and results, (ii) potential collaborative arrangements, (iii) the potential utility of the Company’s proposed products, (iv) reorganization plans, and (v) the need for, and availability of, additional financing.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties. These forward-looking statements are based on assumptions regarding the Company’s business and technology, which involve judgments with respect to, among other things, future scientific, economic, regulatory and competitive conditions, collaborations with third parties, and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the Company’s control. Although the Company believes that the assumptions underlying the forward-looking statements are reasonable, actual results may differ materially from those set forth in the forward-looking statements. In light of the significant uncertainties inherent in the forward-looking information included herein, the inclusion of such information should not be regarded as a representation by the Company or any other person that the Company’s objectives or plans will be achieved.

Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies or changes thereto, available cash, research and development results, competition from other similar businesses, interest of third parties in collaborations with us, and market and general economic factors. This discussion should be read in conjunction with the condensed consolidated financial statements (unaudited) and notes thereto included in Item 1 of this Quarterly Report on Form 10-Q and the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2017, including the section entitled “Item 1A. Risk Factors.” The Company does not intend to update or revise any forward-looking statements to reflect new information, future events or otherwise.

**PART I - FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****RESPIRERX PHARMACEUTICALS INC.****AND SUBSIDIARY****CONDENSED CONSOLIDATED BALANCE SHEETS**

|  | <b>September<br/>30, 2018</b><br>(unaudited) | <b>December 31,<br/>2017</b> |
|--|--|------------------------------|
| <b>ASSETS</b>  |  |                              |
| Current assets:  |  |                              |
| Cash and cash equivalents  | \$80,686                                     | \$84,902                     |
| Advance payment on research contract   | 48,912                                       | 48,912                       |
| Prepaid expenses, including current portion of long-term prepaid insurance of \$14,945 at September 30, 2018 and December 31, 2017   | 67,137                                       | 42,897                       |
| Total current assets   | 196,735                                      | 176,711                      |
| Long-term prepaid insurance, net of current portion of \$14,945 at September 30, 2018 and December 31, 2017  | 6,850  | 18,059                       |
| Total assets   | \$203,585                                    | \$194,770                    |
| <b>LIABILITIES AND STOCKHOLDERS' DEFICIENCY</b>  |  |                              |
| Current liabilities:   |  |                              |
| Accounts payable and accrued expenses, including \$364,837 and \$228,939 payable to related parties at September 30, 2018 and December 31, 2017, respectively                                      | \$3,254,290                                  | \$2,922,013                  |
| Accrued compensation and related expenses  | 1,115,800                                    | 479,300                      |
| Convertible notes payable, currently due and payable on demand, including accrued interest of \$57,647 and \$98,646 at September 30, 2018 and December 31, 2017, respectively (Note 4)             | 182,647                                      | 374,646                      |
| Note payable to SY Corporation, including accrued interest of \$303,216 and \$267,335 at September 30, 2018 and December 31, 2017, respectively (payment obligation currently in default – Note 4) | 728,290                                      | 583,827                      |
| Notes payable to officers, including accrued interest of \$45,808 and \$26,538 as of September 30, 2018 and December 31, 2017, respectively (Note 4)   | 251,009                                      | 181,738                      |
| Other short-term notes payable   | 30,703                                       | 8,630                        |

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|  |               |               |
|--|---------------|---------------|
| Total current liabilities  | 5,562,739     | 4,550,154     |
| Commitments and contingencies (Note 8)   |               |               |
| Stockholders' deficiency: (Note 6)   |               |               |
| Series B convertible preferred stock, \$0.001 par value; \$0.6667 per share liquidation preference; aggregate liquidation preference \$25,001; shares authorized: 37,500; shares issued and outstanding: 11 common shares issuable upon conversion at 0.00030 common shares per Series B share | 21,703        | 21,703        |
| Common stock, \$0.001 par value; shares authorized: 65,000,000; shares issued and outstanding: 3,588,433 and 3,065,261 at September 30, 2018 and December 31, 2017, respectively (Note 2)  | 3,588         | 3,065         |
| Additional paid-in capital   | 158,335,634   | 157,422,110   |
| Accumulated deficit  | (163,720,079) | (161,802,262) |
| Total stockholders' deficiency   | (5,359,154 )  | (4,355,384 )  |
| Total liabilities and stockholders' deficiency   | \$203,585     | \$194,770     |

See accompanying notes to condensed consolidated financial statements (unaudited).



**RESPIRERX PHARMACEUTICALS INC.****AND SUBSIDIARY****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)**

|   | <b>Three Months Ended</b> |              | <b>Nine Months Ended</b> |                |
|---|---------------------------|--------------|--------------------------|----------------|
|   | <b>September 30,</b>      |              | <b>September 30,</b>     |                |
|   | <b>2018</b>               | <b>2017</b>  | <b>2018</b>              | <b>2017</b>    |
| Operating expenses:   |                           |              |                          |                |
| General and administrative, including \$204,383 and \$232,401 to related parties for the three months ended September 30, 2018 and 2017, respectively, and \$614,465 and \$1,671,765 to related parties for the nine months ended September 30, 2018 and 2017, respectively | \$330,560                 | \$404,642    | \$1,118,335              | \$2,415,718    |
| Research and development, including \$122,400 and \$133,983 to related parties for the three months ended September 30, 2018 and 2017, respectively, and \$367,613 and \$702,718 to related parties for the nine months ended September 30, 2018 and 2017, respectively     | 173,036                   | 188,506      | 478,262                  | 1,147,633      |
| Total operating expenses  | 503,596                   | 593,148      | 1,596,597                | 3,563,351      |
| Loss from operations  | (503,596 )                | (593,148 )   | (1,596,597 )             | (3,563,351 )   |
| Loss on extinguishment of debt and other liabilities in exchange for equity   | -                         | -            | (116,407 )               | -              |
| Interest expense, including \$11,714 and \$3,992 to related parties for the three months ended September 30, 2018 and 2017, respectively, and \$29,937 and \$11,688 to related parties for the nine months ended September 30, 2018 and 2017, respectively                  | (35,161 )                 | (26,354 )    | (96,231 )                | (77,674 )      |
| Foreign currency transaction gain (loss)  | 2,983                     | 960          | (108,582 )               | (30,728 )      |
| Net loss  | (535,774 )                | (618,542 )   | (1,917,817 )             | (3,671,753 )   |
| Net loss attributable to common stockholders  | \$(535,774 )              | \$(618,542 ) | \$(1,917,817 )           | \$(3,671,753 ) |
| Net loss per common share - basic and diluted   | \$(0.16 )                 | \$(0.27 )    | \$(0.59 )                | \$(1.62 )      |
| Weighted average common shares outstanding - basic and diluted  | 3,398,940                 | 2,333,257    | 3,228,528                | 2,261,160      |

See accompanying notes to condensed consolidated financial statements (unaudited).



**RESPIRERX PHARMACEUTICALS INC.****AND SUBSIDIARY****CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' DEFICIENCY****(Unaudited)****Nine Months Ended September 30, 2018**

|  | Series B<br>Convertible<br>Preferred Stock |          | Common Stock |              | Additional         | Accumulated     | Total                       |
|--|--|----------|--------------|--------------|--------------------|-----------------|-----------------------------|
|  | Shares                                     | Amount   | Shares       | Par<br>Value | Paid-in<br>Capital | Deficit         | Stockholders'<br>Deficiency |
| Balance, December 31, 2017   | 37,500                                     | \$21,703 | 3,065,261    | \$3,065      | \$157,422,110      | \$(161,802,262) | \$(4,355,384 )              |
| Fair value of common stock<br>options issued to consultants                          | -  | -        | -            | -            | 349,777            | -               | 349,777                     |
| Common stock issued<br>related to extinguishment of<br>convertible notes             | -  | -        | 284,358      | 284          | 318,236            | -               | 318,520                     |
| Sale of common stock units<br>in private placement, net of<br>escrow fees of \$5,000 | -  | -        | 191,194      | 191          | 195,559            | -               | 195,750                     |
| Issuance of common stock<br>units in exchange for note<br>payable to officer         | -  | -        | 47,620       | 48           | 49,952             | -               | 50,000                      |
| Net loss   | -  | -        | -            | -            | -                  | (1,917,817 )    | (1,917,817 )                |
| Balance, September 30,<br>2018   | 37,500                                     | \$21,703 | 3,588,433    | \$3,588      | \$158,335,634      | \$(163,720,079) | \$(5,359,154 )              |

See accompanying notes to condensed consolidated financial statements (unaudited).

**RESPIRERX PHARMACEUTICALS INC.****AND SUBSIDIARY****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)**

|   | Nine Months Ended<br>September 30, |               |
|---|------------------------------------|---------------|
|   | 2018                               | 2017          |
| Cash flows from operating activities:                                       |                                    |               |
| Net loss  | \$(1,917,817)                      | \$(3,671,753) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                    |               |
| Depreciation expense  | -                                  | 4,860         |
| Stock-based compensation expense included in -                              |                                    |               |
| General and administrative expenses   | 14,248                             | 1,150,925     |
| Research and development expenses   | -                                  | 606,901       |
| Foreign currency transaction loss   | 108,582                            | 30,728        |
| Loss on extinguishment of debt  | 105,253                            | -             |
| Loss on extinguishment of other liabilities                                 | 11,154                             | -             |
| Changes in operating assets and liabilities:                                |                                    |               |
| (Increase) decrease in -  |                                    |               |
| Prepaid expenses  | (13,030 )                          | 5,599         |
| Increase (decrease) in -  |                                    |               |
| Accounts payable and accrued expenses                                       | 456,302                            | 463,510       |
| Accrued compensation and related expenses                                   | 836,849                            | 812,874       |
| Notes payable and accrued interest  | 198,493                            | 75,540        |
| Short-term note payable   | -                                  | 24,999        |
| Net cash used in operating activities                                       | (199,966 )                         | (495,817 )    |
| Cash flows from financing activities:                                       |                                    |               |
| Proceeds from sale of common stock units                                    | 200,750                            | 476,000       |
| Placement agent and other offering fees                                     | (5,000 )                           | (20,000 )     |
| Net cash provided by financing activities                                   | 195,750                            | 456,000       |
| Cash and cash equivalents:  |                                    |               |
| Net (decrease) increase   | (4,216 )                           | (39,817 )     |
| Balance at beginning of period  | 84,902                             | 92,040        |
| Balance at end of period  | \$80,686                           | \$52,223      |

(Continued)



**RESPIRERX PHARMACEUTICALS INC.****AND SUBSIDIARY****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)****(Unaudited)**

|   | Nine Months Ended<br>September 30, |           |
|---|------------------------------------|-----------|
|   | 2018                               | 2017      |
| Supplemental disclosures of cash flow information:  |                                    |           |
| Cash paid for -   |                                    |           |
| Interest  | \$2,802                            | \$2,133   |
| Non-cash financing activities:  |                                    |           |
| 10% convertible notes payable, including accrued interest of \$62,267, exchanged for common stock               | \$213,266                          | \$-       |
| Accounts payable and accrued expenses extinguished with common stock options                                    | \$335,529                          | -         |
| Officer note payable, exchanged for common stock units  | \$50,000                           | \$-       |
| Accrual of fees payable to placement agent in connection with the sale of common stock units                    | \$-                                | \$20,000  |
| Fair value of common stock warrants issued to placement agent in connection with the sale of common stock units | \$-                                | \$27,648  |
| Reclassification of non-permanent equity  | \$-                                | \$185,000 |

See accompanying notes to condensed consolidated financial statements (unaudited).

**RESPIRERX PHARMACEUTICALS INC.**

**AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**Three Months and Nine Months Ended September 30, 2018 and 2017**

**1. Organization and Basis of Presentation**

**Organization**

RespireRx Pharmaceuticals Inc. (“RespireRx”) was formed in 1987 under the name Cortex Pharmaceuticals, Inc. to engage in the discovery, development and commercialization of innovative pharmaceuticals for the treatment of neurological and psychiatric disorders. On December 16, 2015, RespireRx filed a Certificate of Amendment to its Second Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to amend its Second Restated Certificate of Incorporation to change its name from Cortex Pharmaceuticals, Inc. to RespireRx Pharmaceuticals Inc. While developing potential applications for respiratory disorders, RespireRx has retained and expanded its ampakine intellectual property and data with respect to neurological and psychiatric disorders and is considering developing certain potential products in this platform, pending additional financing and/or strategic relationships.

In August 2012, RespireRx acquired Pier Pharmaceuticals, Inc. (“Pier”), which is now its wholly-owned subsidiary.

**Basis of Presentation**

The condensed consolidated financial statements are of RespireRx and its wholly-owned subsidiary, Pier (collectively referred to herein as the “Company” or “we” or “our” unless the context indicates otherwise). The condensed consolidated financial statements of the Company at September 30, 2018 and for the three and nine month periods ended September 30, 2018 and 2017, are unaudited. In the opinion of management, all adjustments (including normal

recurring adjustments) have been made that are necessary to present fairly the condensed consolidated financial position of the Company as of September 30, 2018, the results of its condensed consolidated operations for the three and nine month periods ended September 30, 2018 and 2017, and its condensed consolidated cash flows for the nine months ended September 30, 2018 and 2017. Condensed consolidated operating results for the interim periods presented are not necessarily indicative of the results to be expected for a full fiscal year. The consolidated balance sheet at December 31, 2017 has been derived from the Company's audited consolidated financial statements at such date.

The condensed consolidated financial statements and related notes have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been omitted pursuant to such rules and regulations. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and other information included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, as filed with the SEC.

## **2. Business**

The mission of the Company is to develop innovative and revolutionary treatments to combat diseases caused by disruption of neuronal signaling. We are developing treatment options that address conditions that affect millions of people, but for which there are few or poor treatment options, including obstructive sleep apnea ("OSA"), attention deficit hyperactivity disorder ("ADHD") and recovery from spinal cord injury ("SCI"), as well as certain neurological orphan diseases such as Fragile X Syndrome. RespireRx is developing a pipeline of new drug products based on our broad patent portfolios for two drug platforms: cannabinoids, including dronabinol ("Δ9-THC"), and the ampakines, proprietary compounds that positively modulate AMPA-type glutamate receptors to promote neuronal function.

RespireRx is developing a number of potential products. From the cannabinoid platform, two Phase 2 clinical trials have been completed demonstrating the ability of dronabinol to significantly reduce the symptoms of OSA, which management believes is potentially a multi-billion-dollar market. Subject to raising sufficient financing, we believe that we have put most of the necessary pieces into place to rapidly initiate a Phase 3 clinical trial program. By way of definition, when a new drug is allowed by the United States Food and Drug Administration ("FDA") to be tested in humans, Phase 1 clinical trials are conducted in healthy people to determine safety and pharmacokinetics. If successful, Phase 2 clinical trials are conducted in patients to determine safety and preliminary efficacy. Phase 3 trials, large scale studies to determine efficacy and safety, are the final step prior to seeking FDA approval to market a drug.



From our ampakine platform, our lead clinical compounds, CX717 and CX1739, have successfully completed multiple Phase 1 safety trials. Both compounds have also completed Phase 2 efficacy trials demonstrating target engagement, by antagonizing the ability of opioids to induce respiratory depression. CX717 has completed a Phase 2 trial demonstrating the ability to significantly reduce the symptoms of adult ADHD. In an early Phase 2 study, CX1739 improved breathing in patients with central sleep apnea. Preclinical studies have highlighted the potential ability of these ampakines to improve motor function in animals with spinal injury. Subject to raising sufficient financing (of which no assurance can be provided), we believe that we will be able to rapidly initiate a human Phase 2 study with CX1739 and/or CX717 in patients with spinal cord injury and a human Phase 2B study in patients with ADHD with either CX717 or CX1739.

RespireRx is considering an internal restructuring plan that contemplates spinning out the cannabinoid platform into what would initially be a wholly-owned subsidiary that the Company currently intends would ultimately have its own management team and board of directors. This spin-out company would be tasked with raising financing in order to develop and commercialize the dronabinol platform for the treatment of OSA.

As previously disclosed on June 19, 2018, James S. Manuso, Ph.D., the Company's former President and Chief Executive Officer, resigned as an officer and as Vice Chairman and a member of the Company's Board of Directors, effective as of the end of the term of his employment agreement, September 30, 2018. On October 12, 2018, Arnold S. Lippa, Ph.D. was named Interim President and Interim Chief Executive Officer. Dr. Lippa continues to serve as the Company's Chief Scientific Officer and Chairman of the Board of Directors.

### ***Going Concern***

The Company's condensed consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has incurred net losses of \$1,917,817 for the nine months ended September 30, 2018 and \$4,291,483 for the fiscal year ended December 31, 2017, and negative operating cash flows of \$199,966 for the nine months ended September 30, 2018 and \$697,009 for the fiscal year ended December 31, 2017. The Company also had a stockholders' deficiency of \$5,359,154 at September 30, 2018 and expects to continue to incur net losses and negative operating cash flows for at least the next few years. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern, and the Company's independent registered public accounting firm, in its report on the Company's consolidated financial statements for the year ended December 31, 2017, expressed substantial doubt about the Company's ability to continue as a going concern.

The Company is currently, and has for some time, been in significant financial distress. It has extremely limited cash resources and current assets and has no ongoing source of sustainable revenue. Management is continuing to address various aspects of the Company's operations and obligations, including, without limitation, debt obligations, financing

requirements, intellectual property, licensing agreements, legal and patent matters and regulatory compliance, and has taken steps to continue to raise new debt and equity capital to fund the Company's business activities from both related and unrelated parties.

The Company is continuing its efforts to raise additional capital in order to be able to pay its liabilities and fund its business activities on a going forward basis, including the pursuit of the Company's planned research and development activities. The Company regularly evaluates various measures to satisfy the Company's liquidity needs, including development and other agreements with collaborative partners and, when necessary, seeking to exchange or restructure the Company's outstanding securities. The Company is evaluating certain changes to its operations and structure to facilitate raising capital from sources that may be interested in financing only discrete aspects of the Company's development programs. Such changes could include a significant reorganization, which may include the formation of one or more subsidiaries into which one or more programs may be contributed. As a result of the Company's current financial situation, the Company has limited access to external sources of debt and equity financing. Accordingly, there can be no assurances that the Company will be able to secure additional financing in the amounts necessary to fully fund its operating and debt service requirements. If the Company is unable to access sufficient cash resources, the Company may be forced to discontinue its operations entirely and liquidate.

### **3. Summary of Significant Accounting Policies**

#### ***Principles of Consolidation***

The accompanying condensed consolidated financial statements are prepared in accordance with United States generally accepted accounting principles ("GAAP") and include the financial statements of RespireRx and its wholly-owned subsidiary, Pier. Intercompany balances and transactions have been eliminated in consolidation.

### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions. These estimates and assumptions affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include, among other things, accounting for potential liabilities, and the assumptions used in valuing stock-based compensation issued for services. Actual amounts may differ from those estimates.

### ***Concentrations of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company limits its exposure to credit risk by investing its cash with high quality financial institutions. The Company's cash balances may periodically exceed federally insured limits. The Company has not experienced a loss in such accounts to date.

### ***Cash Equivalents***

The Company considers all highly liquid short-term investments with maturities of less than three months when acquired to be cash equivalents.

### ***Fair Value of Financial Instruments***

The authoritative guidance with respect to fair value of financial instruments established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below. Disclosure as to transfers into and out of Levels 1 and 2, and activity in Level 3 fair value measurements, is also required.

Level 1. Observable inputs such as quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include active-exchange traded securities and exchange-based derivatives.

Level 2. Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange-based derivatives, mutual funds, and fair-value hedges.

Level 3. Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently-traded, non-exchange-based derivatives and commingled investment funds, and are measured using present value pricing models.

The Company determines the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, the Company performs an analysis of the assets and liabilities at each reporting period end.

The carrying amounts of financial instruments (consisting of cash, cash equivalents, advances on research grants and accounts payable and accrued expenses) are considered by the Company to be representative of the respective fair values of these instruments due to the short-term nature of those instruments. With respect to the note payable to SY Corporation and the convertible notes payable, management does not believe that the credit markets have materially changed for these types of borrowings since the original borrowing date. The Company considers the carrying amounts of the notes payable to officers, inclusive of accrued interest, to be representative of the respective fair values of such instruments due to the short-term nature of those instruments and their terms.

### ***Deferred Financing Costs***

Costs incurred in connection with ongoing debt and equity financings, including legal fees, are deferred until the related financing is either completed or abandoned.

Costs related to abandoned debt or equity financings are charged to operations in the period of abandonment. Costs related to completed debt financings are presented as a direct deduction from the carrying amount of the related debt liability (see “Capitalized Financing Costs” below). Costs related to completed equity financings are charged directly to additional paid-in capital.

### ***Capitalized Financing Costs***

The Company presents debt issuance costs related to debt liability in its condensed consolidated balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with the presentation for debt discounts.

### ***Convertible Notes Payable***

#### ***Original Issuance of Notes and Warrants***

Convertible notes are evaluated to determine if they should be recorded at amortized cost. To the extent that there are associated warrants, the convertible notes and warrants are evaluated to determine if there are embedded derivatives to be identified, bifurcated and valued at fair value in connection with and at the time of such financing.

#### ***2018 Notes Exchange***

In cases where debt or other liabilities are exchanged for equity, the Company compares the carrying value of debt, inclusive of accrued interest, if applicable, being exchanged for equity to the fair value of the equity issued and records any loss or gain as a result of such exchange. See Note 4. Notes Payable.



### ***Extinguishment of Debt***

The Company accounts for the extinguishment of debt in accordance with GAAP by comparing the carrying value of the debt to the fair value of consideration paid or assets given up and recognizing a loss or gain in the condensed consolidated statement of operations in the amount of the difference in the period in which such transaction occurs.

### ***Equipment***

Equipment is recorded at cost and depreciated on a straight-line basis over their estimated useful lives, which range from three to five years. All equipment was fully depreciated as of September 30, 2018.

### ***Long-Term Prepaid Insurance***

Long-term prepaid insurance represents the premium paid in March 2017 for directors' and officers' insurance tail coverage, which is being amortized on a straight-line basis over the policy period of six years. The amount amortizable in the ensuing twelve-month period is recorded as a current asset in the Company's condensed consolidated balance sheet at each reporting date.

### ***Impairment of Long-Lived Assets***

The Company reviews its long-lived assets, including long-term prepaid insurance, for impairment whenever events or changes in circumstances indicate that the total amount of an asset may not be recoverable, but at least annually. An impairment loss is recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition is less than the asset's carrying amount. The Company has not deemed any long-lived assets as impaired at September 30, 2018.

### ***Stock-Based Compensation***

The Company periodically issues common stock and stock options to officers, directors, Scientific Advisory Board members, consultants and other vendors for services rendered. Such issuances vest and expire according to terms established at the issuance date of each grant.

The Company accounts for stock-based payments to officers and directors by measuring the cost of services received in exchange for equity awards based on the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards. The Company accounts for stock-based payments to Scientific Advisory Board members, consultants and other vendors by determining the value of the stock compensation based upon the measurement date at either (a) the date at which a performance commitment is reached, or (b) at the date at which the necessary performance to earn the equity instruments is complete.

Stock grants, which are generally subject to time-based vesting, are measured at the grant date fair value and charged to operations ratably over the vesting period.



Stock options granted to members of the Company's Scientific Advisory Board, outside consultants and other vendors are revalued each reporting period until vested to determine the amount to be recorded as an expense in the respective period. As the stock options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the value on the date of vesting.

The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the life of the equity award, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock over the term of the equity award. Estimated volatility is based on the historical volatility of the Company's common stock. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of common stock is determined by reference to the quoted market price of the Company's common stock.

Stock options and warrants issued to non-employees as compensation for services to be provided to the Company or in settlement of debt are accounted for based upon the fair value of the services provided or the estimated fair value of the stock option or warrant, whichever can be more clearly determined. Management uses the Black-Scholes option-pricing model to determine the fair value of the stock options and warrants issued by the Company. The Company recognizes this expense over the period in which the services are provided.

There were no stock options requiring an assessment of value during the nine months ended September 30, 2018.

For stock options requiring an assessment of value during the nine months ended September 30, 2017, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model using the following assumptions:

|                         |               |       |
|-------------------------|---------------|-------|
| Risk-free interest rate | 1.83% to 1.92 | %     |
| Expected dividend yield | 0             | %     |
| Expected volatility     | 132.87        | %     |
| Expected life           | 4.833         | years |

The Company recognizes the fair value of stock-based compensation in general and administrative costs and in research and development costs, as appropriate, in the Company's condensed consolidated statements of operations. The Company issues new shares of common stock to satisfy stock option and warrant exercises. There were no stock options exercised during the nine months ended September 30, 2018. and 2017.

There were no warrants issued as compensation or for services during the nine months ended September 30, 2018 requiring such assessment. During the nine months ended September 30, 2017, the Company issued warrants to purchase 8,000 shares of the Company's common stock at an exercise price of \$2.75 per share and expiring on December 31, 2021 to Aurora Capital LLC, an affiliate of the Company, for placement agent services. The warrants were valued at \$27,648 and were accounted for in Additional paid-in capital as of March 31, 2017, the date of issuance, and remain valued at that amount as of September 30, 2017 and December 31, 2017.

### *Income Taxes*

The Company accounts for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

Pursuant to Internal Revenue Code Sections 382 and 383, use of the Company's net operating loss and credit carryforwards may be limited if a cumulative change in ownership of more than 50% occurs within any three-year period since the last ownership change. The Company may have had a change in control under these Sections. However, the Company does not anticipate performing a complete analysis of the limitation on the annual use of the net operating loss and tax credit carryforwards until the time that it anticipates it will be able to utilize these tax attributes.

As of September 30, 2018, the Company did not have any unrecognized tax benefits related to various federal and state income tax matters and does not anticipate any material amount of unrecognized tax benefits within the next 12 months.

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. As of September 30, 2018, the Company had not recorded any liability for uncertain tax positions. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

### ***Foreign Currency Transactions***

The note payable to SY Corporation, which is denominated in a foreign currency (the South Korean Won), is translated into the Company's functional currency (the United States Dollar) at the exchange rate on the balance sheet date. The foreign currency exchange gain or loss resulting from translation is recognized in the related condensed consolidated statements of operations.

### ***Research and Development***

Research and development costs include compensation paid to management directing the Company's research and development activities, and fees paid to consultants and outside service providers and organizations (including

research institutes at universities), and other expenses relating to the acquisition, design, development and clinical testing of the Company's treatments and product candidates.

Research and development costs incurred by the Company under research grants are expensed as incurred over the life of the underlying contracts, unless the terms of the contract indicate that a different expensing schedule is more appropriate.

The Company reviews the status of its research and development contracts on a quarterly basis.

On May 6, 2016, the Company made an advance payment to Duke University with respect to the Phase 2A clinical trial of CX1739. At September 30, 2018, an asset balance of \$48,912 remained from the advance payment.

### *License Agreements*

Obligations incurred with respect to mandatory payments provided for in license agreements are recognized ratably over the appropriate period, as specified in the underlying license agreement, and are recorded as liabilities in the Company's condensed consolidated balance sheet, with a corresponding charge to research and development costs in the Company's condensed consolidated statement of operations. Obligations incurred with respect to milestone payments provided for in license agreements are recognized when it is probable that such milestone will be reached and are recorded as liabilities in the Company's condensed consolidated balance sheet, with a corresponding charge to research and development costs in the Company's condensed consolidated statement of operations. Payments of such liabilities are made in the ordinary course of business.

### *Patent Costs*

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and any related patent applications, all patent costs, including patent-related legal and filing fees, are expensed as incurred.

### *Earnings per Share*

The Company's computation of earnings per share ("EPS") includes basic and diluted EPS. Basic EPS is measured as the income (loss) attributable to common stockholders divided by the weighted average common shares outstanding for the period. Diluted EPS is similar to basic EPS but presents the dilutive effect on a per share basis of potential common shares (e.g., warrants and options) as if they had been converted at the beginning of the periods presented, or issuance date, if later. Potential common shares that have an anti-dilutive effect (i.e., those that increase income per share or decrease loss per share) are excluded from the calculation of diluted EPS.

Net income (loss) attributable to common stockholders consists of net income or loss, as adjusted for actual and deemed preferred stock dividends declared, amortized or accumulated.

Loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the respective periods. Basic and diluted loss per common share is the same for all periods presented because all warrants and stock options outstanding are anti-dilutive.

At September 30, 2018 and 2017, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

|                                      | September 30, |           |
|--------------------------------------|---------------|-----------|
|                                      | 2018          | 2017      |
| Series B convertible preferred stock | 11            | 11        |
| Convertible notes payable            | 16,061        | 32,239    |
| Common stock warrants                | 1,703,229     | 985,915   |
| Common stock options                 | 4,323,317     | 2,046,749 |
| Total                                | 6,042,618     | 3,064,914 |

***Reclassifications***

Certain comparative figures in 2017 have been reclassified to conform to the current quarter's presentation. These reclassifications were immaterial, both individually and in the aggregate.

***Recent Accounting Pronouncements***

Management does not believe that any recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's financial statement presentation or disclosures.

**4. Notes Payable**

***Convertible Notes Payable***

The convertible notes sold to investors in 2014 and 2015, which aggregated a total of \$579,500, had a fixed interest rate of 10% per annum and those that remain outstanding are convertible into common stock at a fixed price of \$11.3750 per share. The convertible notes have no reset rights or other protections based on subsequent equity transactions, equity-linked transactions or other events. The warrants to purchase 50,945 shares of common stock issued in connection with the sale of the convertible notes were exercisable at a fixed price of \$11.3750 per share. All such warrants have either been exchanged as part of April and May 2016 note and warrant exchange agreements or expired on September 15, 2016.

The maturity date of the convertible notes was extended to September 15, 2016 and included the issuance of 27,936 additional warrants to purchase common stock, exercisable at \$11.375 per share of common stock, which expired on September 15, 2016.

The convertible notes (including those for which default notices have been received) consist of the following at September 30, 2018 and December 31, 2017:

|                                   | September<br>30, 2018 | December<br>31, 2017 |
|-----------------------------------|-----------------------|----------------------|
| Principal amount of notes payable | \$ 125,000            | \$ 276,000           |
| Add accrued interest payable      | 57,647                | 98,646               |
|                                   | \$ 182,647            | \$ 374,646           |

Between October 3, 2016 and October 25, 2016, the Company received several notices of default from holders of convertible notes. The effect of such notices of default was to increase the annual interest rate from 10% to 12% with respect to the convertible notes to which such notices applied. On February 28, 2018, two of such convertible notes

were exchanged for common stock of the Company and were extinguished. The Company measured the fair value of the shares of common stock issued to the holder in respect to the extinguishment of the two convertible notes as compared to the aggregate of principal and interest on such notes and recorded a loss of \$66,782 which is the amount of the excess fair value paid as compared to the aggregate principal and interest extinguished. The total amount of principal and accrued interest that was due and payable was \$43,552. The convertible notes were exchanged for 58,071 shares of the Company's common stock. The effective exchange rate was \$0.75 per share of the Company's common stock. The closing price of the Company's common stock on February 28, 2018, was \$1.90 as reported by the OTC Markets.

On February 28, 2018, the Board of Directors authorized the offering of a similar exchange arrangement at the same effective exchange rate of \$0.75 per share of the Company's common stock to all remaining holders of 10% Convertible Notes (some of which convertible notes are the subject of notices of default and therefore accruing annual interest at 12%).

On May 31, 2018, the Company entered into exchange agreements with four holders of convertible notes who agreed to exchange their convertible notes for the Company's common stock at an exchange rate of \$0.75 per share. The note holders, in the aggregate, agreed to exchange \$169,715 of principal and accrued interest for 226,287 shares of the Company's common stock. The closing price of the Company's common stock on May 31, 2018 was \$0.92 per share. As a result of the exchange, \$169,715 of convertible notes, inclusive of accrued interest, were cancelled and \$208,185 market value of common stock was issued, resulting in a loss on extinguishment of debt of \$38,470.



As of September 30, 2018, principal and accrued interest on the remaining outstanding convertible note subject to a default notice totaled \$37,817, of which \$12,817 was accrued interest. As of December 31, 2017, principal and accrued interest on convertible notes subject to default notices totaled \$91,028 of which \$25,028 was accrued interest.

As of September 30, 2018, the remaining total outstanding convertible notes, inclusive of accrued interest, were convertible into 16,061 shares of the Company's common stock, including 5,071 shares attributable to accrued interest of \$57,647 payable as of such date. As of December 31, 2017, the outstanding convertible notes were convertible into 32,941 shares of the Company's common stock, including 8,677 shares attributable to accrued interest of \$98,646 payable as of such date. Such convertible notes will continue to accrue interest until exchanged, paid or otherwise discharged. There can be no assurance that any of the additional holders of the remaining 10% Convertible Notes will exchange their notes.

***Note Payable to SY Corporation Co., Ltd.***

On June 25, 2012, the Company borrowed 465,000,000 Won (the currency of South Korea, equivalent to approximately \$400,000 United States Dollars) from and executed a secured note payable to SY Corporation Co., Ltd., formerly known as Samyang Optics Co. Ltd. ("SY Corporation"), an approximately 20% common stockholder of the Company at that time. SY Corporation was a significant stockholder and a related party at the time of the transaction but has not been a significant stockholder or related party of the Company subsequent to December 31, 2014. The note accrues simple interest at the rate of 12% per annum and had a maturity date of June 25, 2013. The Company has not made any payments on the promissory note. At June 30, 2013 and subsequently, the promissory note was outstanding and in default, although SY Corporation has not issued a notice of default or a demand for repayment. Management believes that SY Corporation is in default of its obligations under its January 2012 license agreement, as amended, with the Company, but the Company has not yet issued a notice of default. The Company has in the past made several efforts towards a comprehensive resolution of the aforementioned matters involving SY Corporation. During the nine months ended September 30, 2018, there were no further communications between the Company and SY Corporation.

The promissory note is secured by collateral that represents a lien on certain patents owned by the Company, including composition of matter patents for certain of the Company's high impact ampakine compounds and the low impact ampakine compounds CX2007 and CX2076, and other related compounds. The security interest does not extend to the Company's patents for its ampakine compounds CX717, CX1739 and CX1942, or to the patent for the use of ampakine compounds for the treatment of respiratory depression.

Note payable to SY Corporation consists of the following at September 30, 2018 and December 31, 2017:

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|   | September<br>30, 2018 | December<br>31, 2017 |
|---|-----------------------|----------------------|
| Principal amount of note payable        | \$ 399,774            | \$ 399,774           |
| Accrued interest payable                | 303,216               | 267,335              |
| Foreign currency transaction adjustment | 25,300                | (83,282 )            |
|   | \$ 728,290            | \$ 583,827           |

Interest expense with respect to this promissory note was \$12,092 and \$12,092 for each of the three months ended September 30, 2018 and 2017, respectively. Interest expense with respect to this promissory note was \$35,881 and \$35,881 for nine months ended September 30, 2018 and 2017, respectively.

*Advances and Notes Payable to Officers*

On January 29, 2016, Dr. Arnold S. Lippa, the Company's Interim President, Interim Chief Executive Officer, Chief Scientific Officer and Chairman of the Board of Directors, advanced \$52,600 to the Company for working capital purposes under a demand promissory note with interest at 10% per annum. On September 23, 2016, Dr. Lippa advanced \$25,000 to the Company for working capital purposes under a second demand promissory note with interest at 10% per annum. The notes are secured by the assets of the Company. Additionally, on April 9, 2018, Dr. Lippa advanced another \$50,000 to the Company as discussed in more detail below. During the three and nine months ended September 30, 2018, \$3,319 and \$8,963 was charged to interest expense with respect to these notes, respectively. In connection with the loans, Dr. Lippa was issued fully vested warrants to purchase 15,464 shares of the Company's common stock, 10,309 of which have an exercise price of \$5.1025 per share and 5,155 of which have an exercise price of \$4.85 which were the closing prices of the Company's common stock on the respective dates of grant. The warrants expire on January 29, 2019 and September 23, 2019 respectively and may be exercised on a cashless basis.

On February 2, 2016, Dr. James S. Manuso, the Company's then Chief Executive Officer and Vice Chairman of the Board of Directors, advanced \$52,600 to the Company for working capital purposes under a demand promissory note with interest at 10% per annum. On September 22, 2016, Dr. Manuso, advanced \$25,000 to the Company for working capital purposes under a demand promissory note with interest at 10% per annum. The notes are secured by the assets of the Company. Additionally, on April 9, 2018, Dr. Manuso advanced another \$50,000 to the Company as discussed in more detail below. During the three and nine months ended September 30, 2018, \$3,964 and \$9,206 was charged to interest expense with respect to these notes, respectively. In connection with the loans, Dr. Manuso was issued fully vested warrants to purchase 13,092 shares of the Company's common stock, 8,092 of which have an exercise price of \$6.50 per share and 5,000 of which have an exercise price of \$5.00, which were the closing market prices of the Company's common stock on the respective dates of grant. The warrants expire on February 2, 2019 and September 22, 2019, respectively, and may be exercised on a cashless basis.

On April 9, 2018, Dr. Arnold S. Lippa, the Company's Interim President, Interim Chief Executive Officer, Chief Scientific Officer and Chairman of the Board of Directors and Dr. James S. Manuso, the Company's then Chief Executive Officer and Vice Chairman of the Board of Directors, advanced \$50,000 each, for a total of \$100,000, to the Company for working capital purposes. Each note is payable on demand after June 30, 2018. Each note was subject to a mandatory exchange provision that provided that the principal amount of the note would be mandatorily exchanged into a board approved offering of the Company's securities, if such offering held its first closing on or before June 30, 2018 and the amount of proceeds from such first closing was at least \$150,000, not including the principal amounts of the notes that would be exchanged, or \$250,000 including the principal amounts of such notes. Upon such exchange, the notes would be deemed repaid and terminated. Any accrued but unpaid interest outstanding at the time of such exchange will be (i) repaid to the note holder or (ii) invested in the offering, at the note holder's election. A first closing did not occur on or before June 30, 2018. Dr. Arnold S. Lippa agreed to exchange his note into the board approved offering that had its initial closing on September 12, 2018. Accrued interest on Dr. Lippa's note did not exchange. As of September 30, 2018, Dr. James S. Manuso had not exchanged his note.



### ***Other Short-Term Notes Payable***

Other short-term notes payable at September 30, 2018 and December 31, 2017 consisted of premium financing agreements with respect to various insurance policies. At September 30, 2018, a premium financing agreement was payable in the initial amount of \$63,750, with interest at 8.930% per annum, in ten monthly installments of \$6,639, and another premium financing arrangement was payable in the initial amount of \$9,322 payable in equal quarterly installments. At September 30, 2018, the aggregate amount of the short-term notes payable was \$30,703.

### **5. Settlement and Payments**

On April 5, 2018, the Company issued 185,388 common stock purchase options to Robert N. Weingarten, the Company's former Chief Financial Officer and 125,000 common stock purchase options to Pharmaland Executive Consulting Services LLC ("Pharmaland") exercisable until April 5, 2023 at \$1.12 per share of common stock which was the closing price of the common stock as quoted on the OTC QB on that date. All of these common stock purchase options vested immediately. Each of the common stock purchase options were valued on the issuance date based upon a Black-Scholes valuation method at \$1.081. The assumptions used for the Black Scholes calculation were a volatility of 186.07%, a risk-free rate of 2.64%, a zero-dividend yield and a five-year period to option maturity. Mr. Weingarten simultaneously with the issuance of the common stock purchase options, agreed to forgive \$200,350 of accrued compensation owed to him. The value of the options granted to Mr. Weingarten was \$200,404. The resulting loss on extinguishment of the accrued liability was \$54. The common stock purchase options issued to Pharmaland was in partial payment of accounts payable owed. The common stock purchase options issued to Pharmaland had a value of \$135,125 and the accounts payable paid was \$124,025. The loss on extinguishment of this accounts payable was \$11,100.

The Company continues to explore ways to reduce its indebtedness, and might in the future enter additional settlements of potential claims or payments with respect to outstanding debts. As of September 30, 2018 and December 31, 2017, total stockholders' deficiency was \$5,359,154 and \$4,355,384, respectively.

### **6. Stockholders' Deficiency**

Company has 70,000,000 authorized shares of stock, consisting of 65,000,000 shares designated as common stock, par value \$0.001 per share, and 5,000,000 shares designated as preferred stock, par value \$0.001 per share.

### ***Preferred Stock***

The Company has authorized a total of 5,000,000 shares of preferred stock, par value \$0.001 per share. As of September 30, 2018 and December 31, 2017, 1,250,000 shares were designated as 9% Cumulative Convertible Preferred Stock (non-voting, "9% Preferred Stock"); 37,500 shares were designated as Series B Convertible Preferred Stock (non-voting, "Series B Preferred Stock"); 205,000 shares were designated as Series A Junior Participating Preferred Stock (non-voting, "Series A Junior Participating Preferred Stock"); and 1,700 shares were designated as Series G 1.5% Convertible Preferred Stock. Accordingly, as of September 30, 2018 and December 31, 2017, 3,505,800 shares of preferred stock were undesignated and may be issued with such rights and powers as the Board of Directors may designate.

There were no shares of 9% Preferred Stock, Series A Junior Participating Preferred Stock, or Series G 1.5% Convertible Preferred Stock outstanding as of September 30, 2018 and December 31, 2017.

Series B Preferred Stock outstanding as of September 30, 2018 and December 31, 2017 consisted of 37,500 shares issued in a May 1991 private placement. Each share of Series B Preferred Stock is convertible into approximately 0.00030 shares of common stock at an effective conversion price of \$2,208.375 per share of common stock, which is subject to adjustment under certain circumstances. As of September 30, 2018 and December 31, 2017, the shares of Series B Preferred Stock outstanding were convertible into 11 shares of common stock. The Company may redeem the Series B Preferred Stock for \$25,001, equivalent to \$0.6667 per share of Series B Preferred Stock, an amount equal to its liquidation preference, at any time upon 30 days prior notice.

### ***Common Stock***

There are 3,588,433 shares of the Company's Common Stock outstanding as of September 30, 2018. After reserving for conversions of convertible debt as well as common stock purchase options and warrants exercises, there are 52,566,553 shares of the Company's Common Stock available for future issuances.

### *2018 Unit Offering*

On September 12, 2018, the Company consummated an initial closing on an offering (“2018 Unit Offering”) of Units comprised of one share of the Company’s common stock and one common stock purchase warrant. The 2018 Unit Offering may be up to \$1.5 million and has a final closing date of October 15, 2018. The initial closing was for \$250,750 of which \$200,750 was the gross cash proceeds. The additional \$50,000 was represented by the conversion or exchange into the 2018 Unit Offering of the principal amount of the Arnold S. Lippa, Demand Promissory Note described below. Units were sold for \$1.05 per unit and the warrants issued in connection with the units are exercisable through April 30, 2023 at a fixed price of 150% of the unit purchase price. The warrants contain a cashless exercise provision and certain blocker provisions preventing exercise if the investor would beneficially own more than 4.99% of the Company’s outstanding shares of common stock as a result of such exercise. The warrants are also subject to redemption by the Company at \$0.001 per share upon ten (10) days written notice if the Company’s common stock closes at \$3.00 or more for any five (5) consecutive trading days. In total, 238,814 shares of the Company’s common stock and 238,814 common stock purchase warrants were purchased. Other than Arnold S. Lippa, the investors in the offering were not affiliates of the Company. Investors also received an unlimited number of piggy-back registration rights in respect to the shares of common stock and the shares of common stock underlying the common stock purchase warrants, unless such common stock is eligible to be sold with volume limits under an exemption from registration under any rule or regulation of the SEC that permits the holder to sell securities of the Company to the public without registration and without volume limits (assuming the holder is not an affiliate).

The shares of common stock and common stock purchase warrants were offered and sold without registration under the Securities Act of 1933, as amended (the “Securities Act”) in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as provided in Rule 506(b) of Regulation D promulgated thereunder. None of the shares of common stock issued as part of the units, the common stock purchase warrants, the Common Stock issuable upon exercise of the common stock purchase warrants or any warrants issued to a qualified referral source (of which there were none in the initial closing) have been registered under the Securities Act or any other applicable securities laws, and unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

Prior to the initial closing of the 2018 Unit Offering, the Company issued to Arnold S. Lippa, Ph.D, the Company’s Interim President, Interim Chief Executive Officer, Executive Chairman and Chief Scientific Officer and James S. Manuso, Ph.D., the Company’s then Vice Chairman and then Chief Executive Officer, respectively, \$100,000 aggregate principal amount (\$50,000 each) of demand promissory notes bearing interest at 10% (the “Demand Promissory Notes”). The Demand Promissory Note issued to Dr. Lippa, exclusive of any interest accrued, was exchanged into the 2018 Unit Offering simultaneously with its initial closing. The principal amount of, but not the interest on, the Demand Promissory Note was taken into consideration when determining if the Company had achieved the minimum amount necessary to effect the initial closing of the 2018 Unit Offering. The Demand Promissory Note issued to Dr. Manuso was not exchanged or converted in connection with the closing of the 2018 Unit Offering.

In addition, as set forth in the Purchase Agreements, each Purchaser has an unlimited number of exchange rights, which are options and not obligations, to exchange such Purchaser's entire investment as defined (but not less than the entire investment) into one or more subsequent equity financings (consisting solely of convertible preferred stock or common stock or units containing preferred stock or common stock and warrants exercisable only into preferred stock or common stock) that would be considered as "permanent equity" under United States Generally Accepted Accounting Principles and the rules and regulations of the United States Securities and Exchange Commission, and therefore classified within stockholders' equity, and excluding any form of debt or convertible debt or preferred stock redeemable at the discretion of the holder (each such financing a "Subsequent Equity Financing"). These exchange rights are effective until the earlier of: (i) the completion of any number of Subsequent Equity Financings that aggregate at least \$15 million of gross proceeds, or (ii) December 30, 2018. For clarity, a Purchaser's entire investment is the entire amount invested ("Investment Amount") (for purposes of the multiple described below) and all of the Common Stock and Warrants purchased (for purposes of the exchange) pursuant to the Purchase Agreement of such Purchaser, however, if the Warrants have been exercised in part or in whole on a cashless basis, then the Investment Amount (for purposes of the multiple described below) will be the Investment Amount (for purposes of the multiple described below) and all of the Common Stock initially purchased pursuant to the Purchase Agreement of such Purchaser plus any shares of Common Stock issued pursuant to a cashless exercise and any Warrants remaining after such cashless exercise (for purposes of the exchange), or, if the Warrants have been exercised for cash, then the entire investment will be the Investment Amount plus the amount of cash paid upon cash exercise (for purposes of the multiple described below) and all of the Common Stock initially purchased pursuant to the Purchase Agreement of such Purchaser plus any shares of Common Stock issued pursuant to the cash exercise and any Warrants remaining after such cash exercise (for purposes of the exchange).

### *1<sup>st</sup> 2017 Unit Offering*

On March 10, 2017 and March 28, 2017, the Company sold units to investors for aggregate gross proceeds of \$350,000, with each unit consisting of one share of the Company's common stock and one common stock purchase warrant to purchase one share of the Company's common stock (the "2017 Unit Offering"). Units were sold for \$2.50 per unit and the warrants issued in connection with the units were exercisable through December 31, 2021 at a fixed price \$2.75 per share of the Company's common stock. The warrants contained a cashless exercise provision and certain blocker provisions preventing exercise if the investor would beneficially own more than 4.99% of the Company's outstanding shares of common stock as a result of such exercise. The warrants were also subject to redemption by the Company at \$0.001 per share upon ten (10) days written notice if the Company's common stock closed at 200% or more of the unit purchase price for any five (5) consecutive trading days. Investors were not affiliates of the Company. The investors received an unlimited number of piggy-back registration rights. Investors also received an unlimited number of exchange rights, which were options and not obligations, to exchange such investor's entire investment (and not less than the entire investment) into one or more subsequent equity financings (consisting solely of convertible preferred stock or common stock or units containing preferred stock or common stock and warrants exercisable only into preferred stock or common stock) that would be considered as "permanent equity" under United States Generally Accepted Accounting Principles and the rules and regulations of the United States Securities and Exchange Commission, and therefore classified as stockholders' equity, and excluding any form of debt or convertible debt (each such financing a "Subsequent Equity Financing"). These exchange rights were effective until the earlier of: (i) the completion of any number of subsequent financings aggregating at least \$15 million gross proceeds to the Company, or (ii) December 30, 2017. The dollar amount used to determine the amount invested or exchanged into the subsequent financing would be 1.2 times the amount of the original investment. Under certain circumstances, the ratio might have been 1.4 instead of 1.2. The exchange right did not permit the investors to exchange into a debt offering or into redeemable preferred stock, therefore, unlike the 2<sup>nd</sup> 2016 Unit Offering, the 2017 Unit Offering resulted in the issuance of permanent equity. The Company evaluated whether the warrants or the exchange rights met



criteria to be accounted for as a derivative in accordance with Accounting Standard Codification Topic (ASC) 815 and determined that the derivative criteria were not met. Therefore, the Company determined no bifurcation and separate valuation was necessary and that the warrants and exchange right should be accounted for with the host instrument. The closing market prices of the Company's common stock on March 10, 2017 and March 28, 2017 were \$4.05 and \$3.80 respectively. In connection with this transaction, Aurora Capital LLC ("Aurora") served as a placement agent and earned \$20,000 fees and 8,000 placement agent common stock warrants associated with the closing of 1<sup>st</sup> 2017 Unit Offering. The fees were unpaid as of June 30, 2018 and have been accrued in accounts payable and accrued expenses and charged against Additional paid-in capital as of December 31, 2017 and June 30, 2018. The placement agent common stock warrants were valued at \$27,648 and were accounted for in Additional paid-in capital as of September 30, 2017 and remain valued at that amount as of September 30, 2018.

On July 26, 2017, the Company's Board approved an offering of securities conducted via private placement (the "2<sup>nd</sup> 2017 Unit Offering" described below) that, because of the terms of the 2<sup>nd</sup> 2017 Unit Offering as compared to the terms of the 1<sup>st</sup> 2017 Unit Offering, resulted in an exchange of all of the units from the 1<sup>st</sup> 2017 Unit Offering into equity securities of the Company in the 2<sup>nd</sup> 2017 Unit Offering by all of the investors in the 1<sup>st</sup> 2017 Unit Offering.

*2<sup>nd</sup> 2017 Unit Offering*

On August 29, 2017, September 27, 2017, September 28, 2017, October 5, 2017, October 25, 2017, November 29, 2017, December 13, 2017, December 21, 2017, December 22, 2017 and December 29, 2017 the Company sold units in the 2<sup>nd</sup> 2017 Unit Offering to investors for aggregate gross proceeds of \$404,500, with each unit consisting of one share of the Company's common stock and one common stock purchase warrant to purchase one share of the Company's common stock. Units were sold for \$1.00 per unit and the warrants issued in connection with the units are exercisable through September 29, 2022 at a fixed price \$1.10 per share of the Company's common stock. The warrants contain a cashless exercise provision and certain blocker provisions preventing exercise if the investor would beneficially own more than 4.99% of the Company's outstanding shares of common stock as a result of such exercise. The warrants are also subject to redemption by the Company at \$0.001 per share upon ten (10) days written notice if the Company's common stock closes at 250% or more of the unit purchase price for any five (5) consecutive trading days. The investors were not affiliates of the Company. Investors received an unlimited number of piggy-back registration rights. Investors also received an unlimited number of exchange rights, which were options and not obligations, to exchange such investor's entire investment (and not less than the entire investment) into one or more subsequent equity financings (consisting solely of convertible preferred stock or common stock or units containing preferred stock or common stock and warrants exercisable only into preferred stock or common stock) that would be considered as "permanent equity" under United States Generally Accepted Accounting Principles and the rules and regulations of the United States Securities and Exchange Commission, and therefore classified as stockholders' equity, and excluding any form of debt or convertible debt (each such financing a "Subsequent Equity Financing" as in the<sup>61</sup> 2017 Unit Offering). These exchange rights were effective until the earlier of: (i) the completion of any number of subsequent financings aggregating at least \$15 million gross proceeds to the Company, or (ii) December 30, 2017 and have therefore expired. The dollar amount used to determine the amount invested or exchanged into the subsequent financing would have been 1.2 times the amount of the original investment. Under certain circumstances, the ratio might have been 1.4 instead of 1.2. The exchange right did not permit the investors to exchange into a debt offering or into redeemable preferred stock, therefore, unlike the 2<sup>nd</sup> 2016 Unit Offering, the 2<sup>nd</sup> 2017 Unit Offering resulted in the issuance of permanent equity. All exchange rights have expired as of December 30, 2017. The Company evaluated whether the warrants or the exchange rights met criteria to be accounted for as a derivative in accordance with Accounting Standard Codification Topic (ASC) 815 and determined that the derivative criteria were not met. Therefore, the Company determined no bifurcation and separate valuation was necessary and that the warrants and exchange right should be accounted for with the host instrument. The closing market prices of the Company's common stock on August 29, 2017, September 27, 2017, September 28, 2017, October 5, 2017, October 25, 2017, November 29, 2017, December 13, 2017, December 21, 2017, December 22, 2017 and December 29, 2017 were \$1.00, \$1.40, \$1.40, \$1.50, \$0.80, \$1.05, \$1.45, \$1.51, \$1.45 and \$1.14, respectively. There was no placement agent and therefore no fees associated with the 2<sup>nd</sup> 2017 Unit Offering.

The terms of the 2<sup>nd</sup> 2017 Unit Offering, as compared to the terms of the 2<sup>nd</sup> 2016 Unit Offering and the 1<sup>st</sup> 2017 Unit Offering, resulted in an exchange of all of the units from each of the 2<sup>nd</sup> 2016 Unit Offering and the 1<sup>st</sup> 2017 Unit Offering into equity securities of the 2<sup>nd</sup> 2017 Unit Offering. The 1<sup>st</sup> 2017 Unit Offering and the 2<sup>nd</sup> 2017 Unit Offering were both originally accounted for as equity.

*Common Stock Warrants*

A summary of warrant activity for the nine months ended September 30, 2018 is presented below.

|  | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Life (in<br>Years) |
|--|---------------------|--|---|
| Warrants outstanding at December 31, 2017  | 1,464,415           | \$2.68146                                | 3.73  |
| Issued                                     | 238,814             | 1.57500                                  | 4.58  |
| Warrants outstanding at September 30, 2018 | 1,703,229           | \$2.52632                                | 4.08  |
| Warrants exercisable at December 31, 2017  | 1,464,415           | \$2,68146                                | 3.73  |
| Warrants exercisable at September 30, 2018 | 1,703,229           | \$2.52632                                | 4.08  |

The exercise prices of common stock warrants outstanding and exercisable are as follows at September 30, 2018:

| Exercise<br>Price | Warrants<br>Outstanding<br>(Shares) | Warrants<br>Exercisable<br>(Shares) | Expiration Date    |
|-------------------|-------------------------------------|-------------------------------------|--------------------|
| \$1.0000          | 916,217                             | 916,217                             | September 20, 2022 |
| \$1.2870          | 41,002                              | 41,002                              | April 17, 2019     |
| \$1.5620          | 130,284                             | 130,284                             | December 31, 2021  |
| \$1.5750          | 238,814                             | 238,814                             | April 30, 2023     |
| \$2.7500          | 8,000                               | 8000                                | September 20, 2022 |
| \$4.8500          | 5,155                               | 5,155                               | September 23, 2019 |
| \$4.8750          | 108,594                             | 108,594                             | September 30, 2020 |
| \$5.0000          | 5,000                               | 5,000                               | September 22, 2019 |
| \$5.1025          | 10,309                              | 10,309                              | January 29, 2019   |
| \$6.5000          | 8,092                               | 8,092                               | February 4, 2019   |
| \$6.8348          | 145,758                             | 145,758                             | September 30, 2020 |
| \$7.9300          | 86,004                              | 86,004                              | February 28, 2021  |
|                   | 1,703,229                           | 1,703,229                           |                    |

Based on a fair market value of \$0.7101 per share on September 30, 2018, there were no exercisable in-the money common stock warrants as of September 30, 2018.



A summary of warrant activity for the nine months ended September 30, 2017 is presented below.

|  | Number<br>of<br>Shares | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Life (in<br>Years) |
|--|------------------------|--|---|
| Warrants outstanding at December 31, 2016  | 540,198                | \$4.84842                                |   |
| Issued                                     | 445,717                | 1.36478                                  |   |
| Warrants outstanding at September 30, 2017 | 985,915                | \$3.27352                                | 4.7567  |
| Warrants exercisable at December 31, 2016  | 540,198                | \$4.84842                                |   |
| Warrants exercisable at September 30, 2017 | 985,915                | \$3.27352                                | 4.7567  |

The exercise prices of common stock warrants outstanding and exercisable are as follows at September 30, 2017:

| Exercise<br>Price | Warrants<br>Outstanding<br>(Shares) | Warrants<br>Exercisable<br>(Shares) | Expiration Date    |
|-------------------|-------------------------------------|-------------------------------------|--------------------|
| \$1.2870          | 41,002                              | 41,002                              | April 17, 2019     |
| \$1.5620          | 0                                   | 0                                   | December 31, 2021  |
| \$4.8500          | 5,155                               | 5,155                               | September 23, 2019 |
| \$4.8750          | 108,594                             | 108,594                             | September 30, 2020 |
| \$5.0000          | 5,000                               | 5,000                               | September 22, 2019 |
| \$5.1025          | 10,309                              | 10,309                              | January 29, 2019   |
| \$6.5000          | 8,092                               | 8,092                               | February 4, 2019   |
| \$6.8348          | 145,758                             | 145,758                             | September 30, 2020 |
| \$7.9300          | 86,005                              | 86,005                              | February 28, 2021  |
| \$2.7500          | 108,000                             | 108,000                             | December 31, 2021  |
| \$1.1000          | 468,000                             | 468,000                             | September 29, 2022 |
|                   | 985,915                             | 985,915                             |                    |

Based on a fair market value of \$1.40 per share on September 30, 2017, the intrinsic value of exercisable in-the-money common stock warrants was \$144,633 as of September 30, 2017.

### *Stock Options*

On March 18, 2014, the stockholders of the Company holding a majority of the votes to be cast on the issue approved the adoption of the Company's 2014 Equity, Equity-Linked and Equity Derivative Incentive Plan (the "2014 Plan"), which had been previously adopted by the Board of Directors of the Company, subject to stockholder approval. The Plan permits the grant of options and restricted stock with respect to up to 325,025 shares of common stock, in addition to stock appreciation rights and phantom stock, to directors, officers, employees, consultants and other service providers of the Company.

On June 30, 2015, the Board of Directors adopted the 2015 Stock and Stock Option Plan (the “2015 Plan”). The 2015 Plan initially provided for, among other things, the issuance of either or any combination of restricted shares of common stock and non-qualified stock options to purchase up to 461,538 shares of the Company’s common stock for periods up to ten years to management, members of the Board of Directors, consultants and advisors. The Company has not and does not intend to present the 2015 Plan to stockholders for approval. On August 18, 2015, the Board of Directors increased the number of shares that may be issued under the 2015 Plan to 769,231 shares of the Company’s common stock. On March 31, 2016, the Board of Directors further increased the number of shares that may be issued under the 2015 Plan to 1,538,461 shares of the Company’s common stock. On January 17, 2017, the Board of Directors further increased the number of shares that may be issued under the 2015 Plan to 3,038,461 shares of the Company’s common stock. On December 9, 2017, the Board of Directors further increased the number of shares that may be issued under the 2015 Plan to 6,985,260 shares of the Company’s common stock.

Information with respect to the Black-Scholes variables used in connection with the evaluation of the fair value of stock-based compensation is provided at Note 3.

A summary of stock option activity for the nine months ended September 30, 2018 is presented below.

|   | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Life (in<br>Years) |
|---|---------------------|--|---|
| Options outstanding at December 31, 2017  | 3,996,167           | \$ 3.7634                                | 6.30  |
| Granted                                   | 327,150             | 1.1267                                   | 4.50  |
| Options outstanding at September 30, 2018 | 4,323,317           | \$ 3.5855                                | 6.17  |
| Options exercisable at December 31, 2017  | 3,996,167           | \$ 3.7634                                | 6.30  |
| Options exercisable at September 30, 2018 | 4,323,317           | \$ 3.5855                                | 6.17  |

The exercise prices of common stock options outstanding and exercisable were as follows at September 30, 2018:

| Exercise Price | Options Outstanding (Shares) | Options Exercisable (Shares) | Expiration Date    |
|----------------|------------------------------|------------------------------|--------------------|
| \$1.1200       | 310,388                      | 310,388                      | April 5, 2023      |
| \$1.2500       | 16,762                       | 16,762                       | December 7, 2022   |
| \$1.3500       | 34,000                       | 34,000                       | July 28, 2022      |
| \$1.4500       | 1,849,418                    | 1,849,418                    | December 9, 2027   |
| \$1.4500       | 100,000                      | 100,000                      | December 9, 2027   |
| \$2.0000       | 285,000                      | 285,000                      | June 30, 2022      |
| \$2.0000       | 25,000                       | 25,000                       | July 26, 2022      |
| \$3.9000       | 395,000                      | 395,000                      | January 17, 2022   |
| \$4.5000       | 7,222                        | 7,222                        | September 2, 2021  |
| \$5.6875       | 89,686                       | 89,686                       | June 30, 2020      |
| \$5.7500       | 2,608                        | 2,608                        | September 12, 2021 |
| \$6.4025       | 27,692                       | 27,692                       | August 18, 2020    |
| \$6.4025       | 129,231                      | 129,231                      | August 18, 2022    |
| \$6.4025       | 261,789                      | 261,789                      | August 18, 2025    |
| \$6.8250       | 8,791                        | 8,791                        | December 11, 2020  |
| \$7.3775       | 523,077                      | 523,077                      | March 31, 2021     |
| \$8.1250       | 169,231                      | 169,231                      | June 30, 2022      |
| \$13.0000      | 7,385                        | 7,385                        | March 13, 2019     |
| \$13.0000      | 3,846                        | 3,846                        | April 14, 2019     |
| \$13.9750      | 3,385                        | 3,385                        | March 14, 2024     |
| \$15.4700      | 7,755                        | 7,755                        | April 8, 2020      |
| \$15.9250      | 2,462                        | 2,462                        | February 28, 2024  |
| \$16.0500      | 46,154                       | 46,154                       | July 17, 2019      |
| \$16.6400      | 1,538                        | 1,538                        | January 29, 2020   |
| \$19.5000      | 9,487                        | 9,487                        | July 17, 2022      |
| \$19.5000      | 6,410                        | 6,410                        | August 10, 2022    |
|                | 4,323,317                    | 4,323,317                    |                    |

Based on a fair market value of \$0.7101 per share on September 30, 2018, there were no exercisable in-the-money common stock options as of September 30, 2018.

A summary of stock option activity for the nine months ended September 30, 2017 is presented below.

| Number of Shares | Weighted Average Exercise | Weighted Average Remaining |
|------------------|---------------------------|----------------------------|
|------------------|---------------------------|----------------------------|



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|   |           | Price     | Contractual<br>Life (in<br>Years) |
|---|-----------|-----------|-----------------------------------|
| Options outstanding at December 31, 2016  | 1,307,749 | \$ 7.6515 |                                   |
| Granted                                   | 739,000   |           |                                   |
| Options outstanding at September 30, 2017 | 2,046,749 | \$ 6.0125 | 4.54                              |
| Options exercisable at December 31, 2016  | 1,307,749 | \$ 7.6515 |                                   |
| Options exercisable at September 30, 2017 | 2,019,249 | \$ 6.0125 | 4.54                              |

The exercise prices of common stock options outstanding and exercisable were as follows at September 30, 2017:

| Exercise<br>Price | Options<br>Outstanding<br>(Shares) | Options<br>Exercisable<br>(Shares) | Expiration Date    |
|-------------------|------------------------------------|------------------------------------|--------------------|
| \$1.3500          | 34,000                             | 19,000                             | July 28, 2022      |
| \$2.0000          | 285,000                            | 285,000                            | June 30, 2022      |
| \$2.0000          | 25,000                             | 12,500                             | July 26, 2022      |
| \$3.9000          | 395,000                            | 395,000                            | January 17, 2022   |
| \$4.5000          | 7,222                              | 7,222                              | September 2, 2021  |
| \$5.6875          | 89,686                             | 89,686                             | June 30, 2020      |
| \$5.7500          | 2,608                              | 2,608                              | September 12, 2021 |
| \$6.4025          | 27,692                             | 27,692                             | August 18, 2020    |
| \$6.4025          | 129,231                            | 129,231                            | August 18, 2022    |
| \$6.4025          | 261,789                            | 261,789                            | August 18, 2025    |
| \$6.8250          | 8,791                              | 8,791                              | December 11, 2020  |
| \$7.3775          | 523,077                            | 523,077                            | March 31, 2021     |
| \$8.1250          | 169,231                            | 169,231                            | June 30, 2022      |
| \$13.0000         | 7,385                              | 7,385                              | March 13, 2019     |
| \$13.0000         | 3,846                              | 3,846                              | April 14, 2019     |
| \$13.9750         | 3,385                              | 3,385                              | March 14, 2024     |
| \$15.4700         | 7,755                              | 7,755                              | April 8, 2020      |
| \$15.9250         | 2,462                              | 2,462                              | February 28, 2024  |
| \$16.0500         | 46,154                             | 46,154                             | July 17, 2019      |
| \$16.6400         | 1,538                              | 1,538                              | January 29, 2020   |
| \$19.5000         | 9,487                              | 9,487                              | July 17, 2022      |
| \$19.5000         | 6,410                              | 6,410                              | August 10, 2022    |
|                   | 2,046,749                          | 2,019,249                          |                    |

Based on a fair market value of \$1.40 per share on September 30, 2017, exercisable in-the-money common stock options had an intrinsic value of \$950.

For the nine months ended September 30, 2018 and 2017, stock-based compensation costs included in the condensed consolidated statements of operations consisted of general and administrative expenses of \$14,248 and \$1,150,925, respectively, and research and development expenses of \$0 and \$606,901, respectively.

### *Pier Contingent Stock Consideration*

In connection with the merger transaction with Pier effective August 10, 2012, RespireRx issued 179,747 newly issued shares of its common stock with an aggregate fair value of \$3,271,402 (\$18.2000 per share), based upon the closing price of RespireRx's common stock on August 10, 2012. The shares of common stock were distributed to stockholders, convertible note holders, warrant holders, option holders, and certain employees and vendors of Pier in satisfaction of their interests and claims. The common stock issued by RespireRx represented approximately 41% of the 443,205 common shares outstanding immediately following the closing of the transaction.

Pursuant to the terms of the transaction, RespireRx agreed to issue additional contingent consideration, consisting of up to 56,351 shares of common stock, to Pier's former security holders and certain other creditors and service providers (the "Pier Stock Recipients") that received RespireRx's common stock as part of the Pier transaction if certain of RespireRx's stock options and warrants outstanding immediately prior to the closing of the merger were subsequently exercised. In the event that such contingent shares were issued, the ownership percentage of the Pier Stock Recipients, following their receipt of such additional shares, could not exceed their ownership percentage as of the initial transaction date.

The stock options and warrants outstanding at June 30, 2012 were all out-of-the-money on August 10, 2012. During late July and early August 2012, shortly before completion of the merger, the Company issued options to officers and directors at that time to purchase a total of 22,651 shares of common stock exercisable for ten years at \$19.5000 per share. By October 1, 2012, these options, as well as the options and warrants outstanding at June 30, 2012, were also out-of-the-money and continued to be out-of-the-money through September 30, 2018.

There were no stock options or warrants exercised subsequent to August 10, 2012 that triggered additional contingent consideration, and the only remaining stock options outstanding that could still trigger the additional contingent consideration remained out-of-the-money through September 30, 2018. As of September 30, 2018, due to the expirations and forfeitures of RespireRx stock options and warrants occurring since August 10, 2012, 6,497 contingent shares of common stock remained potentially issuable under the Pier merger agreement.

The Company concluded that the issuance of any of the contingent shares to the Pier Stock Recipients was remote, as a result of the large spread between the exercise prices of these stock options and warrants as compared to the common stock trading range, the subsequent expiration or forfeiture of most of the options and warrants, the

Company's distressed financial condition and capital requirements, and that these stock options and warrants have remained significantly out-of-the-money through September 30, 2018. Accordingly, the Company considered the fair value of the contingent consideration to be immaterial and therefore did not ascribe any value to such contingent consideration. If any such shares are ultimately issued to the former Pier stockholders, the Company will recognize the fair value of such shares as a charge to operations at that time.

***Reserved and Unreserved Shares of Common Stock***

On January 17, 2017, the Board of Directors of the Company approved the adoption of an amendment of the Amended and Restated RespireRx Pharmaceuticals, Inc. 2015 Stock and Stock Option Plan (as amended, the "2015 Plan"). That amendment increases the shares issuable under the plan by 1,500,000, from 1,538,461 to 3,038,461. On December 9, 2017, the Board of Directors further amended the 2015 Plan to increase the number of shares that may be issued under the 2015 Plan to 6,985,260 shares of the Company's common stock.

Other than the change in the number of shares available under the 2015 Plan, no other changes were made to the 2015 Plan by these amendments.

At September 30, 2018, the Company had 65,000,000 shares of common stock authorized and 3,588,433 shares of common stock issued and outstanding. Furthermore, as of September 30, 2018, the Company had reserved an aggregate of 11 shares for issuance upon conversion of the Series B Preferred Stock; 1,703,229 shares for issuance upon exercise of warrants; 4,323,317 shares for issuance upon exercise of outstanding stock options; 63,236 shares to cover equity grants available for future issuance pursuant to the 2014 Plan; 2,732,662 shares to cover equity grants available for future issuance pursuant to the 2015 Plan; 16,061 shares for issuance upon conversion of the Convertible Notes; and 6,497 shares issuable as contingent shares pursuant to the Pier merger. Accordingly, as of September 30, 2018, the Company had an aggregate of 8,845,013 shares of common stock reserved for issuance and 52,566,553 shares of common stock unreserved and available for future issuance. The Company expects to satisfy its future common stock commitments through the issuance of authorized but unissued shares of common stock.

## 7. Related Party Transactions

Dr. Arnold S. Lippa and Jeff E. Margolis, officers and directors of the Company since March 22, 2013, have indirect ownership interests and managing memberships in Aurora Capital LLC (“Aurora”) through interests held in its members, and Jeff. E. Margolis is also an officer of Aurora. Aurora is a boutique investment banking firm specializing in the life sciences sector that is also a full-service brokerage firm.

On March 31, 2013, the Company accrued \$85,000 as reimbursement for legal fees incurred by Aurora in conjunction with the removal of the Company’s prior Board of Directors on March 22, 2013, which amount has been included in accounts payable and accrued expenses at September 30, 2018 and December 31, 2017.

On June 30, 2015, the Board of Directors of the Company awarded, but did not pay, cash bonuses totaling \$215,000, including an aggregate of \$195,000 to certain of the Company’s executive officers and an aggregate of \$20,000 to the independent members of the Company’s Board of Directors. The cash bonuses awarded to executive officers were as follows: Dr. Arnold S. Lippa - \$75,000; Jeff E. Margolis - \$60,000; and Robert N. Weingarten (resigned as an officer and director of the Company in February 2017, but remains a consultant to the Company) - \$60,000. The cash bonuses awarded to the two independent members of the Company’s Board of Directors were as follows: James E. Sapirstein - \$10,000; and Kathryn MacFarlane - \$10,000. The cash bonuses were awarded as partial compensation for services rendered by such persons from January 1, 2015 through June 30, 2015.

On June 30, 2015, the Board of Directors also established cash compensation arrangements for certain of the Company’s executive officers at the following monthly rates: Dr. Arnold S. Lippa - \$12,500; Jeff E. Margolis -

\$10,000; and Robert N. Weingarten (resigned as an officer and director of the Company in February 2017, but remains a consultant to the Company) - \$10,000. In addition, the Company established quarterly cash board fees for the two independent members of the Company's Board of Directors as follows: James E. Sapirstein - \$5,000; and Kathryn MacFarlane - \$5,000. This compensation was payable in arrears and commenced on July 1, 2015. On August 18, 2015, the cash compensation arrangements for these executive officers were further revised as described below in Note 8. These new compensation arrangements have been extended through September 30, 2018.

Both the cash bonuses and the cash monthly compensation were accrued and will not be paid in cash until such time as the Board of Directors of the Company determines that sufficient capital has been raised by the Company or is otherwise available to fund the Company's operations on an ongoing basis. Such amounts of accrued compensation through September 30, 2017 were forgiven on December 9, 2017 when, on the same date certain amounts were granted as options, as further described below, and therefore such amounts are no longer included in accrued compensation and related expenses as of September 30, 2018 or December 31, 2017.

Effective August 18, 2015, Company entered into employment agreements with Dr. Arnold S. Lippa, Robert N. Weingarten and Jeff E. Margolis, which superseded the compensation arrangements previously established for those officers on June 30, 2015, excluding the cash bonuses referred to above.

On February 17, 2017, Robert N. Weingarten resigned as a director and as the Company's Vice President and Chief Financial Officer, but remains a consultant to the Company.

Jeff E. Margolis' employment agreement was amended effective July 1, 2017. The employment agreement amendment called for payment in three installments in cash of the \$60,000 bonus granted on June 30, 2015. A minimum of \$15,000 was to be payable in cash as follows: (a) \$15,000 payable in cash upon the next closing (after July 1, 2017) of any financing in excess of \$100,000 (b) \$15,000 payable by the end of the following month assuming cumulative closings (beginning with the closing that triggered (a)) in excess of \$200,000 and (c) \$30,000 payable in cash upon the next closing of any financing in excess of an additional \$250,000. The conditions of (a), (b) and (c) above were met as of December 31, 2017, however Mr. Margolis has waived the Company's obligation to make any payments of the cash bonus until the Board of Directors of the Company determines that sufficient capital has been raised by the Company or is otherwise available to fund the Company's operations on an ongoing basis. Obligations through September 30, 2017 were forgiven by Mr. Margolis as described below.

On March 28, 2017, Aurora earned \$20,000 of cash fees and 8,000 placement agent common stock warrants associated with the closing of 1<sup>st</sup> 2017 Unit Offering. The cash fees were unpaid as of September 30, 2018 and have been included in accounts payable and accrued expenses and charged against Additional paid-in capital as of September 30, 2018 and December 31, 2017. The placement agent common stock warrants were valued at \$27,648 and were accounted for in "Additional paid-in capital" as of September 30, 2018 and December 31, 2017.

On December 9, 2017, the Company accepted offers from Dr. Arnold S. Lippa, Dr. James S. Manuso, Jeff E. Margolis, James E. Sapirstein, Kathryn MacFarlane and Robert N. Weingarten (former Chief Financial Officer) pursuant to which such individuals would forgive accrued compensation and related accrued expenses as of September 30, 2017 in the following amounts: \$807,497; \$878,360; \$560,876; \$55,000; \$55,000 and \$200,350 respectively for a total of \$2,557,083. On the same date, the Company granted to the same individuals, or designees of such individuals from the 2015 Plan, non-qualified stock options, exercisable for 10 years with an exercise price of \$1.45 per share of common stock, among other terms and features as follows: 559,595; 608,704; 388,687; 38,114; 38,114 and 138,842 respectively, for options exercisable into a total of 1,772,055 shares of common stock with a total value of \$2,475,561.

Dr. James S. Manuso resigned as the Company's President and Chief Executive Officer as well as Vice Chairman and member of the Board of Directors effective as of September 30, 2018.

As a result of his resignation in February 2017, Mr. Weingarten is no longer considered a related party of the Company as of September 30, 2018.

A description of advances and notes payable to officers is provided at Note 4.

## **8. Commitments and Contingencies**

### *Pending or Threatened Legal Action and Claims*

By letter dated May 18, 2018, the Company received notice from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purports to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. The Company remains in discussions with TEC Edmonton to determine whether and under what conditions a resolution to the dispute can be reached and the parties have extended the applicable deadlines under the license agreement to continue those discussions, but a resolution has not yet been reached. No assurance can be provided that the parties will reach an acceptable resolution and we cannot estimate the possible impact of this disagreement on the Company's operations or business prospects.

By e-mail dated July 21, 2016, the Company received a demand from an investment banking consulting firm that represented the Company in 2012 in conjunction with the Pier transaction alleging that \$225,000 is due and owing for unpaid investment banking services rendered. Such amount has been accrued at September 30, 2018 and December 31, 2017.

By letter dated February 5, 2016, the Company received a demand from a law firm representing a professional services vendor of the Company alleging an amount due and owing for unpaid services rendered. On January 18, 2017, following an arbitration proceeding, an arbitrator awarded the vendor the full amount sought in arbitration of \$146,082. Additionally, the arbitrator granted the vendor attorneys' fees and costs of \$47,937. All such amounts have been accrued at September 30, 2018 and December 31, 2017, including accrued interest at 4.5% annually from February 26, 2018, the date of the judgment, through September 30, 2018, totaling \$5,239.

The Company is periodically the subject of various pending and threatened legal actions and claims. In the opinion of management of the Company, adequate provision has been made in the Company's consolidated financial statements as of September 30, 2018 and December 31, 2017 with respect to such matters, including, specifically, the matters noted above. The Company intends to vigorously defend itself if any of the matters described above results in the filing of a lawsuit or formal claim.

### ***Significant Agreements and Contracts***

#### ***Consulting Agreement***

Richard Purcell, the Company's Senior Vice President of Research and Development since October 15, 2014, provides his services to the Company on a month-to-month basis through his consulting firm, DNA Healthlink, Inc., through which the Company has contracted for his services, for a monthly cash fee of \$12,500. Additional information with respect to shares of common stock that have been issued to Mr. Purcell is provided at Note 6. Cash compensation expense pursuant to this agreement totaled \$37,500 for the three months ended September 30, 2018 and 2017 and \$112,500 for the nine months ended September 30, 2018 and 2017, which is included in research and development expenses in the Company's condensed consolidated statements of operations for such periods.

#### ***Employment Agreements***

On August 18, 2015, the Company entered into an employment agreement with Dr. James S. Manuso, Ph.D., to be its new President and Chief Executive Officer. Dr. Manuso resigned as President and Chief Executive Officer effective September 30, 2018 and therefore Dr. Manuso's employment agreement was not automatically extended as described below. Pursuant to the agreement, which was for an initial term through September 30, 2018 (and which would have been deemed to be automatically extended, upon the same terms and conditions, for successive periods of one year, unless either party provided written notice of its intention not to extend the term of the agreement at least 90 days prior to the applicable renewal date, except that Dr. Manuso resigned effective September 30, 2018), Dr. Manuso received an annual base salary of \$375,000. Dr. Manuso was, through September 30, 2018, also eligible to earn a performance-based annual bonus award of up to 50% of his base salary, based upon the achievement of annual



performance goals established by the Board of Directors in consultation with the executive prior to the start of such fiscal year, or any amount at the discretion of the Board of Directors. No such bonuses were earned or granted during the three and nine-month periods ended September 30, 2018 and September 30, 2017. Additionally, Dr. Manuso was granted stock options to acquire 261,789 shares of common stock of the Company and was eligible to receive additional awards under the Company's Plans in the discretion of the Board of Directors. No such awards were granted to Dr. Manuso granted during the three and nine-month periods ended September 30, 2018 and September 30, 2017. Dr. Manuso was also entitled to receive, until such time as the Company established a group health plan for its employees, \$1,200 per month, on a tax-equalized basis, as additional compensation to cover the cost of health coverage and up to \$1,000 per month, on a tax-equalized basis, as additional compensation for a term life insurance policy and disability insurance policy. Such amounts were accrued for the three and nine-month periods ended September 30, 2018 and September 30, 2017. Dr. Manuso was also entitled to be reimbursed for business expenses. The Company has accrued all submitted and approved business expenses as of September 30, 2018, December 30, 2017 and September 30, 2017. Additional information with respect to the stock options granted to Dr. Manuso is provided at Note 6. Cash compensation accrued pursuant to this agreement totaled \$103,650 for each of the three months ended September 2018, and 2017, respectively and \$310,950 for the nine months ended September 30, 2018 and 2017, respectively. Such amounts were included in accrued compensation and related expenses in the Company's condensed consolidated balance sheet at June 30, 2018 and 2017, respectively, and in general and administrative expenses in the Company's consolidated statement of operations for the three and six months ended June 30, 2018 and 2017, as appropriate. On December 9, 2017, Dr. Manuso forgave \$878,360 of accrued compensation and related expenses which was the amount owed by the Company as of September 30, 2017, as described in more detail below. On the same date, Dr. Manuso received options to purchase 608,704 shares of common stock, as described in more detail below. Dr. Manuso did not receive any additional compensation for serving as Vice Chairman or a member of on the Board of Directors. Amounts accruing after September 30, 2017 have not been paid to Dr. Manuso. Effective on September 30, 2018, Dr. Manuso resigned as Vice Chairman and as a member of the Board of Directors.

On August 18, 2015, concurrently with the hiring of Dr. James S. Manuso as the Company's President and Chief Executive Officer, Dr. Arnold S. Lippa resigned as the Company's President and Chief Executive Officer. On October 12, 2018, Dr. Lippa was named Interim President and Interim Chief Executive Officer (see Note 9. Subsequent Events) to replace Dr. Manuso who resigned effective September 30, 2018. Dr. Lippa continues to serve as the Company's Executive Chairman and as a member of the Board of Directors. Also on August 18, 2015, Dr. Lippa was named Chief Scientific Officer of the Company, and the Company entered into an employment agreement with Dr. Lippa in that capacity. Pursuant to the agreement, which is for an initial term through September 30, 2018 (and which will be deemed to be automatically extended, upon the same terms and conditions, for successive periods of one year, unless either party provides written notice of its intention not to extend the term of the agreement at least 90 days prior to the applicable renewal date), Dr. Lippa received an annual base salary of \$300,000. Dr. Lippa is also eligible to earn a performance-based annual bonus award of up to 50% of his base salary, based upon the achievement of annual performance goals established by the Board of Directors in consultation with the executive prior to the start of such fiscal year, or any amount at the discretion of the Board of Directors. Additionally, Dr. Lippa was granted stock options to acquire 30,769 shares of common stock of the Company and is eligible to receive additional awards under the Company's Plans at the discretion of the Board of Directors. Dr. Lippa is also entitled to receive, until such time as the Company establishes a group health plan for its employees, \$1,200 per month, on a tax-equalized basis, as additional compensation to cover the cost of health coverage and up to \$1,000 per month, on a tax-equalized basis, as reimbursement for a term life insurance policy and disability insurance policy. Dr. Lippa is also entitled to be reimbursed for business expenses. Additional information with respect to the stock options granted to Dr. Lippa is provided at Note 6. Cash compensation accrued pursuant to this agreement totaled \$84,900 for each of the three months ended September 30, 2018 and 2017, respectively, and \$254,700 for the nine months ended September 30, 2018 and 2017, respectively, which amounts are included in accrued compensation and related expenses in the Company's consolidated balance sheet at September 30, 2018 and December 31, 2017, and in research and development expenses in the Company's consolidated statement of operations. Cash compensation accrued to Dr. Lippa for bonuses and under a prior superseded arrangement, while still serving as the Company's President and Chief Executive Officer, totaled \$94,758 and was part of the amount forgiven on December 9, 2017 and therefore is no longer included in accrued compensation and related expenses as of September 30, 2018 and December 31, 2017. Dr. Lippa does not receive any additional compensation for serving as Executive Chairman and on the Board of Directors. On December 9, 2017, Dr. Lippa forgave \$807,497 of accrued compensation and related expenses which was the amount owed by the Company as of September 30, 2017. On the same date, Dr. Lippa received options to purchase 559,595 shares of common stock, as described in more detail below.

On August 18, 2015, the Company also entered into an employment agreement with Jeff E. Margolis, in his continuing role as Vice President, Secretary and Treasurer. Pursuant to the agreement, which was for an initial term through September 30, 2016 (and which will be deemed to be automatically extended upon the same terms and conditions, for successive periods of one year, unless either party provides written notice of its intention not to extend the term of the agreement at least 90 days prior to the applicable renewal date), Mr. Margolis received an annual base salary of \$195,000, and is also eligible to receive performance-based annual bonus awards ranging from \$65,000 to \$125,000, based upon the achievement of annual performance goals established by the Board of Directors in consultation with the executive prior to the start of such fiscal year, or any amount at the discretion of the Board of Directors. Additionally, Mr. Margolis was granted stock options to acquire 30,769 shares of common stock of the Company and is eligible to receive additional awards under the Company's Plans at the discretion of the Board of Directors. Mr. Margolis is also entitled to receive, until such time as the Company establishes a group health plan for its employees, \$1,200 per month, on a tax-equalized basis, as additional compensation to cover the cost of health coverage and up to \$1,000 per month, on a tax-equalized basis, as reimbursement for a term life insurance policy and disability insurance policy. Mr. Margolis is also each entitled to be reimbursed for business expenses. Additional

information with respect to the stock options granted to Mr. Margolis is provided at Note 6. Jeff E. Margolis' employment agreement was amended effective July 1, 2017. The employment agreement amendment called for payment in three installments in cash of the \$60,000 bonus granted on June 30, 2015. A minimum of \$15,000 was to be payable in cash as follows: (a) \$15,000 payable in cash upon the next closing (after July 1, 2017) of any financing in excess of \$100,000 (b) \$15,000 payable by the end of the following month assuming cumulative closings (beginning with the closing that triggered (a)) in excess of \$200,000 and (c) \$30,000 payable in cash upon the next closing of any financing in excess of an additional \$250,000. The conditions of (a), (b) and (c) above were met as of December 31, 2017, however Mr. Margolis has waived the Company's obligation to make any payments of the cash bonus until the Board of Directors of the Company determines that sufficient capital has been raised by the Company or is otherwise available to fund the Company's operations on an ongoing basis. Recurring cash compensation accrued pursuant to this amended agreement totaled \$80,400 and \$54,150 for the three months ended September 30, 2018 and September 30, 2017, respectively, and \$241,200 and \$188,700 for the nine months ended September 30, 2018 and 2017, respectively, which amounts are included in accrued compensation and related expenses in the Company's consolidated balance sheet at September 30, 2018, September 30, 2017 and December 31, 2017, respectively, and in general and administrative expenses in the Company's consolidated statement of operations.

The employment agreements between the Company and each of Dr. Manuso, Dr. Lippa, and Mr. Margolis, respectively, provided that the payment obligations associated with the first year base salary were to accrue, but no payments were to be made, until at least \$2,000,000 of net proceeds from any offering or financing of debt or equity, or a combination thereof, was received by the Company, at which time scheduled payments were to commence. As this financing milestone has not been achieved, Dr. Manuso, Dr. Lippa, and Mr. Margolis (who are or were each also directors of the Company) have each agreed, effective as of August 11, 2016, to continue to defer the payment of such amounts indefinitely, until such time as the Board of Directors of the Company determines that sufficient capital has been raised by the Company or is otherwise available to fund the Company's operations on an ongoing basis.

On December 9, 2017, the Company accepted offers from Dr. Arnold S. Lippa, Dr. James S. Manuso, Jeff E. Margolis, James E. Sapirstein, Kathryn MacFarlane and Robert N. Weingarten (former Chief Financial Officer) pursuant to which such individuals would forgive accrued compensation and related accrued expenses as of September 30, 2017 in the following amounts: \$807,497, \$878,360, \$560,876, \$55,000, \$55,000, and \$200,350, respectively, for a total of \$2,557,083. On the same date, the Company granted to the same individuals, or designees of such individuals from the 2015 Plan, non-qualified stock options, exercisable for 10 years with an exercise price of \$1.45 per share of common stock, among other terms and features as follows: 559,595, 608,704, 388,687, 38,114, 38,114, and 138,842, respectively, for options exercisable into a total of 1,772,055 shares of common stock with a total value of \$2,475,561.

#### *University of California, Irvine License Agreements*

The Company entered into a series of license agreements in 1993 and 1998 with the University of California, Irvine ("UCI") that granted the Company proprietary rights to certain chemical compounds that acted as ampakines and to their therapeutic uses. These agreements granted the Company, among other provisions, exclusive rights: (i) to practice certain patents and patent applications, as defined in the license agreement, that were then held by UCI; (ii) to identify, develop, make, have made, import, export, lease, sell, have sold or offer for sale any related licensed products; and (iii) to grant sub-licenses of the rights granted in the license agreements, subject to the provisions of the license agreements. The Company was required, among other terms and conditions, to pay UCI a license fee, royalties, patent costs and certain additional payments.

On April 15, 2013, the Company received a letter from UCI indicating that the license agreements between UCI and the Company had been terminated due to the Company's failure to make certain payments required to maintain the agreements. Since the patents covered in these license agreements had begun to expire and the therapeutic uses described in these patents were no longer germane to the Company's new focus on respiratory disorders, the loss of these license agreements is not expected to have a material impact on the Company's current drug development programs. In the opinion of management, the Company has made adequate provision for any liability relating to this matter in its consolidated financial statements at September 30, 2018 and December 31, 2017.



### ***University of Alberta License Agreement***

On May 9, 2007, the Company entered into a license agreement, as amended, with the University of Alberta granting the Company exclusive rights to practice patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. The Company agreed to pay the University of Alberta a licensing fee and a patent issuance fee, which were paid, and prospective payments consisting of a royalty on net sales, sublicense fee payments, maintenance payments and milestone payments. The prospective maintenance payments commence on the enrollment of the first patient into the first Phase 2B clinical trial and increase upon the successful completion of the Phase 2B clinical trial. As the Company does not at this time anticipate scheduling a Phase 2B clinical trial in the near term, no maintenance payments to the University of Alberta are currently due and payable, nor are any maintenance payments expected to be due in the near future in connection with the license agreement. On May 18, 2018, the Company received a letter from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purports to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 (as subsequently amended) between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. The Company remains in discussions with TEC Edmonton to determine whether and under what conditions a resolution to the dispute can be reached and the parties have extended the applicable deadlines under the license agreement to continue those discussions. No assurance can be provided that the parties will reach an acceptable resolution and we cannot estimate the possible impact of this disagreement on the Company's operations or business prospects.

### ***Transactions with Biovail Laboratories International SRL***

In March 2010, the Company entered into an asset purchase agreement with Biovail Laboratories International SRL ("Biovail"). Pursuant to the asset purchase agreement, Biovail acquired the Company's interests in CX717, CX1763, CX1942 and the injectable dosage form of CX1739, as well as certain of its other ampakine compounds and related intellectual property for use in the field of respiratory depression or vaso-occlusive crises associated with sickle cell disease. The agreement provided the Company with the right to receive milestone payments in an aggregate amount of up to \$15,000,000 plus the reimbursement of certain related expenses, conditioned upon the occurrence of particular events relating to the clinical development of certain assets that Biovail acquired. None of these events occurred.

As part of the transaction, Biovail licensed back to the Company certain exclusive and irrevocable rights to some acquired ampakine compounds, other than CX717, an injectable dosage form of CX1739, CX1763 and CX1942, for use outside of the field of respiratory depression or vaso-occlusive crises associated with sickle cell disease. Accordingly, following the transaction with Biovail, the Company retained its rights to develop and commercialize the non-acquired ampakine compounds as a potential treatment for neurological diseases and psychiatric disorders. Additionally, the Company retained its rights to develop and commercialize the ampakine compounds as a potential treatment for sleep apnea disorders, including an oral dosage form of ampakine CX1739.

In September 2010, Biovail's parent corporation, Biovail Corporation, combined with Valeant Pharmaceuticals International in a merger transaction and the combined company was renamed "Valeant Pharmaceuticals International, Inc." ("Valeant"). Following the merger, Valeant and Biovail conducted a strategic and financial review of their product pipeline and, as a result, in November 2010, Biovail announced its intent to exit from the respiratory depression project acquired from the Company in March 2010.

Following that announcement, the Company entered into discussions with Biovail regarding the future of the respiratory depression project. In March 2011, the Company entered into a new agreement with Biovail to reacquire the ampakine compounds, patents and rights that Biovail had acquired from the Company in March 2010. The new agreement provided for potential future payments of up to \$15,150,000 by the Company based upon the achievement of certain developments, including new drug application submissions and approval milestones. Biovail is also eligible to receive additional payments of up to \$15,000,000 from the Company based upon the Company's net sales of an intravenous dosage form of the compounds for respiratory depression.

At any time following the completion of Phase 1 clinical studies and prior to the end of Phase 2A clinical studies, Biovail retains an option to co-develop and co-market intravenous dosage forms of an ampakine compound as a treatment for respiratory depression and vaso-occlusive crises associated with sickle cell disease. In such an event, the Company would be reimbursed for certain development expenses to date and Biovail would share in all such future development costs with the Company. If Biovail makes the co-marketing election, the Company would owe no further milestone payments to Biovail and the Company would be eligible to receive a royalty on net sales of the compound by Biovail or its affiliates and licensees.

### *University of Illinois 2014 Exclusive License Agreement*

On June 27, 2014, the Company entered into an Exclusive License Agreement (the “2014 License Agreement”) with the University of Illinois, the material terms of which were similar to a License Agreement between the parties that had been previously terminated on March 21, 2013. The 2014 License Agreement became effective on September 18, 2014, upon the completion of certain conditions set forth in the 2014 License Agreement, including: (i) the payment by the Company of a \$25,000 licensing fee, (ii) the payment by the Company of outstanding patent costs aggregating \$15,840, and (iii) the assignment to the University of Illinois of rights the Company held in certain patent applications, all of which conditions were fulfilled.

The 2014 License Agreement granted the Company (i) exclusive rights to several issued and pending patents in numerous jurisdictions and (ii) the non-exclusive right to certain technical information that is generated by the University of Illinois in connection with certain clinical trials as specified in the 2014 License Agreement, all of which relate to the use of cannabinoids for the treatment of sleep related breathing disorders. The Company is developing dronabinol ( $\Delta^9$ -tetrahydrocannabinol), a cannabinoid, for the treatment of OSA, the most common form of sleep apnea.

The 2014 License Agreement provides for various commercialization and reporting requirements commencing on June 30, 2015 and also requires the Company to pay the University of Illinois a license fee, royalties, patent costs and certain milestone payments. The 2014 License Agreement provides for various royalty payments by the Company, including a royalty on net sales of 4%, payment on sub-licensee revenues of 12.5%, and a minimum annual royalty of \$100,000 beginning in 2015, which is due and payable on December 31 of each year. The 2017 minimum annual royalty of \$100,000 was paid as scheduled in December 2017. In the year after the first application for market approval is submitted to the FDA and until approval is obtained, the minimum annual royalty will increase to \$150,000. In the year after the first market approval is obtained from the FDA and until the first sale of a product, the minimum annual royalty payable by the Company will increase to \$200,000. In the year after the first commercial sale of a product, the minimum annual royalty will increase to \$250,000.

The 2014 License Agreement also provides for certain one-time milestone payments by the Company. A payment of \$75,000 is due within five days after any one of the following: (a) dosing of the first patient with a product in a Phase 2 human clinical study anywhere in the world that is not sponsored by the University of Illinois, (b) dosing of the first



patient in a Phase 2 human clinical study anywhere in the world with a low dose of dronabinol, or (c) dosing of the first patient in a Phase 1 human clinical study anywhere in the world with a proprietary reformulation of dronabinol. A payment of \$350,000 is due within five days after dosing of the first patient with a product in a Phase 3 human clinical trial anywhere in the world. A payment of \$500,000 is due within five days after the first new drug application filing with the FDA or a foreign equivalent for a product. A payment of \$1,000,000 is due within 12 months after the first commercial sale of a product.

During the three and nine months ended September 30, 2018 and 2017, the Company recorded charges to operations of \$25,000 and \$75,000, respectively, with respect to its 2018 and 2017 minimum annual royalty obligation, which is included in research and development expenses in the Company's condensed consolidated statement of operations for the three and nine months ended September 30, 2018 and 2017.

***Research Contract with the University of Alberta***

On January 12, 2016, the Company entered into a Research Contract with the University of Alberta in order to test the efficacy of ampakines at a variety of dosage and formulation levels in the potential treatment of Pompe Disease, apnea of prematurity and spinal cord injury, as well as to conduct certain electrophysiological studies to explore the ampakine mechanism of action for central respiratory depression. The Company agreed to pay the University of Alberta total consideration of approximately CAD\$146,000 (approximately US\$111,000), consisting of approximately CAD\$85,000 (approximately US\$65,000) of personnel funding in cash in four installments during 2016, to provide approximately CAD\$21,000 (approximately US\$16,000) in equipment, to pay patent costs of CAD\$20,000 (approximately US\$15,000), and to underwrite additional budgeted costs of CAD\$20,000 (approximately US\$15,000). As of December 31, 2017, the Company had recorded final amounts payable in respect to this Research Contract of US\$16,207 (CAD\$21,222) which amount was paid in US dollars in January 2018 and completed the payments under the contract. The conversion to US dollars above utilizes an exchange rate of approximately US\$0.76 for every CAD\$1.00.

The University of Alberta received matching funds through a grant from the Canadian Institutes of Health Research in support of this research. The Company retained the rights to research results and any patentable intellectual property generated by the research. Dr. John Greer, faculty member of the Department of Physiology, Perinatal Research Centre and Women & Children's Health Research Institute at the University of Alberta collaborated on this research. The studies were completed in 2016.

See "University of Alberta License Agreement" above for more information on the related license agreement.

***National Institute of Drug Abuse Agreement***

As a result of agreements entered into on October 19, 2015 and January 19, 2016, the Medications Development Program of the National Institute of Drug Abuse ("NIDA") funded and conducted research on the Company's ampakine compounds CX717 and CX1739 to determine their potential usefulness for the treatment of cocaine and methamphetamine addiction and abuse. The Company retains all intellectual property resulting from this research, as well as proprietary and commercialization rights to these compounds.

In general, the ampakines did not produce behavioral effects in rats and mice that are commonly associated with administration of stimulants such as cocaine or amphetamines. Instead, the ampakines reduced the stimulation produced by both of these drugs. In addition, the ampakines were not recognized as cocaine- or amphetamine-like when administered to rats that had been trained to recognize whether they had been administered these drugs. The absence of stimulant properties on the part of the ampakines may confirm their value as potential non-stimulant

treatments for ADHD.

***Duke University Clinical Trial Agreement***

On January 27, 2015, the Company entered into a Clinical Study and Research Agreement with Duke University (as amended, the “Duke Agreement”) to develop and conduct a protocol for a program of clinical study and research which was amended on October 30, 2015 and further amended on July 28, 2016, which agreement, as amended, resulted in a total amount payable under the Agreement to \$678,327. During the nine months ended September 30, 2018 and 2017, the Company charged \$0 to research and development expenses with respect to work conducted pursuant to the Duke Agreement. The clinical trial completed in October 2016 and the Company announced the study results on December 15, 2016. Amounts still owing under this agreement are in the Company’s balance sheets at September 30, 2018 and December 31, 2017

***Sharp Clinical Services, Inc. Agreement***

The Company has various agreements with Sharp Clinical Services, Inc. to provide packaging, labeling, distribution and analytical services.

***Covance Laboratories Inc. Agreement***

On October 26, 2016, the Company entered into a twelve month agreement with Covance Laboratories Inc. to provide compound testing and storage services with respect to CX1739, CX1866 and CX1929 at a total budgeted cost of \$35,958. This agreement was renewed in October 2017.

***Noramco Inc. - Dronabinol Development and Supply Agreement***

On September 4, 2018, RespireRx entered into a dronabinol Development and Supply Agreement with Noramco Inc., one of the world's major dronabinol manufacturers. Under the terms of the Agreement, Noramco agreed to (i) provide all of the active pharmaceutical ingredient ("API") estimated to be needed for the clinical development process for both the first- and second-generation products (each a "Product" and collectively, the "Products"), three validation batches for New Drug Application ("NDA") filing(s) and adequate supply for the initial inventory stocking for the wholesale and retail channels, subject to certain limitations, (ii) maintain or file valid drug master files ("DMFs") with the FDA or any other regulatory authority and provide the Company with access or a right of reference letter entitling the Company to make continuing reference to the DMFs during the term of the agreement in connection with any regulatory filings made with the FDA by the Company, (iii) participate on a development committee, and (iv) make available its regulatory consultants, collaborate with any regulatory consulting firms engaged by the Company and participate in all FDA or Drug Enforcement Agency ("DEA") meetings as appropriate and as related to the API.

In consideration for these supplies and services, the Company has agreed to purchase exclusively from Noramco during the commercialization phase all API for its Products at a pre-determined price subject to certain producer price adjustments and agreed to Noramco's participation in the economic success of the commercialized Product or Products up to the earlier of the achievement of a maximum dollar amount or the expiration of a period of time.

### ***Summary of Principal Cash Obligations and Commitments***

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of September 30, 2018, aggregating \$1,086,200. Amounts included in the 2018 column represent amounts contractually due at from September 30, 2018 through the remainder of the 2018 fiscal year ending December 31, 2018.

|  | Total       | Payments Due By Year |           |           |           |           |
|--|-------------|----------------------|-----------|-----------|-----------|-----------|
|  |             | 2018                 | 2019      | 2020      | 2021      | 2022      |
| License agreements                       | \$425,000   | \$25,000             | \$100,000 | \$100,000 | \$100,000 | \$100,000 |
| Employment and consulting agreements (1) | 661,200     | 165,300              | 495,900   | -         | -         | -         |
| Total                                    | \$1,086,200 | \$190,300            | \$595,900 | \$100,000 | \$100,000 | \$100,000 |

(1) The payment of such amounts has been deferred indefinitely, as described above at "Employment Agreements". 2018 obligations include three months of employment agreement obligations for Dr. Lippa and Mr. Margolis as their employment contracts renewed on September 30, 2018 and 2019 obligations include nine months of obligations through September 30, 2019.

## **9. Subsequent Events**

The Company performed an evaluation of subsequent events through the date of filing these financial statements with the SEC. There were no material subsequent events which affected, or could affect, the amounts or disclosures in the condensed consolidated financial statements, other than those discussed below.

On October 12, 2018, Dr. Lippa was named Interim President and Interim Chief Executive Officer to replace Dr. Manuso who resigned effective September 30, 2018. Dr. Lippa continues to serve as the Company's Executive Chairman and as a member of the Board of Directors as well as the Company's Chief Scientific Officer.

The 2018 Unit Offering terminated on October 15, 2018 without any additional closings.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Overview

The mission of RespireRx Pharmaceuticals Inc. ("RespireRx" or the "Company" or "we" or "our") is to develop innovative and revolutionary treatments to combat diseases caused by disruption of neuronal signaling. We are developing treatment options that address conditions that affect millions of people, but for which there are few or poor treatment options, including obstructive sleep apnea ("OSA"), attention deficit hyperactivity disorder ("ADHD") and recovery from spinal cord injury ("SCI"), as well as certain neurological orphan diseases such as Fragile X Syndrome. RespireRx is developing a pipeline of new drug products based on our broad patent portfolios for two drug platforms: ampakines, proprietary compounds that positively modulate AMPA-type glutamate receptors to promote neuronal function and cannabinoids, including dronabinol (" $\Delta$ 9-THC").

### *Ampakines*

Since its formation in 1987, RespireRx Pharmaceuticals Inc. (formerly known as Cortex Pharmaceuticals, Inc.) has been engaged in the research and clinical development of a class of proprietary compounds known as ampakines, a term used to designate their actions as positive allosteric modulators of the alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid ("AMPA") glutamate receptor. Ampakines are small molecule compounds that enhance the excitatory actions of the neurotransmitter glutamate at the AMPA receptor complex, which mediates most excitatory transmission in the central nervous system ("CNS"). These drugs do not have agonistic or antagonistic properties but instead modulate the receptor rate constants for transmitter binding, channel opening, and desensitization. We currently are developing two lead clinical compounds, CX717 and CX1739, and one pre-clinical compound, CX1942. These compounds belong to a new class of ampakines that do not display the electrophysiological and biochemical effects that lead to undesirable side effects, namely convulsive activities, previously reported in animal models of earlier generations.

The Company owns patents and patent applications, or the rights thereto, for certain families of chemical compounds, including ampakines, which claim the chemical structures, their actions as ampakines and their use in the treatment of various disorders. Patents claiming a family of chemical structures, including CX1739 and CX1942, as well as their use in the treatment of various disorders extend through at least 2028. Additional patent applications claiming the use of ampakines in the treatment of certain neurological and neuropsychiatric disorders, such as Attention Deficit Hyperactivity Disorder ("ADHD") have been or are expected to be filed in the near future.

In 2007, we determined that expansion of our strategic development into the areas of central respiratory dysfunction, including drug-induced respiratory dysfunction represented cost-effective opportunities for potentially rapid development and commercialization of RespireRx's compounds. On May 8, 2007, RespireRx entered into a license agreement, as subsequently amended, with the University of Alberta granting RespireRx exclusive rights to method of treatment patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. These patents, along with RespireRx's own patents claiming chemical structures, comprise RespireRx's principal intellectual property supporting RespireRx's research and clinical development program in the use of ampakines for the treatment of central and drug-induced respiratory disorders. On May 18, 2018, the Company received a letter from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purports to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 (as subsequently amended) between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. There have been several communications between Company counsel, the Company and representatives of TEC Edmonton to determine whether and under what terms a resolution to the dispute can be reached, and the parties have extended the applicable deadlines under the license agreement to continue those discussions, but a resolution has not yet been reached. No assurance can be provided that the parties will reach an acceptable resolution and we cannot estimate the possible impact of this disagreement on the Company's operations or business prospects.

Through an extensive translational research effort from the cellular level through Phase 2 clinical trials, the Company has developed a family of novel, low impact ampakines, including CX717, CX1739 and CX1942 that have clinical application in the treatment of neurobehavioral disorders, CNS-driven respiratory disorders, spinal cord injury, neurological diseases, and orphan indications. We have been addressing CNS-driven respiratory disorders that affect millions of people, but for which there are few treatment options and limited drug therapies, including opioid induced respiratory disorders, such as apnea (transient cessation of breathing) or hypopnea (transient reduction in breathing). When these symptoms become severe, as in opioid overdose, they are the primary cause of opioid lethality.

RespireRx has completed pre-clinical studies indicating that several of its ampakines, including CX717, CX1739 and CX1942, were efficacious in treating drug induced respiratory depression caused by opioids or certain anesthetics without altering the analgesic effects of the opioids or the anesthetic effects of the anesthetics. The results of our preclinical research studies have been replicated in three separate Phase 2A human clinical trials with two ampakines, CX717 and CX1739, confirming the translational mechanism and target site engagement and demonstrating proof of principle that ampakines act as positive allosteric modulators of AMPA receptors in humans and can be used in humans for the prevention of opioid induced apnea. In addition, RespireRx has conducted a Phase 2A clinical study in which patients with sleep apnea were administered CX1739, RespireRx's lead clinical compound. The results suggested that CX1739 might have use as a treatment for central sleep apnea ("CSA") and mixed sleep apnea, but not OSA.

RespireRx is committed to advancing the ampakines through the clinical and regulatory path to approval and commercialization. Until recently, RespireRx has focused on the ampakines' ability to antagonize opioid induced respiratory depression both as a translational tool to verify target engagement, as well as an eventual commercial



indication. We believe the loss of over 70,000 lives in our country last year alone demands that new solutions for opioid induced deaths be developed to ensure the public health.

To this end, the Company has conducted preclinical and clinical research with CX1739, CX717 and CX1942 in the prevention, treatment, and management of opioid induced apnea, the primary cause of overdose deaths. In particular, we have conducted several Phase 2 clinical trials demonstrating that both CX717 and CX1739 significantly reduced opioid induced respiratory depression (“OIRD”) without altering analgesia. Since one of the primary risk factors for opioid overdose is CSA, it is significant that a Phase 2A clinical study with CX1739 produced data suggesting a possible reduction in central sleep apnea.

With neither drugs nor devices approved to treat CSA, Company management believes there is the potential for a rapid path to commercialization. Unfortunately, rather than support novel approaches for opioid treatment, the recent public and governmental discourses regarding the “opioid epidemic” has focused almost entirely on the distribution of naloxone, an opioid antagonist used for acute emergency situations, so-called “non-abuseable” opioid formulations, as well as on means of reducing opioid consumption by limiting production of opioids and access to legal opioid prescriptions. It remains to be seen whether these approaches will have an impact on the situation. Nevertheless, as a result, we believe that there is an ongoing industry-wide pullback from opioids, as evidenced by a reduction in opioid prescriptions and a major reduction in manufacturing by two of the largest opioid manufactures in the United States.

These factors have made it difficult to raise capital or find strategic partners for the development of ampakines for the treatment of opioid induced respiratory depression and we are assessing whether to continue with this program. In addition, as noted above, we have been notified by the University of Alberta (“TEC Edmonton”) that they consider our license agreement to be terminated and we are in discussions with them to determine whether and under what conditions a resolution to the dispute can be reached. At the present time, we are suspending the development of this program until we reach an understanding with the University of Alberta, the political climate is clarified and we are able to either raise funding or enter into a strategic relationship for this purpose. Nevertheless, the valuable data derived from these translational studies have established antagonism of OIRD as a biomarker for demonstrating proof of principle and target engagement in support of continued ampakine development for other indications.

In addition, the Company is pursuing potentially promising clinical development programs in neuro-behavioral and cognitive disorders, with translational and clinical research programs focused on the use of ampakines for the treatment of ADHD and, together with our academic collaborators, motor impairment resulting from SCI and for Fragile X Autism.

ADHD is one of the most common neurobehavioral disorders, with 6.1% of American children taking medication for treatment, and ADHD is estimated to affect 7.8% of U.S. children aged 4 to 17, according to the U.S. Centers for Disease Control and Prevention (“CDC”) or approximately 4.5 million children. The principal characteristics of ADHD are inattention, hyperactivity and impulsivity. ADHD symptoms are known to persist into adulthood. In a study published in *Psychiatry Res* in May 2010, up to 78% of children affected by this disorder showed at least one of the major symptoms of ADHD when followed up 10 years later. According to the CDC, approximately 4% of the US adult population has ADHD, which can negatively impair many aspects of daily life, including home, school, work and interpersonal relationships.

Currently available treatments for ADHD include amphetamine-type stimulants and non-stimulant agents targeting the monoaminergic receptor systems in the brain. However, these receptors are not restricted to the brain and are widely found throughout the body. Thus, while these agents can be effective in ameliorating ADHD symptoms, they also can produce adverse cardiovascular effects, such as increased heart rate and blood pressure. Existing treatments also affect eating habits and can reduce weight gain and growth in children and have been associated with suicidal ideation in adolescents and adults. In addition, approved stimulant treatments are DEA classified as controlled substances and present logistical issues for distribution and protection from diversion. Approved non-stimulant treatments, such as

atomoxetine, can take four to eight weeks to become effective and undesirable side effects have been observed.

Various investigators have generated data supporting the concept that alterations in AMPA receptor function might underlie the production of some of the symptoms of ADHD. In rodent and primate models of cognition, ampakines have been demonstrated to reduce inattention and impulsivity, two of the cardinal symptoms of ADHD. Furthermore, ampakines do not stimulate spontaneous locomotor activity in either mice or rats, unlike the stimulants presently used for the treatment of ADHD, nor do they increase the stimulation produced by amphetamine or cocaine. These preclinical considerations prompted us to conduct a randomized, double-blind, placebo controlled, two period crossover study to assess the efficacy and safety of CX717 in adults with ADHD.

In a repeated measures analysis, a statistically significant treatment effect on ADHD Rating Scale (ADHD-RS), the primary outcome measure, was observed after a three-week administration of CX717, 800 mg BID. Differences between this dose of CX717 and placebo were seen as early as week one of treatment and continued throughout the remainder of the study. The low dose of CX717, 200 mg BID, did not differ from placebo. In general, results from both the ADHD-RS hyperactivity and inattentiveness subscales, which were secondary efficacy variables, paralleled the results of the total score. CX717 was considered safe and well tolerated.

Based on these clinical results, ampakines such as CX717 might represent a breakthrough opportunity to develop a non-stimulating therapeutic for ADHD with the rapidity of onset normally seen with stimulants. Subject to raising sufficient financing (of which no assurance can be provided), we are planning to continue this program with a Phase 2B clinical trial in patients with adult ADHD.

Ampakines also may have potential utility in the treatment and management of SCI to enhance motor functions and improve the quality of life for SCI patients. An estimated 17,000 new cases of SCI occur each year in the United States, most a result of automobile accidents. Currently, there are roughly 282,000 people living with spinal cord injuries, which often produce impaired motor function.

SCI can profoundly impair neural plasticity leading to significant morbidity and mortality in human accident victims. Plasticity is a fundamental property of the nervous system that enables continuous alteration of neural pathways and synapses in response to experience or injury. One frequently studied model of plasticity is long-term facilitation of motor nerve output (“LTF”). A large body of literature exists regarding the ability of ampakines to stimulate neural plasticity, possibly due to an enhanced synthesis and secretion of various growth factors.

Recently, studies of acute intermittent hypoxia (“AIH”) in patients with SCI demonstrate that neural plasticity can be induced to improve motor function. This LTF is based on physiological mechanisms associated with the ability of spinal circuitry to learn how to adjust spinal and brainstem synaptic strength following repeated hypoxic bouts. Because AIH induces spinal plasticity, the potential exists to harness repetitive AIH as a means of inducing functional recovery of motor function following SCI.

RespireRx has been working with Dr. David Fuller, at the University of Florida with funding from the National Institutes of Health, to evaluate the use of ampakines for the treatment of compromised motor function in SCI. Using mice that have received spinal hemisections, CX717 was observed to increase motor nerve activity bilaterally. The effect on the hemisectioned side was greater than that measured on the intact side, with the recovery approximating that seen on the intact side prior to administration of ampakine. In addition, CX717 was observed to produce a dramatic and long-lasting effect on LTF produced by AIH. The doses of ampakines active in SCI were comparable to those demonstrating antagonism of OIRD, indicating target engagement of the AMPA receptors.

These animal models of motor nerve function following SCI support proof of concept for a new treatment paradigm using ampakines to improve motor functions in patients with SCI. With additional funding recently granted by NIH to Dr. Fuller, RespireRX is continuing its collaborative preclinical research with Dr. Fuller while it is planning a clinical trial program focused on developing ampakines for the restoration of certain motor functions in patients with SCI. The Company is working with our Clinical Advisory Panel and with researchers at highly regarded clinical sites to finalize a Phase 2 clinical trial protocol. Subject to raising sufficient financing (of which no assurance can be provided), we believe that a clinical study could be initiated as early as 2019

According to the Autism Society, more than 3.5 million Americans live with an Autism Spectrum Disorder (“ASD”), a complex neurodevelopmental disorder. Fragile X Syndrome (“FXS”) is the most common identifiable single-gene cause of autism, affecting approximately 1.4 in every 10,000 males and 0.9 in every 10,000 females, according to the CDC. Individuals with FXS and ASD exhibit a range of abnormal behaviors comprising hyperactivity and attention problems, executive function deficits, hyper-reactivity to stimuli, anxiety and mood instability. Also, according to the Autism Society, the prevalence rate of ASD has risen from 1 in 150 children in 2000 to 1 in 68 children in 2010, with current estimates indicating a significant rise in ASD diagnosis to 1 in 59 births, placing a significant emotional and economic burden on families and educational systems. The Autism Society estimates the economic cost to U.S. citizens of autism services to be between \$236 and \$262 billion annually.

Since “autistic disturbances” were first identified in children in 1943, extensive research efforts have attempted to identify the genetic, molecular, environmental, and clinical causes of ASD, but until recently the underlying etiology of the disorder remained elusive. Today, there are no medications that can treat ASD or its core symptoms, and only two anti-psychotic drugs approved by the United States Food and Drug Administration (“FDA”), aripiprazole and risperidone, are approved for the treatment of irritability associated with ASD.

Thanks to wide ranging translational research efforts, FXS and ASD are currently recognized as disorders of the synapse with alterations in different forms of synaptic communication and neuronal network connectivity. Focusing on the proteins and subunits of the AMPA receptor complex, autism researchers at the University of San Diego (“UCSD”) have proposed that AMPA receptor malfunction and disrupted glutamate signal transmission may play an etiologic role in the behavioral, emotional and neurocognitive phenotypes that remain the standard for ASD diagnosis. For example, Stargazin, also known as CACNG2 (Ca<sup>2+</sup> channel 2 subunit), is one of four closely related proteins recently categorized as transmembrane AMPA receptor regulating proteins (“TARPs”).

Researchers at the UCSD have been studying genetic mutations in the AMPA receptor complex that lead to cognitive and functional deficiencies along the autism spectrum. They work with patients and their families to conduct detailed genetic analyses in order to better understand the underlying mechanisms of autism. In one case, they have been working with a teenage patient who has an autism diagnosis, with a phenotype that is characterized by subtle Tourette-like behaviors, extreme aggression, and verbal and physical outbursts with disordered thought. Despite the behaviors, his language is normal. Using next generation sequencing and genome editing technologies, the researchers identified a specific mutation in stargazin, a transmembrane AMPA receptor regulatory protein that alters the configuration and kinetics of the AMPA receptor. When the aberrant sequence was introduced into C57bL6 mice using CRISPR (Clustered Regulatory Interspaced Short Palindromic Repeats), the heterozygous allele had a dominant negative effect on the trafficking of post-synaptic AMPA receptors and produced behaviors consistent with a glutamatergic deficit and similar to what has been observed in the teenage patient.

With funding from the National Institutes of Health to UCSD, RespireRx is working with UCSD to explore the use of ampakines for the amelioration of the cognitive and other deficits associated with AMPA receptor gene mutations. Because CX1739 has an open IND, subject to securing sufficient outside funding (of which no assurance can be provided), we are considering a Phase 2A clinical trial sometime in 2019.

### *Cannabinoids*

OSA is a sleep-related breathing disorder that afflicts an estimated 29 million people in the United States according to the American Academy of Sleep Medicine (“AASM”), and an additional 26 million in Germany and 8 million in the United Kingdom, as presented at the European Respiratory Society’s (“ERS”) annual Congress in Paris, France. OSA involves a decrease or complete halt in airflow despite an ongoing effort to breathe during sleep. When the muscles relax during sleep, soft tissue in the back of the throat collapses and obstructs the upper airway. OSA remains significantly under-recognized, as only 20% of cases in the United States according to the AASM and 20% of cases globally have been properly diagnosed. About 24 percent of adult men and 9 percent of adult women have the breathing symptoms of OSA with or without daytime sleepiness. OSA significantly impacts the lives of sufferers who do not get enough sleep; their quality of sleep is deteriorated such that daily function is compromised and limited. OSA is associated with decreased quality of life, significant functional impairment, and increased risk of road traffic accidents, especially in professions like transportation and shipping.

Research has established links between OSA and several important co-morbidities, including hypertension, type II diabetes, obesity, stroke, congestive heart failure, coronary artery disease, cardiac arrhythmias, and even early mortality. The consequences of undiagnosed and untreated OSA are medically serious and economically costly. According to the AASM, the estimated economic burden of OSA in the United States is approximately \$162 billion annually. We believe that a new drug therapy that is effective in reducing the medical and economic burden of OSA would have significant advantages for optimal pricing in this costly disease indication.

Continuous Positive Airway Pressure (“CPAP”) is the most common treatment for OSA. CPAP devices work by blowing pressurized air into the nose (or mouth and nose), which keeps the pharyngeal airway open. CPAP is not curative, and patients must use the mask whenever they sleep. Reduction of the apnea/hypopnea index (“AHI”) is the standard objective measure of therapeutic response in OSA. Apnea is the cessation of breathing for 10 seconds or more and hyponea is a reduction in breathing. AHI is the sum of apnea and hypopnea events per hour. In the sleep laboratory, CPAP is highly effective at reducing the AHI. However, the device is cumbersome and difficult for many patients to tolerate. Most studies describe that 25-50% of patients refuse to initiate or completely discontinue CPAP use within the first several months and that most patients who continue to use the device do so only intermittently.

Oral devices may be an option for patients who cannot tolerate CPAP. Several dental devices are available including the Mandibular Advancement Device (“MAD”) and the Tongue Retaining Device (“TRD”). The MAD is the most widely used dental device for sleep apnea and is similar in appearance to a sports mouth guard. It forces the lower jaw forward and down slightly which keeps the airway more open. The TRD is a splint that holds the tongue in place to keep the airway as open as possible. Like CPAP, oral devices are not curative for patients with OSA. The cost of these devices tends to be high and side effects associated with them include night time pain, dry lips, tooth discomfort, and excessive salivation.

Patients with clinically significant OSA who cannot be treated adequately with CPAP or oral devices can elect to undergo surgery. The most common surgery is uvulopalatopharyngoplasty which involves the removal of excess tissue in the throat to make the airway wider. Other possible surgeries include tracheostomies, rebuilding of the lower jaw, and nose surgery. Patients who undergo surgery for the treatment of OSA risk complications, including infection, changes in voice frequency, and impaired sense of smell. Surgery is often unsuccessful and, at present, no method exists to reliably predict therapeutic outcome from these forms of OSA surgery.

Recently, another surgical option has become available based on upper airway stimulation. It is a combination of an implantable nerve stimulator and an external remote controlled by the patient. The hypoglossal nerve is a motor nerve that controls the tongue. The implanted device stimulates the nerve with every attempted breath, regardless of whether such stimulation is needed for that breath, to increase muscle tone to prevent the tongue and other soft tissues from collapsing. The surgically implanted device is turned on at night and off in the morning by the patient with the remote.

The poor tolerance and long-term adherence to CPAP, as well as the limitations of mechanical devices and surgery, make discovery of therapeutic alternatives clinically relevant and important. RespireRx’s translational research results demonstrate that dronabinol has the potential to become the first drug treatment for this large and underserved market.

In order to expand RespireRx’s respiratory disorders program and develop cannabinoids for the treatment of OSA, RespireRx acquired 100% of the issued and outstanding equity securities of Pier effective August 10, 2012 pursuant to an Agreement and Plan of Merger. Pier had been formed in June 2007 (under the name SteadySleep Rx Co.) as a clinical stage pharmaceutical company to develop a pharmacologic treatment for OSA and had been engaged in research and clinical development activities.

Through the merger, RespireRx gained access to an Exclusive License Agreement (as amended, the “Old License Agreement”) that Pier had entered into with the University of Illinois Chicago (“UIC”) on October 10, 2007. The Old License Agreement covered certain patents and patent applications in the United States and other countries claiming the use of certain compounds referred to as cannabinoids, of which dronabinol is a specific example, for the treatment of sleep-related breathing disorders (including sleep apnea). Pier’s business plan was to determine whether dronabinol would significantly improve subjective and objective clinical measures in patients with OSA.



The Old License Agreement was terminated effective March 21, 2013 and the Company entered into a new license agreement (the “2014 License Agreement”) with the UIC on June 27, 2014, the material terms of which were substantially similar to the Old License Agreement. The 2014 License Agreement grants the Company, among other provisions, exclusive rights: (i) to practice certain patents in the United States, Germany and the United Kingdom, as defined in the 2014 License Agreement, that are held by the UIC; (ii) to identify, develop, make, have made, import, export, lease, sell, have sold or offer for sale any related licensed products; and (iii) to grant sub-licenses of the rights granted in the 2014 License Agreement, subject to the provisions of the 2014 License Agreement. The Company is required under the 2014 License Agreement, among other terms and conditions, to pay UIC a license fee, royalties, patent costs and certain milestone payments.

Dronabinol is a synthetic derivative of  $\Delta^9$ -THC, one of the pharmacologically active substances naturally occurring in the cannabis plant. Dronabinol is a Schedule III, controlled generic drug that has been approved by the FDA for the treatment of AIDS-related anorexia and chemotherapy-induced nausea and vomiting. Dronabinol is available in the United States as the branded prescription drug product Marinol® capsules. Marinol®, together with numerous generic formulations, is available in 2.5, 5, and 10 mg capsules, with a maximum labelled dosage of 20 mg/day for the AIDS indication, or 15 mg/m<sup>2</sup> per dose for chemotherapy-induced nausea and vomiting.

The Company conducted a 21 day, randomized, double-blind, placebo-controlled, dose escalation Phase 2A clinical study in 22 patients with OSA, in which dronabinol produced a statistically significant reduction in AHI, the primary therapeutic end-point, and was observed to be safe and well tolerated, with the frequency of side effects no different from placebo (Prasad *et al*, *Frontiers in Psychiatry*, 2013).

With approximately \$5 million in funding from the National Heart, Lung and Blood Institute of National Institutes of Health (“NIH”), Dr. David Carley of UIC, along with his colleagues at UIC and Northwestern University, recently completed a Phase 2B multi-center, double-blind, placebo-controlled clinical trial of dronabinol in patients with OSA. Entitled Pharmacotherapy of Apnea with Cannabimimetic Enhancement (“PACE”), this study replicated the earlier Phase 2A study. The authors reported (Carley *et al*, *Sleep*, 2018) that, in a dose dependent fashion, treatment with 2.5mg and 10mg of dronabinol once a day at night, significantly reduced, compared to placebo, the AHI during sleep in 56 patients with moderate to severe OSA who completed the study. Additionally, treatment with 10mg of dronabinol significantly improved daytime sleepiness as measured by the Epworth Sleepiness Scale and achieved the greatest overall patient satisfaction. As in the previous study, dronabinol was observed to be safe and well tolerated, with the frequency of side effects no different from placebo. The Company did not manage or fund this clinical trial which was funded by the National Heart, Lung and Blood Institute of NIH.

The use of dronabinol for the treatment of OSA is a novel indication for an already approved drug and, as such, the Company believes that it would allow us or a development partner to submit a 505(b)(2) New Drug Application (“NDA”) to FDA for approval of a new dronabinol label, as opposed to the submission and approval of a full 505(b)(1) NDA. The 505(b)(2) NDA was created by the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, in part, to help avoid unnecessary duplication of studies already performed on a previously approved drug; the section gives the FDA express permission to rely on data not developed by the NDA applicant. A 505(b)(2) NDA contains full safety and effectiveness reports but allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant. This can result in a less expensive and faster route to approval, compared with a traditional development path, such as 505(b)(1), while creating new, differentiated products with potentially significant commercial value. This regulatory path offers market protections under Hatch-Waxman provisions for market exclusivity at FDA. Other regulatory routes are available to pursue proprietary formulations of dronabinol that will provide further market protections. In Europe, a regulatory approval route similar to the 505(b)(2) pathway is the hybrid procedure based on Article 10 of Directive 2001/83/EC.

In conjunction with its management and consultants, RespireRx has developed a regulatory strategy in which we intend to file a new NDA under Section 505(b)(2) claiming efficacy in the treatment of OSA and, in the process, create a new branded product. We have engaged Camargo Pharmaceutical Services, LLC to act as regulatory consultants and assist with FDA filings and regulatory strategy.

Unlike a standard 505(b)(1) NDA, the 505(b)(2) Abbreviated New Drug Application (“ANDA”) process begins with a pre-IND meeting with the FDA, then moves to formulation development (and nonclinical studies, if necessary) and then to the IND (investigational new drug) filing. Since we intend to utilize an already approved or equivalent

dronabinol product from manufacturers that have approved Drug Master Files, we believe that the pre-IND meeting will forego discussions of CMC (chemistry, manufacturing and controls), formulation and safety, as well as Phase 1 and 2 studies. Instead, we believe that the focus will be on the Phase 3 clinical development program. When a Phase 3 study is required for a 505(b)(2), usually only one study with fewer patients is necessary versus the two, large scale, confirmatory studies generally required for 505(b)(1). With an extensive safety database tracking chronic, long-term use of Marinol® and generics, while no assurance can be provided, we believe that FDA should not have a major safety issue with dronabinol in the treatment of OSA.

We anticipate requesting a pre-IND meeting with the FDA as soon as the first quarter of 2019, which would functionally serve as the equivalent of an end-of-Phase 2 meeting. The FDA responses to this meeting will be incorporated into an IND, which we believe we could be in a position to submit within 60 days of receiving their communication.

RespireRx has worked with the PACE investigators and staff, as well as with our Clinical Advisory Panel to design a Phase 3 protocol that, based on the experience and results from the Phase 2A and Phase 2B trials, we believe will provide sufficient data for FDA approval of a RespireRx dronabinol branded capsule for OSA. Subject to raising sufficient financing (of which no assurance can be provided), RespireRx intends to submit the Phase 3 protocol to the FDA. The current version of the protocol is designed as a 90-day randomized, blinded, placebo controlled study of dronabinol in the treatment of OSA. Depending on feedback from the FDA, RespireRx estimates that the Phase 3 trial would require between 120 and 300 patients at 15 to 20 sites, and take 18 to 24 months to complete, at a cost of between \$10 million and \$14 million.

Subject to raising sufficient financing (of which no assurance can be provided), RespireRx intends to hire Clinilabs Drug Development Corporation, a full-service CRO, to consult and potentially provide clinical site management, monitoring, data management, and centralized sleep monitoring services for the Phase 3 OSA trial. Dr. Gary Zammitt, CEO of Clinilabs, serves on the RespireRx Clinical Advisory Panel, and his management team has provided guidance on study design and CNS drug development that will be relevant for the Phase 3 program. For example, Clinilabs offers specialized clinical trial services for CNS drug development through an alliance with Neuroclinics, including clinical trials examining the effects of drugs on driving, cognitive effects of food and (medicinal) drugs, and sleep and sleep disordered breathing.

On September 4, 2018, RespireRx entered into a dronabinol Development and Supply Agreement with Noramco Inc., one of the world's major dronabinol manufacturers. Under the terms of the Agreement, Noramco agreed to (i) provide all of the active pharmaceutical ingredient ("API") estimated to be needed for the clinical development process for both the first- and second-generation products (each a "Product" and collectively, the "Products"), three validation batches for NDA filing(s) and adequate supply for the initial inventory stocking for the wholesale and retail channels, subject to certain limitations, (ii) maintain or file valid drug master files ("DMFs") with the FDA or any other regulatory authority and provide the Company with access or a right of reference letter entitling the Company to make continuing reference to the DMFs during the term of the agreement in connection with any regulatory filings made with the FDA by the Company, (iii) participate on a development committee, and (iv) make available its regulatory consultants, collaborate with any regulatory consulting firms engaged by the Company and participate in all FDA or Drug Enforcement Agency ("DEA") meetings as appropriate and as related to the API.

In consideration for these supplies and services, the Company has agreed (i) to purchase exclusively from Noramco, during the commercialization phase, all API for its Products at a pre-determined price subject to certain producer price adjustments and (ii) Noramco's participation in the economic success of the commercialized Product or Products up to the earlier of the achievement of a maximum dollar amount or the expiration of a period of time.

We plan to establish strategic relationships with appropriate companies to complete formulation and packaging. RespireRx has identified several candidates to perform the encapsulation. Some of these already supply finished product to generic pharmaceutical companies marketing dronabinol for its current non-OSA indications. In addition, as described below, RespireRx has been in discussions with several companies that have considerable expertise in developing novel formulations for dronabinol and have expressed interest in helping us develop a proprietary controlled release formulation. No assurance can be provided that encapsulation or formulation agreements will be consummated on terms acceptable to us; the failure to consummate these agreements would materially adversely affect the Company.

After considerable research and discussions with consultants, we believe the most direct route to commercialization is to proceed directly to a Phase 3 pivotal clinical trial using the currently available dronabinol formulation (2.5, 5 and 10 mg gel caps) and to commercialize a RespireRx branded dronabinol capsule (“RBDC”) with a new drug application (“NDA”). To that end, RespireRx plans to complete the Phase 3 trial and submit a 505(b)(2) application to FDA for approval of a new, branded, once per day dronabinol gel capsule for the treatment of OSA estimated to occur in 2020. Under the provisions of the Hatch-Waxman Act, the RBDC would have 3-year market exclusivity, as well as further protection from generic substitution through 2025 due to our patents and an anticipated listing in the *Approved Drug Products with Therapeutic Equivalence Evaluations* publication (the “Orange Book”), which identifies drug products approved on the basis of safety and effectiveness by the FDA and related patent and exclusivity information.

In addition, management believes there are numerous opportunities for reformulation of dronabinol to produce a proprietary, branded product for the treatment of OSA. Therefore, simultaneous with the development of the RBDC, RespireRx plans to develop a proprietary dronabinol formulation to optimize the dose and duration of action for treating OSA. An analysis of the time-related efficacy results provides potential guidance on development. We have identified several formulation companies with existing dronabinol formulations, expertise, and licensure to develop a proprietary formulation of dronabinol for RespireRx based on RespireRx's pending patents for low-dose and extended release dronabinol, which we expect would enable brand extensions and market protections through 2036.

Since RBDC is expected, if approved, to be approved under a 505(b)(2) NDA, it would be considered a new, proprietary, branded dronabinol product, with a specific label for OSA. It would be non-identical to any other dronabinol product and there would be no generic equivalents or AB substitutions. There are many examples of branded products that might ordinarily have applied for an ANDA as a branded generic that have successfully utilized this 505(b)(2) NDA approach to grant them new product status and protect them from generic substitution.

Because the 505(b)(2) NDA requires clinical data for approval of a new indication, we anticipate that our RBDC would be eligible for market protection under the Hatch-Waxman Amendment clause for "other significant changes" and we expect would therefore be eligible for 3-years of market exclusivity. At the end of these 3 years, if a generic company wished to challenge our issued patents, they would have to file an ANDA with bioequivalence data to our RBDC and, if our patents were listed in the Orange Book, they would have to simultaneously file a Paragraph 4 certification stating that they are challenging our patent. At that point, we would receive a 30-months stay of the patent challenge.

We believe the 5.5 years of market exclusivity expected to result from the Hatch-Waxman Act and the Orange Book listing will provide adequate time for the development and approval of a novel, proprietary formulation of dronabinol, optimized for all-night treatment of OSA, with patent protections through 2036. If the new formulation is approved, we plan to rescind the 505(b)(2) NDA for RBDC and replace the branded product with the new and improved formulation on the market, with the intention of preventing ANDA competition and protecting market share.

With guidance based on the product launch experience of Dr. MacFarland, a member of our Board of Directors, and Richard Purcell, our senior vice-president of research and development, and the managed markets experience of our consultant, Commercialization Consulting, LLC, we have prepared an approach to marketing and commercialization of both the RBDC and the proprietary dronabinol formulation. An extensive analysis conducted by Commercialization Consulting, LLC estimates that, if we were to execute our strategy, we should not experience a loss of more than approximately 15% of sales due to off-label generic dronabinol sales.

## **Recent Developments**

***Resignation of James S. Manuso, President and Chief Executive Officer, Vice Chairman and Member of the Board of Directors and Appointment of Arnold S. Lippa as Interim President and Interim Chief Executive Officer***

The resignation of Dr. James S. Manuso as the Company's President and Chief Executive Officer, Vice Chairman and Member of the Board of Directors became effective on September 30, 2018, the end of the term of his employment agreement. Dr. Manuso did not resign because of any disagreement with the Company relating to the Company's operations, policies or practices.

On October 12, 2018, Arnold S. Lipka, Ph.D. was named Interim President and Interim Chief Executive Officer. Dr. Lipka continues to serve as the Company's Chief Scientific Officer and Chairman of the Board of Directors.

#### ***University of Alberta (TEC Edmonton)***

On May 18, 2018, the Company received a letter from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purports to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 (as subsequently amended) between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. There have been several communications between Company counsel, the Company and representatives of TEC Edmonton, and some of these communications have taken place after September 30, 2018, but a resolution has not yet been reached. No assurance can be provided that the parties will reach an acceptable resolution and, in light of the early stages of the disagreement, we cannot estimate the possible impact of this disagreement on the Company's operations or business prospects.

#### ***Dronabinol Development and Supply Agreement***

On September 4, 2018, RespireRx entered into a dronabinol Development and Supply Agreement with Noramco Inc., one of the world's major dronabinol manufacturers. Under the terms of the Agreement, Noramco agreed to (i) provide all of the active pharmaceutical ingredient ("API") estimated to be needed for the clinical development process for both the first- and second-generation products (each a "Product" and collectively, the "Products"), three validation batches for NDA filing(s) and adequate supply for the initial inventory stocking for the wholesale and retail channels, subject to certain limitations, (ii) maintain or file valid drug master files ("DMFs") with the FDA or any other regulatory authority and provide the Company with access or a right of reference letter entitling the Company to make continuing reference to the DMFs during the term of the agreement in connection with any regulatory filings made with the FDA by the Company, (iii) participate on a development committee, and (iv) make available its regulatory consultants, collaborate with any regulatory consulting firms engaged by the Company and participate in all FDA or Drug Enforcement Agency ("DEA") meetings as appropriate and as related to the API.

In consideration for these supplies and services, the Company has agreed to purchase exclusively from Noramco during the commercialization phase all API for its Products at a pre-determined price subject to certain producer price adjustments and agreed to Noramco's participation in the economic success of the commercialized Product or Products up to the earlier of the achievement of a maximum dollar amount or the expiration of a period of time.



### *2018 Unit Offering*

On September 12, 2018, the Company consummated an initial closing on an offering (“2018 Unit Offering”) of Units comprised of one share of the Company’s common stock and one common stock purchase warrant. The 2018 Unit Offering may be up to \$1.5 million and has a final closing date of October 15, 2018. The initial closing was for \$250,750 of which \$200,750 was the gross cash proceeds. The additional \$50,000 was represented by the conversion or exchange into the 2018 Unit Offering of the principal amount of the Arnold S. Lippa, Demand Promissory Note described below. Units were sold for \$1.05 per unit and the warrants issued in connection with the units are exercisable through April 30, 2023 at a fixed price of 150% of the unit purchase price. The warrants contain a cashless exercise provision and certain blocker provisions preventing exercise if the investor would beneficially own more than 4.99% of the Company’s outstanding shares of common stock as a result of such exercise. The warrants are also subject to redemption by the Company at \$0.001 per share upon ten (10) days written notice if the Company’s common stock closes at \$3.00 or more for any five (5) consecutive trading days. In total, 238,814 shares of the Company’s common stock and 238,814 common stock purchase warrants were purchased. Other than Arnold S. Lippa, the investors in the offering were not affiliates of the Company. Investors also received an unlimited number of piggy-back registration rights in respect to the shares of common stock and the shares of common stock underlying the common stock purchase warrants, unless such common stock is eligible to be sold with volume limits under an exemption from registration under any rule or regulation of the SEC that permits the holder to sell securities of the Company to the public without registration and without volume limits (assuming the holder is not an affiliate).

The shares of common stock and common stock purchase warrants were offered and sold without registration under the Securities Act of 1933, as amended (the “Securities Act”) in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as provided in Rule 506(b) of Regulation D promulgated thereunder. None of the shares of common stock issued as part of the units, the common stock purchase warrants, the Common Stock issuable upon exercise of the common stock purchase warrants or any warrants issued to a qualified referral source (of which there were none in the initial closing) have been registered under the Securities Act or any other applicable securities laws, and unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

Prior to the initial closing of the 2018 Unit Offering, the Company issued to Arnold S. Lipka, Ph.D, and the Company's Interim President, Interim Chief Executive Officer, Executive Chairman and Chief Scientific Officer and James S. Manuso, Ph.D., the Company's then Vice Chairman and then Chief Executive Officer, \$100,000 aggregate principal amount (\$50,000 each) of demand promissory notes bearing interest at 10% (the "Demand Promissory Notes"). The Demand Promissory Note issued to Dr. Lipka, exclusive of any interest accrued, was exchanged or converted into the 2018 Unit Offering simultaneously with its initial closing. The principal amount of, but not the interest on, the Demand Promissory Note was taken into consideration when determining if the Company had achieved the minimum amount necessary to effect the initial closing of the 2018 Unit Offering. The Demand Promissory Note issued to Dr. Manuso was not exchanged or converted in connection with the 2018 Unit Offering.

In addition, as set forth in the Purchase Agreements, each Purchaser has an unlimited number of exchange rights, which are options and not obligations, to exchange such Purchaser's entire investment, as defined, (but not less than the entire investment) into one or more subsequent equity financings (consisting solely of convertible preferred stock or common stock or units containing preferred stock or common stock and warrants exercisable only into preferred stock or common stock) that would be considered as "permanent equity" under United States Generally Accepted Accounting Principles and the rules and regulations of the United States Securities and Exchange Commission, and therefore classified within stockholders' equity, and excluding any form of debt or convertible debt or preferred stock redeemable at the discretion of the holder (each such financing a "Subsequent Equity Financing"). These exchange rights are effective until the earlier of: (i) the completion of any number of Subsequent Equity Financings that aggregate at least \$15 million of gross proceeds, or (ii) December 30, 2018. For clarity, a Purchaser's entire investment is the entire amount invested ("Investment Amount") (for purposes of the multiple described below) and all of the Common Stock and Warrants purchased (for purposes of the exchange) pursuant to the Purchase Agreement of such Purchaser, however, if the Warrants have been exercised in part or in whole on a cashless basis, then the Investment Amount (for purposes of the multiple described below) will be the Investment Amount (for purposes of the multiple described below) and all of the Common Stock initially purchased pursuant to the Purchase Agreement of such Purchaser plus any shares of Common Stock issued pursuant to a cashless exercise and any Warrants remaining after such cashless exercise (for purposes of the exchange), or, if the Warrants have been exercised for cash, then the entire investment will be the Investment Amount plus the amount of cash paid upon cash exercise (for purposes of the multiple described below) and all of the Common Stock initially purchased pursuant to the Purchase Agreement of such Purchaser plus any shares of Common Stock issued pursuant to the cash exercise and any Warrants remaining after such cash exercise (for purposes of the exchange).

The 2018 Unit Offering was terminated on October 15, 2018 without any additional closings.

## Recent Accounting Pronouncements

Management does not believe that any recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's financial statement presentation or disclosures.

## Concentration of Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company limits its exposure to credit risk by investing its cash with high credit quality financial institutions.

The Company's research and development efforts and potential products rely on licenses from research institutions and if the Company loses access to these technologies or applications, its business could be substantially impaired.

Under a patent license agreement in respect to which, the Company is engaged in a dispute resolution process with TEC Edmonton on behalf of The Governors of the University of Alberta, the Company has exclusive rights to the use of certain ampakine compounds to prevent and treat respiratory depression induced by opioid analgesics, barbiturates and anesthetic and sedative agents.

On May 9, 2007, the Company entered into a license agreement, as subsequently amended, with the University of Alberta granting the Company exclusive rights to practice patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. The Company agreed to pay the University of Alberta a licensing fee and a patent issuance fee, which were paid, and prospective payments consisting of a royalty on net sales, sublicense fee payments, maintenance payments and milestone payments. The prospective maintenance payments commence on the enrollment of the first patient into the first Phase 2B clinical trial and increase upon the successful completion of the Phase 2B clinical trial. As the Company does not at this time anticipate scheduling a Phase 2B clinical trial with respect to the subject matter of this license, no maintenance payments are currently due and payable to the University of Alberta. A prospective payment of approximately \$3,600 is claimed to be currently due and payable by the University of Alberta.

By letter dated May 18, 2018, the Company received notice from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purports to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of

that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. There have been several communications between Company counsel, the Company and representatives of TEC Edmonton, but a resolution has not yet been reached. No assurance can be provided that the parties will reach an acceptable resolution and we cannot estimate the possible impact of this disagreement on the Company's operations or business prospects.

Through the merger with Pier, the Company gained access to the Old License Agreement that Pier had entered into with the University of Illinois on October 10, 2007. The Old License Agreement covered certain patents and patent applications in the United States and other countries claiming the use of certain compounds referred to as cannabinoids for the treatment of sleep related breathing disorders (including sleep apnea), of which dronabinol is a specific example of one type of cannabinoid. Dronabinol is a synthetic derivative of the naturally occurring substance in the cannabis plant, otherwise known as  $\Delta 9$ -THC ( $\Delta 9$ -tetrahydrocannabinol). Dronabinol is currently approved by the FDA and is sold generically for use in refractory chemotherapy-induced nausea and vomiting, as well as for anorexia in patients with AIDS. Pier's business plan was to determine whether dronabinol would significantly improve subjective and objective clinical measures in patients with OSA. The Old License Agreement was terminated effective March 21, 2013 due to the Company's failure to make a required payment and on June 27, 2014, the Company entered into the 2014 License Agreement with the University of Illinois, the material terms of which were similar to the Old License Agreement that had been terminated and also included the assignment of rights to certain patent applications filed by RespireRx. If the Company is unable to comply with the terms of the 2014 License Agreement, such as an inability to make the payments required thereunder, the Company would be at risk of the 2014 License Agreement being terminated.

### **Critical Accounting Policies and Estimates**

The Company prepared its condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed consolidated financial statements requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. Management periodically evaluates the estimates and judgments made. Management bases its estimates and judgments on historical experience and on various factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates as a result of different assumptions or conditions.

The following critical accounting policies affect the more significant judgments and estimates used in the preparation of the Company's condensed consolidated financial statements.

### ***Stock-Based Compensation***

The Company periodically issues common stock and stock options to officers, directors and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date of each grant.

The Company accounts for stock-based payments to officers and directors by measuring the cost of services received in exchange for equity awards based on the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's condensed consolidated financial statements over the vesting period of the awards. The Company accounts for stock-based payments to consultants by determining the value of the stock compensation based upon the measurement date at either (a) the date at which a performance commitment is reached, or (b) at the date at which the necessary performance to earn the equity instruments is complete.

Stock grants, which are generally subject to time-based vesting, are measured at the grant date fair value and charged to operations ratably over the vesting period.

Stock options granted to outside consultants are revalued each reporting period until vested to determine the amount to be recorded as an expense in the respective period. As the stock options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the value on the date of vesting.

The fair value of stock options is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the life of the equity award, the exercise price of the security as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock over the term of the equity award. Estimated volatility is based on the historical volatility of the Company's common stock. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair value of common stock is determined by reference to the quoted market price of the Company's common stock.

Stock options and warrants issued to non-employees as compensation for services to be provided to the Company or in settlement of debt are accounted for based upon the fair value of the services provided or the estimated fair value of the stock option or warrant, whichever can be more clearly determined. Management uses the Black-Scholes option-pricing model to determine the fair value of the stock options and warrants issued by the Company. The Company recognizes this expense over the period in which the services are provided.

The Company recognizes the fair value of stock-based compensation in general and administrative costs and in research and development costs, as appropriate, in the Company's condensed consolidated statements of operations. The Company issues new shares of common stock to satisfy stock option exercises.

### ***Note Exchange Agreements***

See Note 3 to our condensed consolidated financial statements for the three and nine months ended September 30, 2018 and 2017 for information on our "Note Exchange Agreements."

### ***Research and Development Costs***

Research and development costs consist primarily of fees paid to consultants and outside service providers and organizations (including research institutes at universities) and other expenses relating to the acquisition, design, development and testing of the Company's treatments and product candidates.

Research and development costs incurred by the Company under research grants are expensed as incurred over the life of the underlying contracts, unless the terms of the contract indicate that a different expensing schedule is more appropriate.

The Company reviews the status of its research and development contracts on a quarterly basis.

### *License Agreements*

Obligations incurred with respect to mandatory payments provided for in license agreements are recognized ratably over the appropriate period, as specified in the underlying license agreement, and are recorded as liabilities in the Company's condensed consolidated balance sheet, with a corresponding charge to research and development costs in the Company's condensed consolidated statement of operations. Obligations incurred with respect to milestone payments provided for in license agreements are recognized when it is probable that such milestone will be reached and are recorded as liabilities in the Company's condensed consolidated balance sheet, with a corresponding charge to research and development costs in the Company's condensed consolidated statement of operations. Payments of such liabilities are made in the ordinary course of business.

### *Patent Costs*

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and any related patent applications, all patent costs, including patent-related legal and filing fees, are expensed as incurred and, in accordance with SEC accounting, are charged to general and administrative expenses.



## Results of Operations

The Company's condensed consolidated statements of operations as discussed herein are presented below.

|  | Three Months Ended<br>September 30, |              | Nine Months Ended<br>September 30, |                |
|--|-------------------------------------|--------------|------------------------------------|----------------|
|  | 2018                                | 2017         | 2018                               | 2017           |
| Operating expenses:  |                                     |              |                                    |                |
| General and administrative   | \$330,560                           | \$404,642    | \$1,118,335                        | \$2,415,718    |
| Research and development   | 173,036                             | 188,506      | 478,262                            | 1,147,633      |
| Total operating expenses   | 503,596                             | 593,148      | 1,596,597                          | 3,563,351      |
| Loss from operations   | (503,596 )                          | (593,148 )   | (1,596,597 )                       | (3,563,351 )   |
| Loss on extinguishment of debt and other liabilities in<br>exchange for equity | -                                   | -            | (116,407 )                         | -              |
| Interest expense   | (35,161 )                           | (26,354 )    | (96,231 )                          | (77,674 )      |
| Foreign currency transaction gain (loss)                                       | 2,983                               | 960          | (108,582 )                         | (30,728 )      |
| Net loss   | (535,774 )                          | (618,542 )   | (1,917,817 )                       | (3,671,753 )   |
| Net loss attributable to common stockholders                                   | \$(535,774 )                        | \$(618,542 ) | \$(1,917,817 )                     | \$(3,671,753 ) |
| Net loss per common share - basic and diluted                                  | \$(0.16 )                           | \$(0.27 )    | \$(0.59 )                          | \$(1.62 )      |
| Weighted average common shares outstanding - basic and<br>diluted              | 3,398,940                           | 2,333,257    | 3,228,528                          | 2,261,160      |

### Three Months Ended September 30, 2018 and 2017

Revenues. During the three months ended September 30, 2018 and 2017, the Company had no revenues.

General and Administrative. For the three months ended September 30, 2018, general and administrative expenses were \$330,560, a decrease of \$74,082, as compared to \$404,642 for the three months ended September 30, 2017, primarily due to a decrease in legal fees of \$22,179, stock-based compensation of \$23,873 and patent costs of \$29,480, as the Company has taken efforts to reduce costs in light of available resources.

Stock-based compensation costs included in general and administrative expenses were \$0 for the three months ended September 30, 2018, as compared to \$23,873 for the three months ended September 30, 2017, reflecting decrease of

\$23,873. The decrease is the result of the fact that no stock-based compensation was granted to general and administrative employees during the three months ended September 30, 2018. Salaries and employee benefits included in general and administrative expenses were \$167,750 for the three months ended September 30, 2018 and for the three months ended September 30, 2017. Legal fees declined to \$57,833 for the three months ended September 30, 2018 as compared to \$80,012 for the three months ended September 30, 2017, a decrease of \$22,179. The remaining decrease in general and administrative expenses is due to a number of smaller decreases, partially offset by increases in a number of other expense categories.

Research and Development. For the three months ended September 30, 2018, research and development expenses were \$173,036, a decrease of \$15,470, as compared to \$188,506 for the three months ended September 30, 2017, primarily due to a decrease in research contract expenses of \$23,250 and shared based compensation of \$11,700, partially offset by an increase in consulting fees of \$20,000.

Loss on Extinguishment of Debt and other Liabilities in Exchange for Equity. During the three months ended September 30, 2018 and 2017 there was no loss on extinguishment of debt and other liabilities.

Interest Expense. During the three months ended September 30, 2018, interest expense was \$35,161 (including \$11,794 to related parties), an increase of \$14,560, as compared to \$26,354 (including \$3,992 to related parties) for the three months ended September 30, 2017. The net increase is primarily the result of accrual of interest on two new officer notes commencing on April 5, 2018, interest charged by one vendor in respect of aged accounts payable, which vendor is also a related party, and interest related to amounts owed to a second former vendor that is not a related party.

Foreign Currency Transaction Gain (Loss). Foreign currency transaction gain was \$2,983 for the three months ended September 30, 2018, as compared to a foreign currency transaction gain of \$960 for the three months ended September 30, 2017. The foreign currency transaction gains relate to the \$399,774 loan from SY Corporation made in June 2012, which is denominated in the South Korean Won.

Net Loss and Net Loss Attributable to Common Stockholders. For the three months ended September 30, 2018, the Company incurred a net loss and a net loss attributable to common stockholders of \$535,774, as compared to a net loss of \$618,542 for the three months ended September 30, 2017.

### **Nine Months Ended September 30, 2018 and 2017**

Revenues. During the nine months ended September 30, 2018 and 2017, the Company had no revenues.

General and Administrative. For the nine months ended September 30, 2018, general and administrative expenses were \$1,118,335, a decrease of \$1,297,383, as compared to \$2,415,718 for the nine months ended September 30, 2017, primarily due to a decrease in stock-based compensation of \$1,150,925, decreases in legal fees of \$110,139 and decreases in patent related fees of \$25,318, partially offset by an increase in salaries and employee benefits of \$26,856, and a decrease of legal fees of \$87,961, and a decrease in accounting expenses of \$17,833.

Stock-based compensation costs included in general and administrative expenses were \$14,248 for the nine months ended September 30, 2018, as compared to \$1,150,925 for the nine months ended September 30, 2017, reflecting a decrease of \$1,136,677. The decrease is the result of the fact that no stock-based compensation was granted to general and administrative employees during the nine months ended September 30, 2018. Salaries and employee benefits included in general and administrative expenses were \$506,250 for the nine months ended September 30, 2018, as compared to \$479,394 for the nine months ended September 30, 2017, reflecting an increase of \$26,856. The net change is primarily due to the increase in salary for Jeff Margolis effective July 1, 2017. Professional and other consulting fees, primarily consisting of legal, accounting and patent fees included in general and administrative expenses were \$389,119 for the nine months ended September 30, 2018, as compared to \$542,409 for the nine months ended September 30, 2017, reflecting a decrease of \$153,290, comprised primarily of a reduction of legal fees of \$110,139, which is primarily the result of the completion of arbitration proceedings, and a reduction in patent related fees of \$25,318.

Research and Development. For the nine months ended September 30, 2018, research and development expenses were \$478,262, a decrease of \$669,371, as compared to \$1,147,633 for the nine months ended September 30, 2017, primarily as a result of the reduction in stock-based compensation of \$606,901 and a reduction of \$71,797 in research contracts, partially offset by an additional \$20,000 of consulting fees.

Stock-based compensation costs included in research and development expenses were \$0 for the nine months ended September 30, 2018, as compared to \$606,901 for the nine months ended September 30, 2017. The decrease is the result of the fact that no stock-based compensation was granted to research and development employees during the nine months ended September 30, 2018. Salaries and employee benefits included in research and development expenses were \$225,000 for the nine months ended September 30, 2018 and September 30, 2017.

Contractual research expenditures included in research and development expenses were \$9,222 for the nine months ended September 30, 2018, as compared to \$81,019 for the nine months ended September 30, 2017, reflecting a decrease of \$71,797. The net change in contractual clinical research expenditures reflects the reduction to \$0 of clinical trial expenses related to Company's completion of the CX1739 clinical trial at Duke University.

Loss on Extinguishment of Debt and other Liabilities in Exchange for Equity. During the nine months ended September 30, 2018, the Company exchanged certain convertible notes inclusive of accrued interest for equity. In addition, the Company satisfied certain liabilities by issuing options. The loss on the extinguishment of convertible debt was \$105,253. In addition, during the nine months ended September 30, 2018, the Company extinguished liabilities for accrued compensation and other accounts payable for equity resulting in a loss of \$11,154. These represent an aggregate increase of \$116,407 as compared to the nine months ended September 30, 2017 during which period, the amounts were \$0.

Interest Expense. During the nine months ended September 30, 2018, interest expense was \$96,231 (including \$29,937 to related parties), an increase of \$18,557, as compared to \$77,674 (including \$11,688 to related parties) for the nine months ended September 30, 2017. The net increase is primarily the result of accrual of interest on two new officer notes commencing on April 5, 2018 and interest charged by one vendor in respect of aged accounts payable, which vendor is also a related party, and interest related to amounts owed to a second former vendor that is not a related party.

Foreign Currency Transaction Gain (Loss). Foreign currency transaction loss was \$108,582 for the nine months ended September 30, 2017, as compared to a foreign currency transaction loss of \$30,728 for the nine months ended September 30, 2017. The foreign currency transaction loss relates to the \$399,774 loan from SY Corporation made in June 2012, which is denominated in the South Korean Won.

Net Loss and Net Loss Attributable to Common Stockholders. For the nine months ended September 30, 2018, the Company incurred a net loss and net loss attributable to common stockholders of \$1,917,817, as compared to a net loss and a net loss attributable to common stockholders of \$3,671,753 for the nine months ended September 30, 2017.

### **Liquidity and Capital Resources – September 30, 2018**

The Company's condensed consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has incurred net losses of \$1,917,817 for the nine months ended September 30, 2018 and \$4,291,483 for the fiscal year ended December 31, 2017, and negative operating cash flows of \$199,966 for the nine months ended September 30, 2018 and \$697,009 for the fiscal year ended December 31, 2017, had a stockholders' deficiency of \$5,359,154 at September 30, 2018, and expects to continue to incur net losses and negative operating cash flows for at least the next few years. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern. In addition, the Company's independent registered public accounting firm, in its report on the Company's consolidated financial statements for the year ended December 31, 2017, has expressed substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" above).

At September 30, 2018, the Company had a working capital deficit of \$5,366,004, as compared to a working capital deficit of \$4,373,443 at December 31, 2017, reflecting an increase in the working capital deficit of \$992,561 for the nine months ended September 30, 2018. The increase in the working capital deficit during the nine months ended September 30, 2018 is comprised of an increase in total current liabilities of \$1,012,585, partially offset by an increase in current assets of \$20,024. The increase in total current liabilities consists of a net increase in accounts payable and accrued expenses of \$332,277, an increase in accrued compensation and related expenses of \$636,500, a decrease in convertible notes payable of \$191,199, an increase in the note payable to SY Corporation of \$144,463, an increase in notes payable to officers of \$69,271 and an increase in other short-term notes payable of \$22,073.

At September 30, 2018, the Company had cash aggregating \$80,686 as compared to \$84,902 at December 31, 2017, reflecting a decrease in cash of \$4,216 during the nine months ended September 30, 2018.

The Company is currently, and has for some time, been in significant financial distress. It has limited cash resources and current assets and has no ongoing source of sustainable revenue. Management is continuing to address numerous

aspects of the Company's operations and obligations, including, without limitation, debt obligations, financing requirements, intellectual property, licensing agreements, legal and patent matters and regulatory compliance, and has continued to raise new debt and equity capital to fund the Company's business activities.

At September 30, 2018, the Company had \$125,000 principal amount of 10% convertible notes payable outstanding (plus accrued interest of \$57,647), which matured and become due and payable in full on September 15, 2016. Certain of the note holders have notified the Company that the convertible notes are in default. As of the date of such notification, the interest rate on such defaulted convertible notes was increased to 12%. The Company is continuing efforts to extend and/or satisfy these convertible notes payable through the issuance of the Company's securities, although there can be no assurances that the Company will be successful in this regard.

The Company is continuing efforts to raise additional capital in order to pay its liabilities, fund its business activities and underwrite its research and development programs. The Company regularly evaluates various measures to satisfy the Company's liquidity needs, including the development of agreements with collaborative partners and, when necessary, the exchange or restructuring of the Company's outstanding securities. As a result of the Company's current financial situation, the Company has limited access to external sources of debt and equity financing. Accordingly, there can be no assurances that the Company will be able to secure additional financing in the amounts necessary to fund its operating and debt service requirements. If the Company is unable to access sufficient cash resources on a timely basis, the Company may be forced to reduce or suspend operations indefinitely, or to discontinue operations entirely and liquidate.

Operating Activities. For the nine months ended September 30, 2018, operating activities utilized cash of \$199,966 as compared to utilizing cash of \$495,817 for the nine months ended September 30, 2017, to support the Company's ongoing operations and research and development activities.

Financing Activities. For the nine months ended September 30, 2018, financing activities generated cash of \$195,750 in net proceeds from the 2018 Unit Financing, which was a closing of \$250,750, of which \$50,000 was an exchange of the principal amount of one officer note and \$5,000 represented costs associated with the offering. For the nine months ended September 30, 2017, financing activities generated cash of \$476,000 from a common stock and warrant financing, as well as \$24,999 from short-term notes payable.

### **Going Concern**

The Company's condensed consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has incurred net losses of \$535,774 and \$1,917,817 for the three and nine months ended September 30, 2018 respectively, \$618,542 and \$3,671,753 for the three and nine months ended September 30, 2017 and \$4,291,483 for the fiscal year ended December 31, 2017, and negative operating cash flows of \$199,966 for the nine months ended September 30, 2018 as compared to negative operating cash flows of \$495,817 for the nine months ended September 30, 2017 and \$697,009 for the fiscal year ended December 31, 2017. The Company also had a stockholders' deficiency of \$5,359,154 at September 30, 2018, and expects to continue to incur net losses and negative operating cash flows for at least the next few years. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern, and the Company's independent registered public accounting firm, in its report on the Company's consolidated financial statements for the year ended December 31, 2017, expressed substantial doubt about the Company's ability to continue as a going concern.

The Company is currently, and has for some time, been in significant financial distress. It has limited cash resources and current assets and has no ongoing source of sustainable revenue. Management is continuing to address various aspects of the Company's operations and obligations, including, without limitation, debt obligations, financing requirements, intellectual property, licensing agreements, legal and patent matters and regulatory compliance, and has continued to raise new debt and equity capital to fund the Company's business activities from both related and unrelated parties.

The Company is continuing its efforts to raise additional capital in order to be able to pay its liabilities and fund its business activities on a going forward basis, including the pursuit of the Company's planned research and development activities. The Company regularly evaluates various measures to satisfy the Company's liquidity needs, including development and other agreements with collaborative partners and, when necessary, seeking to exchange or restructure the Company's outstanding securities. The Company is evaluating certain changes to its operations and structure to facilitating raising capital from sources that may be interested in financing only discrete aspects of the

Company's development programs. Such changes could include a significant reorganization, which may include the formation of one or more subsidiaries into which one or more programs may be contributed. As a result of the Company's current financial situation, the Company has limited access to external sources of debt and equity financing. Accordingly, there can be no assurances that the Company will be able to secure additional financing in the amounts necessary to fully fund its operating and debt service requirements. If the Company is unable to access sufficient cash resources, the Company may be forced to discontinue its operations entirely and liquidate.

## **Principal Commitments**

### *Employment Agreements*

On August 18, 2015, the Company entered into an employment agreement with Dr. James S. Manuso, Ph.D., to be its new President and Chief Executive Officer. Dr. Manuso resigned as President and Chief Executive Officer effective September 30, 2018 and therefore Dr. Manuso's employment agreement was not automatically extended as described below. Pursuant to the agreement, which was for an initial term through September 30, 2018 (and which would have been deemed to be automatically extended, upon the same terms and conditions, for successive periods of one year, except that Dr. Manuso resigned effective September 30, 2018), Dr. Manuso received an annual base salary of \$375,000. Dr. Manuso was, through September 30, 2018, also eligible to earn a performance-based annual bonus award of up to 50% of his base salary, based upon the achievement of annual performance goals established by the Board of Directors in consultation with the executive prior to the start of such fiscal year, or any amount at the discretion of the Board of Directors. No such bonuses were earned or granted during the three and six month periods ended June 30, 2018 and June 30, 2017. Additionally, Dr. Manuso was granted stock options to acquire 261,789 shares of common stock of the Company and was eligible to receive additional awards under the Company's Plans in the discretion of the Board of Directors. No such awards were granted to Dr. Manuso granted during the three and six month periods ended June 30, 2018 and June 30, 2017. Dr. Manuso was also entitled to receive, until such time as the Company established a group health plan for its employees, \$1,200 per month, on a tax-equalized basis, as additional compensation to cover the cost of health coverage and up to \$1,000 per month, on a tax-equalized basis, as additional compensation for a term life insurance policy and disability insurance policy. Such amounts were accrued for the three and nine month periods ended September 30, 2018 and September 30, 2017. Dr. Manuso was also entitled to be reimbursed for business expenses. The Company has accrued all submitted and approved business expenses as of September 30, 2018, December 30, 2017 and September 30, 2017. Additional information with respect to the stock options granted to Dr. Manuso is provided at Note 6 to the Company's condensed consolidated financial statements for the three months and nine months ended September 30, 2018 and 2017. Cash compensation accrued pursuant to this agreement totaled \$103,650 for each of the three months ended September 2018, and 2017, respectively and \$310,950 for the nine months ended September 30, 2018 and 2017, respectively. Such amounts were included in accrued compensation and related expenses in the Company's condensed consolidated balance sheet at September 30, 2018 and 2017, respectively, and in general and administrative expenses in the Company's consolidated statement of operations for the three and nine months ended September 30, 2018 and 2017, as appropriate. On December 9, 2017, Dr. Manuso forgave \$878,360 of accrued compensation and related expenses which was the amount owed by the Company as of September 30, 2017, as described in more detail below. On the same date, Dr. Manuso received options to purchase 608,704 shares of common stock, as described in more detail below. Dr. Manuso did not receive any additional compensation for serving as Vice Chairman or a member of on the Board of Directors. Amounts accruing after September 30, 2017 have not been paid to Dr. Manuso. Effective on September 30, 2018, Dr. Manuso also resigned as Vice Chairman and as a member of the Board of Directors.





On August 18, 2015, concurrently with the hiring of Dr. James S. Manuso as the Company's new President and Chief Executive Officer, Dr. Arnold S. Lippa resigned as the Company's President and Chief Executive Officer. On October 12, 2018, Dr. Lippa was named Interim President and Interim Chief Executive Officer (see Note 9 to the Company's condensed consolidated financial statements for the three months and nine months ended September 30, 2018 and 2017) to replace Dr. Manuso who resigned effective September 30, 2018. Dr. Lippa continues to serve as the Company's Executive Chairman and as a member of the Board of Directors. Also on August 18, 2015, Dr. Lippa was named Chief Scientific Officer of the Company, and the Company entered into an employment agreement with Dr. Lippa in that capacity. Pursuant to the agreement, which is for an initial term through September 30, 2018 (and which will be deemed to be automatically extended, upon the same terms and conditions, for successive periods of one year, unless either party provides written notice of its intention not to extend the term of the agreement at least 90 days prior to the applicable renewal date), Dr. Lippa received an annual base salary of \$300,000. Dr. Lippa is also eligible to earn a performance-based annual bonus award of up to 50% of his base salary, based upon the achievement of annual performance goals established by the Board of Directors in consultation with the executive prior to the start of such fiscal year, or any amount at the discretion of the Board of Directors. Additionally, Dr. Lippa was granted stock options to acquire 30,769 shares of common stock of the Company and is eligible to receive additional awards under the Company's Plans at the discretion of the Board of Directors. Dr. Lippa is also entitled to receive, until such time as the Company establishes a group health plan for its employees, \$1,200 per month, on a tax-equalized basis, as additional compensation to cover the cost of health coverage and up to \$1,000 per month, on a tax-equalized basis, as reimbursement for a term life insurance policy and disability insurance policy. Dr. Lippa is also entitled to be reimbursed for business expenses. Additional information with respect to the stock options granted to Dr. Lippa is provided at Note 6 to the Company's condensed consolidated financial statements for the three months and nine months ended September 30, 2018 and 2017. Cash compensation accrued pursuant to this agreement totaled \$84,900 for each of the three months ended September 30, 2018 and 2017, respectively, and \$254,700 for the nine months ended September 30, 2018 and 2017 respectively which amounts are included in accrued compensation and related expenses in the Company's consolidated balance sheet at September 30, 2018 and December 31, 2017, and in research and development expenses in the Company's consolidated statement of operations. Cash compensation accrued to Dr. Lippa for bonuses and under a prior superseded arrangement, while still serving as the Company's President and Chief Executive Officer, totaled \$94,758 and was part of the amount forgiven on December 9, 2017 and therefore is no longer included in accrued compensation and related expenses as of September 30, 2018 and December 31, 2017. Dr. Lippa does not receive any additional compensation for serving as Executive Chairman and on the Board of Directors. On December 9, 2017, Dr. Lippa forgave \$807,497 of accrued compensation and related expenses which was the amount owed by the Company as of September 30, 2017. On the same date, Dr. Lippa received options to purchase 559,595 shares of common stock, as described in more detail below.

On August 18, 2015, the Company also entered into an employment agreement with Jeff E. Margolis, in his continuing role as Vice President, Secretary and Treasurer. Pursuant to the agreement, which was for an initial term through September 30, 2016 (and which will be deemed to be automatically extended upon the same terms and conditions, for successive periods of one year, unless either party provides written notice of its intention not to extend the term of the agreement at least 90 days prior to the applicable renewal date), Mr. Margolis received an annual base salary of \$195,000, and is also eligible to receive performance-based annual bonus awards ranging from \$65,000 to \$125,000, based upon the achievement of annual performance goals established by the Board of Directors in consultation with the executive prior to the start of such fiscal year, or any amount at the discretion of the Board of Directors. Additionally, Mr. Margolis was granted stock options to acquire 30,769 shares of common stock of the Company and is eligible to receive additional awards under the Company's Plans at the discretion of the Board of Directors. Mr. Margolis is also entitled to receive, until such time as the Company establishes a group health plan for its employees, \$1,200 per month, on a tax-equalized basis, as additional compensation to cover the cost of health

coverage and up to \$1,000 per month, on a tax-equalized basis, as reimbursement for a term life insurance policy and disability insurance policy. Mr. Margolis is also each entitled to be reimbursed for business expenses. Additional information with respect to the stock options granted to Mr. Margolis is provided at Note 6 to the Company's condensed consolidated financial statements for the three months and nine months ended September 30, 2018 and 2017. Jeff E. Margolis' employment agreement was amended effective July 1, 2017. The employment agreement amendment called for payment in three installments in cash of the \$60,000 bonus granted on June 30, 2015. A minimum of \$15,000 was to be payable in cash as follows: (a) \$15,000 payable in cash upon the next closing (after July 1, 2017) of any financing in excess of \$100,000 (b) \$15,000 payable by the end of the following month assuming cumulative closings (beginning with the closing that triggered (a)) in excess of \$200,000 and (c) \$30,000 payable in cash upon the next closing of any financing in excess of an additional \$250,000. The conditions of (a), (b) and (c) above were met as of December 31, 2017, however Mr. Margolis has waived the Company's obligation to make any payments of the cash bonus until the Board of Directors of the Company determines that sufficient capital has been raised by the Company or is otherwise available to fund the Company's operations on an ongoing basis. Recurring cash compensation accrued pursuant to this amended agreement totaled \$80,400 and \$54,150 for the three months ended September 30, 2018 and September 30, 2017, respectively, and \$241,200 and \$188,700 for the nine months ended September 30, 2018 and 2017, respectively, which amounts are included in accrued compensation and related expenses in the Company's consolidated balance sheet at September 30, 2018, September 30, 2017 and December 31, 2017, and in general and administrative expenses in the Company's consolidated statement of operations.

The employment agreements between the Company and each of Dr. Manuso, Dr. Lippa, and Mr. Margolis (prior to the 2017 amendment), respectively, provided that the payment obligations associated with the first year base salary were to accrue, but no payments were to be made, until at least \$2,000,000 of net proceeds from any offering or financing of debt or equity, or a combination thereof, was received by the Company, at which time scheduled payments were to commence. As this financing milestone has not been achieved, Dr. Manuso, Dr. Lippa, and Mr. Margolis (who are each also directors of the Company) have each agreed, effective as of August 11, 2016, to continue to defer the payment of such amounts indefinitely, until such time as the Board of Directors of the Company determines that sufficient capital has been raised by the Company or is otherwise available to fund the Company's operations on an ongoing basis.

On December 9, 2017, the Company accepted offers from Dr. Arnold S. Lippa, Dr. James S. Manuso, Jeff E. Margolis, James E. Sapirstein, Kathryn MacFarlane and Robert N. Weingarten (former Chief Financial Officer) pursuant to which such individuals would forgive accrued compensation and related accrued expenses as of September 30, 2017 in the following amounts: \$807,497, \$878,360, \$560,876, \$55,000, \$55,000, and \$200,350, respectively, for a total of \$2,557,083. On the same date, the Company granted to the same individuals, or designees of such individuals from the 2015 Plan, non-qualified stock options, exercisable for 10 years with an exercise price of \$1.45 per share of common stock, among other terms and features as follows: 559,595, 608,704, 388,687, 381,114, 38,114, and 138,842, respectively, for options exercisable into a total of 1,772,055 shares of common stock with a total value of \$2,475,561.

#### ***University of Alberta License Agreement***

On May 8, 2007, the Company entered into a license agreement, as amended, with the University of Alberta granting the Company exclusive rights to practice patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. The Company agreed to pay the University of Alberta a licensing fee and a patent issuance fee, which were paid, and prospective payments consisting of a royalty on net sales, sublicense fee payments, maintenance payments and milestone payments. The prospective maintenance payments commence on the enrollment of the first patient into the first Phase 2B clinical trial and increase upon the successful completion of the Phase 2B clinical trial. As the Company does not at this time anticipate scheduling a Phase 2B clinical trial in the near term, no maintenance payments to the University of Alberta are currently due and payable, nor are any maintenance payments expected to be due in the near future in connection with the license agreement.

By letter dated May 18, 2018, the Company received notice from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purports to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. There have been several communications between Company counsel, the Company and representatives of TEC Edmonton to determine whether and under what terms a resolution to the dispute can be reached, and the parties have extended the applicable deadlines under the license

agreement to continue those discussions, but a resolution has not yet been reached. No assurance can be provided that the parties will reach an acceptable resolution and we cannot estimate the possible impact of this disagreement on the Company's operations or business prospects.

*University of Illinois 2014 Exclusive License Agreement*

On June 27, 2014, the Company entered into an Exclusive License Agreement (the “2014 License Agreement”) with the University of Illinois, the material terms of which were similar to a License Agreement between the parties that had been previously terminated on March 21, 2013. The 2014 License Agreement became effective on September 18, 2014, upon the completion of certain conditions set forth in the 2014 License Agreement, including: (i) the payment by the Company of a \$25,000 licensing fee, (ii) the payment by the Company of outstanding patent costs aggregating \$15,840, and (iii) the assignment to the University of Illinois of rights the Company held in certain patent applications, all of which conditions were fulfilled.

The 2014 License Agreement granted the Company (i) exclusive rights to several issued and pending patents in numerous jurisdictions and (ii) the non-exclusive right to certain technical information that is generated by the University of Illinois in connection with certain clinical trials as specified in the 2014 License Agreement, all of which relate to the use of cannabinoids for the treatment of sleep related breathing disorders. The Company is developing dronabinol ( $\Delta^9$ -tetrahydrocannabinol), a cannabinoid, for the treatment of OSA, the most common form of sleep apnea.

The 2014 License Agreement provides for various commercialization and reporting requirements commencing on June 30, 2015. In addition, the 2014 License Agreement provides for various royalty payments, including a royalty on net sales of 4%, payment on sub-licensee revenues of 12.5%, and a minimum annual royalty beginning in 2015 of \$100,000, which is due and payable on December 31 of each year beginning on December 31, 2015. The 2016 minimum annual royalty of \$100,000 was paid as scheduled in December 2016. In the year after the first application for market approval is submitted to the FDA and until approval is obtained, the minimum annual royalty will increase to \$150,000. In the year after the first market approval is obtained from the FDA and until the first sale of a product, the minimum annual royalty will increase to \$200,000. In the year after the first commercial sale of a product, the minimum annual royalty will increase to \$250,000. During the nine months ended September 30, 2018 and 2017, the Company recorded a charge to operations of \$75,000 with respect to its minimum annual royalty obligation, which is included in research and development expenses in the Company’s condensed consolidated statements of operations for the nine months ended September 30, 2018 and 2017.

The 2014 License Agreement also provides for certain one-time milestone payments. A payment of \$75,000 is due within five days after any one of the following: (a) dosing of the first patient with a product in a Phase 2 human clinical study anywhere in the world that is not sponsored by the University of Illinois, (b) dosing of the first patient in a Phase 2 human clinical study anywhere in the world with a low dose of dronabinol, or (c) dosing of the first patient in a Phase 1 human clinical study anywhere in the world with a proprietary reformulation of dronabinol. A payment of \$350,000 is due within five days after dosing of the first patient with a product in a Phase 3 human clinical trial anywhere in the world. A payment of \$500,000 is due within five days after the first new drug application filing with the FDA or a foreign equivalent for a product. A payment of \$1,000,000 is due within 12 months after the first commercial sale of a product.



**Summary of Principal Cash Obligations and Commitments**

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of September 30, 2018, aggregating \$1,086,200. Amounts included in the 2018 column represent amounts contractually due at from September 30, 2018 through the remainder of the 2018 fiscal year ending December 31, 2018.

|  | Total       | Payments Due By Year |           |           |           |           |
|--|-------------|----------------------|-----------|-----------|-----------|-----------|
|  |             | 2018                 | 2019      | 2020      | 2021      | 2022      |
| License agreements                       | \$425,000   | \$25,000             | \$100,000 | \$100,000 | \$100,000 | \$100,000 |
| Employment and consulting agreements (1) | 661,200     | 165,300              | 495,900   | -         | -         | -         |
| Total                                    | \$1,086,200 | \$190,300            | \$595,900 | \$100,000 | \$100,000 | \$100,000 |

(1) The payment of such amounts has been deferred indefinitely, as described above at "Employment Agreements". 2018 obligations include three months of employment agreement obligations for Dr. Lippa and Mr. Margolis as their employment contracts renewed on September 30, 2018 and 2019 obligations include nine months of obligations through September 30, 2019.

**Off-Balance Sheet Arrangements**

At September 30, 2018, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

Not required for smaller reporting companies.

**ITEM 4. CONTROLS AND PROCEDURES**

(a) Evaluation of Disclosure Controls and Procedures



The Company maintains disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) that are designed to ensure that information required to be disclosed in the reports that the Company files with the Securities and Exchange Commission (the “SEC”) under the Exchange Act is 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 its Chief Executive Officer and Chief Financial Officer, to allow for timely decisions regarding required disclosures.

The Company carried out an evaluation, under the supervision and with the participation of its management, consisting of its principal executive officer and principal financial officer, of the effectiveness of the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act). Based upon that evaluation, the Company’s principal executive officer and principal financial officer concluded that, as of the end of the period covered in this report, the Company’s disclosure controls and procedures were not effective to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized and reported within the required time periods and is accumulated and communicated to the Company’s management, consisting of the Company’s principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Current management, which joined the Company in March 2013, has been focusing on developing replacement controls and procedures that are adequate to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized and reported within the required time periods and is accumulated and communicated to the Company’s management, consisting of the Company’s principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Current management has instituted a program to reestablish the Company’s accounting and financial staff and install new accounting and internal control systems, and has retained accounting personnel, established accounting and internal control systems, addressed the preparation of delinquent financial statements, and worked diligently to bring delinquent SEC filings current as promptly as reasonably possible under the circumstances. The Company did not file this Periodic Report on Form 10-Q timely. Having filed it, the Company is current in its SEC periodic reporting obligations, but as of the date of the filing of this Quarterly Report on Form 10-Q, the Company had not yet completed the process to establish adequate internal controls over financial reporting.

The Company's management, consisting of its principal executive officer and principal financial officer, does not expect that its disclosure controls and procedures or its internal controls will prevent all error or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Furthermore, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Management believes that the financial statements included in this report fairly present, in all material respects, the Company's financial condition, results of operations and cash flows for the periods presented.

(b) Changes in Internal Controls over Financial Reporting

The Company's management, consisting of its principal executive officer and principal financial officer, has determined that no change in the Company's internal control over financial reporting (as that term is defined in Rules 13(a)-15(f) and 15(d)-15(f) of the Securities Exchange Act of 1934) occurred during or subsequent to the end of the period covered in this report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

## **PART II - OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

By letter dated May 18, 2018, the Company received notice from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purports to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. There have been several communications between Company counsel, the Company and representatives of TEC Edmonton to determine whether and under what terms a resolution to the dispute can be reached and the parties have extended the applicable deadlines under the license agreement to continue those discussions, but a resolution has not yet been reached. No assurance can be provided that the parties will reach an acceptable resolution and, in light of the early stages of the disagreement, we cannot estimate the possible impact of this disagreement on the Company's operations or business prospects.

By letter dated February 5, 2016, the Company received a demand from a law firm representing a professional services vendor of the Company alleging an amount due and owing for unpaid services rendered. On January 18,

2017, following an arbitration proceeding, an arbitrator awarded the vendor the full amount sought in arbitration of \$146,082. Additionally, the arbitrator granted the vendor attorneys' fees and costs of \$47,937. All such amounts have been accrued at September 30, 2018 and December 31, 2017, including accrued interest at 4.5% annually from February 26, 2018, the date of the judgment, through September 30, 2018, totaling \$5,239.

The Company is periodically subject to various pending and threatened legal actions and claims. See Note 8 to our condensed consolidated financial statements for the nine months ended September 30, 2018 and 2017—Commitments and Contingencies—*Pending or Threatened Legal Actions and Claims* for details regarding these matters.

In the opinion of management of the Company, adequate provision has been made in the Company's condensed consolidated financial statements at September 30, 2018 and our consolidated financial statements at December 31, 2017 with respect to such matters, including, specifically, the matters noted above. The Company intends to vigorously defend itself if any of the matters described above results in the filing of a lawsuit or formal claim.

## ITEM 1A. RISK FACTORS

As of the date of this filing, there have been no material changes to the Risk Factors included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, as filed with the SEC on April 17, 2018 (the "2017 Form 10-K"). The Risk Factors set forth in the 2017 Form 10-K should be read carefully in connection with evaluating the Company's business and in connection with the forward-looking statements contained in this Quarterly Report on Form 10-Q. Any of the risks described in the 2017 Form 10-K could materially adversely affect the Company's business, financial condition or future results and the actual outcome of matters as to which forward-looking statements are made. These are not the only risks that the Company faces. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

## ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On September 12, 2018, the Company consummated an initial closing on an offering ("2018 Unit Offering") of Units comprised of one share of the Company's common stock and one common stock purchase warrant. The 2018 Unit Offering may have been up to \$1.5 million. The 2018 Unit Offering was terminated on October 15, 2018 with no additional closings. The initial closing was for \$250,750 of which \$200,750 was the gross cash proceeds. The additional \$50,000 was represented by the conversion or exchange into the 2018 Unit Offering of the principal amount of the Arnold S. Lippa, Demand Promissory Note described below. Units were sold for \$1.05 per unit and the warrants issued in connection with the units are exercisable through April 30, 2023 at a fixed price of 150% of the unit purchase price. The warrants contain a cashless exercise provision and certain blocker provisions preventing exercise if the investor would beneficially own more than 4.99% of the Company's outstanding shares of common stock as a result of such exercise. The warrants are also subject to redemption by the Company at \$0.001 per share upon ten (10) days written notice if the Company's common stock closes at \$3.00 or more for any five (5) consecutive trading days. In total, 238,814 shares of the Company's common stock and 238,814 common stock purchase warrants were purchased. Other than Arnold S. Lippa, the investors in the offering were not affiliates of the Company. Investors also received an unlimited number of piggy-back registration rights in respect to the shares of common stock and the shares of common stock underlying the common stock purchase warrants, unless such common stock is eligible to be sold with volume limits under an exemption from registration under any rule or regulation of the SEC that permits the holder to sell securities of the Company to the public without registration and without volume limits (assuming the holder is not an affiliate).

The shares of common stock and common stock purchase warrants were offered and sold without registration under the Securities Act of 1933, as amended (the "Securities Act") in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as provided in Rule 506(b) of Regulation D promulgated thereunder. None of the shares of common stock issued as part of the units, the common stock purchase warrants, the Common Stock issuable upon exercise of the common stock purchase warrants or any warrants issued to a qualified referral source (of which there were none in the initial closing) have been registered under the Securities Act or any other applicable securities laws, and unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the

registration requirements of the Securities Act.

Prior to the initial closing of the 2018 Unit Offering, the Company issued to Arnold S. Lippa, Ph.D, the Company's Interim President, Interim Chief Executive Officer, Executive Chairman and Chief Scientific Officer and James S. Manuso, Ph.D., the Company's then Vice Chairman and then Chief Executive Officer, \$100,000 aggregate principal amount (\$50,000 each) of demand promissory notes bearing interest at 10% (the "Demand Promissory Notes"). The Demand Promissory Note issued to Dr. Lippa, exclusive of any interest accrued, was exchanged into the 2018 Unit Offering simultaneously with its initial closing. The principal amount of, but not the interest on, the Demand Promissory Note was taken into consideration when determining if the Company had achieved the minimum amount necessary to effect the initial closing of the 2018 Unit Offering. The Demand Promissory Note issued to Dr. Manuso was not exchanged or converted in connection with the initial closing of the 2018 Unit Offering, but the Company currently anticipates that it will be exchanged or converted in connection with a subsequent offering.

In addition, as set forth in the Purchase Agreements, each Purchaser has an unlimited number of exchange rights, which are options and not obligations, to exchange such Purchaser's entire investment (but not less than the entire investment) into one or more subsequent equity financings (consisting solely of convertible preferred stock or common stock or units containing preferred stock or common stock and warrants exercisable only into preferred stock or common stock) that would be considered as "permanent equity" under United States Generally Accepted Accounting Principles and the rules and regulations of the United States Securities and Exchange Commission, and therefore classified within stockholders' equity, and excluding any form of debt or convertible debt or preferred stock redeemable at the discretion of the holder (each such financing a "Subsequent Equity Financing"). These exchange rights are effective until the earlier of: (i) the completion of any number of Subsequent Equity Financings that aggregate at least \$15 million of gross proceeds, or (ii) December 30, 2018. For clarity, a Purchaser's entire investment is the entire amount invested ("Investment Amount") (for purposes of the multiple described below) and all of the Common Stock and Warrants purchased (for purposes of the exchange) pursuant to the Purchase Agreement of such Purchaser, however, if the Warrants have been exercised in part or in whole on a cashless basis, then the Investment Amount (for purposes of the multiple described below) will be the Investment Amount (for purposes of the multiple described below) and all of the Common Stock initially purchased pursuant to the Purchase Agreement of such Purchaser plus any shares of Common Stock issued pursuant to a cashless exercise and any Warrants remaining after such cashless exercise (for purposes of the exchange), or, if the Warrants have been exercised for cash, then the entire investment will be the Investment Amount plus the amount of cash paid upon cash exercise (for purposes of the multiple described below) and all of the Common Stock initially purchased pursuant to the Purchase Agreement of such Purchaser plus any shares of Common Stock issued pursuant to the cash exercise and any Warrants remaining after such cash exercise (for purposes of the exchange).

Additional information with respect to the transactions described above is provided in the Notes to the Condensed Consolidated Financial Statements for the nine months ended September 30, 2018 and 2017.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

#### ***Note Payable to SY Corporation Co., Ltd.***

On June 25, 2012, the Company borrowed 465,000,000 Won (the currency of South Korea, equivalent to approximately \$400,000 United States Dollars) from and executed a secured note payable to SY Corporation Co., Ltd., formerly known as Samyang Optics Co. Ltd. ("SY Corporation"), an approximately 20% common stockholder of the Company at that time. SY Corporation was a significant stockholder and a related party at the time of the transaction, but has not been a significant stockholder or related party of the Company subsequent to December 31, 2015. The note accrues simple interest at the rate of 12% per annum and had a maturity date of June 25, 2013. The Company has not made any payments on the promissory note. At June 30, 2013 and subsequently, the promissory note was outstanding and in technical default, although SY Corporation has not issued a notice of default or a demand for repayment. The Company believes that SY Corporation is in default of its obligations under its January 2012 license agreement, as amended, with the Company, but the Company has not yet issued a notice of default. The Company is continuing efforts towards a comprehensive resolution of the aforementioned matters involving SY

Corporation.

Note payable to SY Corporation consists of the following at September 30, 2018 and December 31, 2017:

|   | June 30,<br>2018 | December<br>31, 2017 |
|---|------------------|----------------------|
| Principal amount of note payable        | \$ 399,774       | \$ 399,774           |
| Accrued interest payable                | 303,216          | 267,335              |
| Foreign currency transaction adjustment | 25,300           | (83,282 )            |
|   | \$ 728,290       | \$ 583,827           |

Interest expense with respect to this promissory note was \$12,092 and \$12,092 for each of the three months ended September 30, 2018 and 2017, respectively. Interest expense with respect to this promissory note was \$35,881 and \$35,881 for nine months ended September 30, 2018 and 2017, respectively.

***Default on Convertible Notes Payable***

On September 15, 2016, the remaining outstanding Notes previously issued by the Company on November 5, 2014, December 9, 2014, December 31, 2014, and February 2, 2015, matured and the principal and accrued interest under those remaining Notes became due and payable upon demand. At the September 15, 2016 maturity date, Notes totaling \$329,261, which included accrued interest of \$53,261, became due and payable upon demand. During October 2016, holders of four Notes totaling \$73,004, which included accrued interest of \$12,004 at September 30, 2016, issued formal notices of default, and as a result, those four Notes were deemed to be in default under the terms of the Notes and began to accrue interest at the default rate of 12% per annum from the default date in accordance with the terms of the Notes. In February, 2018 and May, 2018, several note holders whose notes were in default exchanged their notes, inclusive of accrued interest into equity. There was one remaining Note in default at September 30, 2018 and the amount owed on that note was \$37,817, comprised of \$25,000 of principal and \$12,817 of accrued interest.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

As previously disclosed on June 19, 2018, James S. Manuso, Ph.D., the Company's former President and Chief Executive Officer, resigned as an officer and as Vice Chairman and a member of the Company's Board of Directors, effective as of the end of the term of his employment agreement, September 30, 2018. As previously disclosed in its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018, on October 12, 2018, Arnold S. Lippa, Ph.D. was named Interim President and Interim Chief Executive Officer. Dr. Lippa continues to serve as the Company's Chief Scientific Officer and Chairman of the Board of Directors. No changes were made to Dr. Lippa's employment agreement or compensation with respect to such interim appointment.

**ITEM 6. EXHIBITS**

**INDEX TO EXHIBITS**



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The following documents are filed or furnished as part of this report:

| Exhibit Number | Description of Document   |
|----------------|---|
| 10.1#*         | <u>Development and Supply Agreement, dated September 4, 2018, between the Company and Noramco, Inc.</u>   |
| 10.2           | <u>Form of Purchase Agreement, (including the form of warrant) (incorporated by reference to the Company's current Report on Form 8-K (file no. 1-16467) dated and filed September 12, 2018).</u> |
| 31.1*          | <u>Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>   |
| 31.2*          | <u>Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>   |
| 32.1**         | <u>Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>   |
| 32.2**         | <u>Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>   |
| 101.INS***     | XBRL Instance Document  |
| 101.SCH***     | XBRL Taxonomy Extension Schema Document   |
| 101.CAL***     | XBRL Taxonomy Extension Calculation Linkbase Document   |
| 101.LAB***     | XBRL Taxonomy Extension Label Linkbase Document   |
| 101.PRE***     | XBRL Taxonomy Extension Presentation Linkbase Document  |
| 101.DEF***     | XBRL Taxonomy Extension Definition Linkbase Document  |

# Confidential portions of this exhibit have been omitted and filed separately with the SEC pursuant to a request for confidential treatment.

\* Filed herewith.

\*\* Furnished herewith.

\*\*\*In accordance with Regulation S-T, the XBRL related information on Exhibit No. 101 to this Quarterly Report on Form 10-Q shall be deemed "furnished" herewith not "filed."

## SIGNATURES

In accordance with the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

RESPIRERX PHARMACEUTICALS INC.  
(Registrant)

Date: November 16, 2018 By: */s/ ARNOLD S. LIPPA*  
Arnold S. Lippa  
Interim President and Interim Chief Executive Officer

Date: November 16, 2018 By: */s/ JEFF E. MARGOLIS*  
Jeff E. Margolis  
Senior Vice President, Treasurer, Secretary and Chief Financial Officer

