

**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 December 31, 2018

OR

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

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

Commission File Number: 333-88480

**OHR PHARMACEUTICAL, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**46-5622433**

(I.R.S. Employer Identification No.)

**800 Third Avenue, 11th Floor  
New York, NY 10022**

(Address of principal executive offices)

**(212) 682-8452**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this Chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
(Do not check if smaller reporting company)		Emerging Growth Company	<input type="checkbox"/>

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 2,829,248 shares of Common Stock outstanding as of February 13, 2019.

TABLE OF CONTENTS

	Page
<a href="#"><u>PART I FINANCIAL INFORMATION</u></a>	3
<a href="#"><u>Item 1. Financial Statements (Unaudited)</u></a>	3
<a href="#"><u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u></a>	13
<a href="#"><u>Item 3. Quantitative and Qualitative Risk</u></a>	16
<a href="#"><u>Item 4. Controls and Procedures</u></a>	16
<a href="#"><u>PART II OTHER INFORMATION</u></a>	16
<a href="#"><u>Item 1. Legal Proceedings</u></a>	16
<a href="#"><u>Item 1A. Risk Factors</u></a>	17
<a href="#"><u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></a>	32
<a href="#"><u>Item 3. Defaults Upon Senior Securities</u></a>	32
<a href="#"><u>Item 4. Mine Safety Disclosures</u></a>	32
<a href="#"><u>Item 5. Other Information</u></a>	32
<a href="#"><u>Item 6. Exhibits</u></a>	32

**Part I FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

TABLE OF CONTENTS	PAGE
<a href="#">Unaudited Consolidated Balance Sheets as of December 31, 2018 and September 30, 2018</a>	4
<a href="#">Unaudited Consolidated Statements of Operations for the three months ended December 31, 2018 and 2017</a>	5
<a href="#">Unaudited Consolidated Statements of Cash Flows for the three months ended December 31, 2018 and 2017</a>	6
<a href="#">Notes to Unaudited Consolidated Financial Statements</a>	7

**OHR PHARMACEUTICAL, INC.**  
**Consolidated Balance Sheets**  
**(Unaudited)**

	<u>December 31,</u> <u>2018</u>	<u>September 30,</u> <u>2018</u>
<u>ASSETS</u>		
CURRENT ASSETS		
Cash and cash equivalents	\$ 3,110,441	\$ 3,750,436
Prepaid expenses and other current assets	103,269	247,998
Total Current Assets	<u>3,213,710</u>	<u>3,998,434</u>
EQUIPMENT, net	<u>13,421</u>	<u>15,763</u>
OTHER ASSETS		
Intangible assets, net	<u>7,446,891</u>	<u>7,611,918</u>
<b>TOTAL ASSETS</b>	<b><u>\$ 10,674,022</u></b>	<b><u>\$ 11,626,115</u></b>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 597,152	\$ 651,781
Notes payable	<u>—</u>	<u>73,217</u>
Total Current Liabilities	<u>597,152</u>	<u>724,998</u>
<b>TOTAL LIABILITIES</b>	<b><u>597,152</u></b>	<b><u>724,998</u></b>
STOCKHOLDERS' EQUITY		
Preferred stock, Series B; 6,000,000 shares authorized, \$0.0001 par value, 0 shares issued and outstanding, respectively	—	—
Common stock; 180,000,000 shares authorized, \$0.0001 par value, 2,829,248 and 2,829,248 shares issued and outstanding, respectively	283	283
Additional paid-in capital	132,299,718	132,226,341
Accumulated deficit	<u>(122,223,131)</u>	<u>(121,325,507)</u>
Total Stockholders' Equity	<u>10,076,870</u>	<u>10,901,117</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b><u>\$ 10,674,022</u></b>	<b><u>\$ 11,626,115</u></b>

The accompanying notes are an integral part of these unaudited consolidated financial statements.

**OHR PHARMACEUTICAL, INC.**  
**Consolidated Statements of Operations**  
**(Unaudited)**

	<b>For the Three Months Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>OPERATING EXPENSES</b>		
General and administrative	\$ 680,995	\$ 1,510,032
Research and development	58,021	2,387,731
Depreciation and amortization	167,370	284,986
<b>OPERATING LOSS</b>	906,386	4,182,749
<b>OTHER INCOME (EXPENSE)</b>		
Interest income	8,762	31,391
<b>Total Other Income</b>	8,762	31,391
<b>LOSS FROM OPERATIONS BEFORE INCOME TAXES</b>	(897,624)	(4,151,358)
<b>NET LOSS</b>	\$ (897,624)	\$ (4,151,358)
<b>BASIC AND DILUTED LOSS PER SHARE (in dollars per share)</b>	\$ (0.32)	\$ (1.48)
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:</b>		
BASIC AND DILUTED	2,829,248	2,810,189

The accompanying notes are an integral part of these unaudited consolidated financial statements.

**OHR PHARMACEUTICAL, INC.**  
**Consolidated Statements of Cash Flows**  
(Unaudited)

	<b>For the Three Months Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (897,624)	\$ (4,151,358)
Adjustments to reconcile net loss to net cash used by operating activities:		
Common stock issued for services	—	135,701
Stock option and warrant expense	73,377	629,286
Depreciation	2,342	2,867
Amortization of intangible assets	165,027	282,118
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	144,729	134,799
Accounts payable and accrued expenses	(54,629)	(1,229,054)
	<u>(566,778)</u>	<u>(4,195,641)</u>
Net Cash Used in Operating Activities	(566,778)	(4,195,641)
<b>FINANCING ACTIVITIES</b>		
Proceeds from warrants exercised for cash	—	225,000
Repayments of short-term notes payable	(73,217)	(106,387)
	<u>(73,217)</u>	<u>118,613</u>
Net Cash Provided by/ (Used in) Financing Activities	(73,217)	118,613
NET CHANGE IN CASH	(639,995)	(4,077,028)
CASH AT BEGINNING OF PERIOD	<u>3,750,436</u>	<u>12,801,085</u>
CASH AT END OF PERIOD	<u>\$ 3,110,441</u>	<u>\$ 8,724,057</u>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION</b>		
CASH PAID FOR:		
Interest	\$ 779	\$ 1,770

The accompanying notes are an integral part of these unaudited consolidated financial statements.

**Notes to Unaudited Consolidated Financial Statements**  
**December 31, 2018**

**NOTE 1 – BASIS OF PRESENTATION**

The accompanying unaudited consolidated financial statements include the accounts of Ohr Pharmaceutical, Inc. and its subsidiaries (the “Company”). The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X related to interim period financial statements. Accordingly, these consolidated financial statements do not include certain information and footnotes required by GAAP for complete financial statements. However, in the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at December 31, 2018, and for all periods presented herein, have been made.

It is suggested that these unaudited consolidated financial statements be read in conjunction with the consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended September 30, 2018. The results of operations for the quarterly periods ended December 31, 2018 and 2017 are not necessarily indicative of the operating results for the full years.

*NeuBase Merger Agreement*

On January 2, 2019, the Company, Ohr Acquisition Corp., a Delaware corporation and a wholly-owned subsidiary of Ohr (“Merger Sub”), and NeuBase Therapeutics, Inc., a Delaware corporation (“NeuBase”), entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into NeuBase, with NeuBase becoming a wholly-owned subsidiary of the Company and the surviving corporation of the merger (the “Merger”). See Note 8 below for more information regarding the Merger.

*Reverse Stock Split*

On January 18, 2019, following a special meeting of the Company’s stockholders, the board of directors of the Company approved a one-for-twenty reverse stock split of the Company’s issued and outstanding shares of common stock (the “Reverse Stock Split”). On January 23, 2019, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation to effect the Reverse Stock Split. The Company’s common stock began trading on a split-adjusted basis when the market opened on February 4, 2019. As a result of the Reverse Stock Split, the outstanding common stock has decreased from 56,466,428 shares of common stock, par value \$0.0001 per share, to 2,829,248 shares of common stock, par value \$0.0001 per share. Unless otherwise noted, impacted amounts and share information included in the financial statements and notes thereto, and elsewhere in this Form 10-Q, have been retroactively adjusted for the Reverse Stock Split as if such Reverse Stock Split occurred on the first day of the first period presented. Certain amounts in the financial statements, the notes thereto, and elsewhere in this Form 10-Q, may be slightly different than previously reported due to rounding of fractional shares as a result of the Reverse Stock Split. See Note 8 below for more information regarding the Reverse Stock Split.

**NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND GOING CONCERN**

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates. Estimates subject to change in the near term include impairment (if any) of long-lived assets and fair value of liabilities.

### Impairment of Long-Lived Assets

Long-lived tangible assets and definite-lived intangible assets are reviewed for possible impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The Company uses an estimate of undiscounted future net cash flows of the assets over the remaining useful lives in determining whether the carrying value of the assets is recoverable. If the carrying values of the assets exceed the expected future cash flows of the assets, the Company recognizes an impairment loss equal to the difference between the carrying values of the assets and their estimated fair values. Impairment of long-lived assets is assessed at the lowest levels for which there are identifiable cash flows that are independent from other groups of assets. The evaluation of long-lived assets requires the Company to use estimates of future cash flows. However, actual cash flows may differ from the estimated future cash flows used in these impairment tests.

### Fair Value of Financial Instruments

In accordance with ASC 820, the carrying value of cash and cash equivalents, accounts payable and notes payable approximates fair value due to the short-term maturity of these instruments. ASC 820 clarifies the definition of fair value, prescribes methods for measuring fair value, and establishes a fair value hierarchy to classify the inputs used in measuring fair value as follows:

Level 1 - Inputs are unadjusted quoted prices in active markets for identical assets or liabilities available at the measurement date.

Level 2 - Inputs are unadjusted quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, inputs other than quoted prices that are observable, and inputs derived from or corroborated by observable market data.

Level 3 - Unobservable inputs, where there is little or no market activity for the asset or liability. These inputs reflect the reporting entity's own beliefs about the assumptions that market participants would use in pricing the asset or liability, based on the best information available in the circumstances.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

There were no financial instruments required to be measured at fair value on a recurring basis as of September 30, 2018 and December 31, 2018.

### Goodwill and Intangibles

The Company evaluates goodwill and other finite-lived intangible assets in accordance with FASB ASC Topic 350, "*Intangibles — Goodwill and Other*." Goodwill is recorded at the time of an acquisition and is calculated as the difference between the total consideration paid for an acquisition and the fair value of the net tangible and intangible assets acquired. Accounting for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired, including in-process research and development ("IPR&D"). Goodwill is deemed to have an indefinite life and is not amortized, but is subject to annual impairment tests. If the assumptions and estimates used to allocate the purchase price are not correct, or if business conditions change, purchase price adjustments or future asset impairment charges could be required. The value of our goodwill could be impacted by future adverse changes such as: (i) any future declines in our operating results, (ii) a decline in the valuation of technology, including the valuation of our common stock, (iii) a significant slowdown in the worldwide economy or (iv) any failure to meet the performance projections included in our forecasts of future operating results. In accordance with FASB ASC Topic 350, the Company tests goodwill for impairment on an annual basis or more frequently if the Company believes indicators of impairment exist. Impairment evaluations involve management estimates of asset useful lives and future cash flows. Significant management judgment is required in the forecasts of future operating results that are used in the evaluations. It is possible, however, that the plans and estimates used may be incorrect. If our actual results, or the plans and estimates used in future impairment analysis, are lower than the original estimates used to assess the recoverability of these assets, we could incur additional impairment charges in a future period.

The Company performs its annual impairment review of goodwill in September, and when a triggering event occurs between annual impairment tests for both goodwill and other finite-lived intangible assets. During the twelve months ended September 30, 2018, the Company determined that due to the reduced price of the Company's common stock and the market capitalization of the Company relative to the value of the intangible assets and goodwill, an impairment analysis was required for the intangible assets and goodwill. The Company performed the tests and concluded that the intangible assets were impaired and recorded a loss of \$5,313,640, and wrote off the \$740,912 goodwill balance.

The Company's finite-lived intangible assets consist of license rights and patents. The Company amortizes its patents over the life of each patent and license rights over the remaining life of the patents that it has rights for. During the quarter ended December 31, 2018, the Company recognized \$165,027 in amortization expense on the patents and license rights.

### Research and Development

Research and development expenses are expensed in the consolidated statements of operations as incurred in accordance with FASB ASC 730, *Research and Development*. Research and development expenses include salaries, related employee expenses, clinical trial expenses, research expenses, manufacturing expenses, consulting fees, and laboratory costs. The Company incurred net research and development expenses of \$58,021, and \$2,387,731, during the quarter ended December 31, 2018, and 2017, respectively.

### Share-Based Compensation

The Company follows the provisions of ASC 718, "Share-Based Payments" which requires all share-based payments to employees, including grants of employee stock options, be recognized in the income statement based on their fair values. The Company uses the Black Scholes pricing model for determining the fair value of stock options and the stock price on the date of issuance to determine the fair value of restricted stock awards.



In accordance with ASC 505, equity instruments issued to non-employees for goods or services are accounted for at fair value and are marked to market until service is complete or a performance commitment date is reached, whichever is earlier.

Stock-based compensation expense is recognized in the Company's financial statements on a straight-line basis over the awards' vesting periods. The stock-based compensation awards generally vest over a period of up to ten years.

#### Loss Per Share

Basic loss per common share is computed by dividing losses attributable to common shareholders by the weighted-average number of shares of common stock outstanding during the period.

Diluted loss per common share is computed by dividing losses attributable to common shareholders by the weighted-average number of shares of common stock outstanding during the period increased to include the number of additional shares of common stock that would have been outstanding if the potentially dilutive securities had been issued. Potentially dilutive securities include outstanding stock options and warrants.

For the quarter ended December 31, 2018, there were no potentially dilutive securities (warrants or options).

#### Going Concern

To date, the Company has no revenue from product sales and management expects continuing operating losses and negative cash outflows in the future. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. Management may seek additional funds through equity or debt financings or through collaboration, licensing transactions, merger, or other sources. The Company may be unable to obtain equity or debt financings or enter into collaboration, merger, or licensing transactions. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

#### Recent Accounting Pronouncements

The Company has implemented all new relevant accounting pronouncements that are in effect through the date of these financial statements. The pronouncements did not have any material impact on the financial statements unless otherwise disclosed, and the Company does not believe that there are any other new accounting pronouncements that have been issued that might have a material impact on its consolidated financial position or results of operations.

### **NOTE 3 – INTANGIBLE ASSETS**

Intangible assets at December 31, 2018 and September 30, 2018:

	<b>December 31, 2018</b>	<b>September 30, 2018</b>
License Rights	\$ 17,712,991	\$ 17,712,991
Patent Costs	100,000	100,000
	<u>17,812,991</u>	<u>17,812,991</u>
Accumulated Amortization and impairment	(10,366,100)	(10,201,073)
Total Intangible Assets	<u>\$ 7,446,891</u>	<u>\$ 7,611,918</u>

During the three month period ended December 31, 2018 the Company recognized \$165,027 in amortization expense on the patents and license rights.

### **NOTE 4 – NOTES PAYABLE**

On February 28, 2018, the Company entered into a premium financing arrangement for its directors' and officers' insurance policy in the amount of \$323,094. The financing arrangement is a short term note, bears interest at a rate of 7.29% per annum, matures on November 28, 2018, and is secured by the underlying insurance policies and rights thereunder. During the quarter ended December 31, 2018, the Company had repaid the remaining \$73,217 and recorded interest of \$779.

## NOTE 5 – EQUITY

### Common Stock Warrants

Below is a table summarizing the warrants issued and outstanding as of December 31, 2018 (“Price” reflects the weighted average exercise price per share):

	Warrants	Price
Outstanding at September 30, 2018	805,968	\$ 24.39
Granted		
Investor warrants	—	—
Stock-based compensation warrants	—	—
Exercised		
Investor warrants	—	—
Stock-based compensation warrants	—	—
Forfeited or expired		
Investor warrants	—	—
Stock-based compensation warrants	—	—
Outstanding at December 31, 2018	805,968	\$ 24.39
Exercisable at December 31, 2018	805,968	\$ 24.39

As of December 31, 2018, the warrants have a weighted average remaining term of 3.2 years and have no intrinsic value.

### Stock Based Compensation

The Company’s Consolidated 2016 Stock Plan (“the Plan”) provides for granting stock options and restricted stock awards to employees, directors and consultants of the Company. The Company uses the Black-Scholes pricing model for determining the fair value of stock options and warrants granted as share based compensation.

**Warrants.** During the three month period ended December 31, 2018, the Company did not recognize any expense related to warrants granted as stock based compensation. There is no unamortized expense as of December 31, 2018 for outstanding warrants issued as stock based compensation. Refer to the Common Stock Warrants table within this note for information regarding all outstanding warrants.

**Options.** During the three month period ended December 31, 2018, the Company recognized \$73,377 of expense related to options granted. Unamortized option expense as of December 31, 2018 for all options outstanding amounted to \$212,631. The Company expects to recognize this compensation cost over a weighted-average period of .71 years.

Below is a table summarizing the Company’s activity for the three month period ended December 31, 2018 (“Price” reflects the weighted average exercise price per share):

	Options	Price
Outstanding at September 30, 2018	156,625	\$ 57.86
Granted	—	\$ —
Exercised	—	\$ —
Forfeited or expired	—	\$ —
Outstanding at December 31, 2018	156,625	\$ 57.86
Exercisable at December 31, 2018	124,370	\$ 69.40

As of December 31, 2018, the outstanding options have a weighted average remaining term of 3.77 years and no intrinsic value.

**Restricted Stock.** During the three month period ended December 31, 2018, the Company did not recognize any expense related to restricted stock awards. As of December 31, 2018, all restricted stock shares are fully vested, and there is no remaining unamortized expense.

## NOTE 6 – COMMITMENTS AND CONTINGENCIES

### Legal Proceedings

The Company has become involved in certain legal proceedings and claims which arise in the normal course of business. If an unfavorable ruling were to occur, there exists the possibility of a material adverse impact on the Company’s results of operations, prospects, cash flows, financial position and brand.

On February 14, 2018, plaintiff, Jeevesh Khanna, commenced an action in the Southern District of New York, against the Company and several current and former officers, alleging that they violated federal securities laws between June 24, 2014 and January 4, 2018. On August 7, 2018, the lead plaintiffs, now George Lehman and Insured Benefit Plans, Inc. filed an amended complaint, stating the class period to be April 8, 2014 through January 4, 2018. The plaintiffs did not quantify any alleged damages in their complaint but, in addition to attorneys’ fees and costs, they seek to maintain the action as a class action and to recover damages on behalf of themselves and other persons who purchased or otherwise acquired our stock during the putative class period and purportedly suffered financial harm as a result. The Company and the individuals dispute these claims and intend to defend the matter vigorously. On September 17, 2018, we filed a motion to dismiss the complaint. On November 13, 2018, plaintiffs filed a motion to strike exhibits appended to the motion to dismiss. A decision on the motion to strike is pending, and the motion to dismiss will then be fully briefed based on a schedule to be determined by the court. This litigation could result in substantial costs and a diversion of management’s resources and attention, which could harm the Company’s business and the value of the Company’s common stock.

On May 3, 2018, plaintiff Adele J. Barke, derivatively on behalf of the Company, commenced an action against Michael Ferguson, Orin Hirschman, Thomas M. Riedhammer, June Almenoff and Jason Slakter in the Supreme Court, State of New York, alleging that the action was brought in the right and for the benefit of Ohr seeking to remedy their “breach of fiduciary duties, corporate waste and unjust enrichment that occurred between June 24, 2014 and the present.” It does not quantify any alleged damages. The Company and the individuals dispute these claims and intend to defend the matter vigorously. Such litigation has been stayed pursuant to a stipulation by the parties, which has been so ordered by the court, pending a decision in the Southern District case on the motion to dismiss, but that status could change. This litigation could result in substantial costs and a diversion of management’s resources and attention, which could harm the Company’s business and the value of the Company’s common stock.

In September 2018, plaintiff John Tomson, derivatively and on behalf of the Company, commenced an action against Michael Ferguson, Sam Backenroth, Irach Taraporewala, Orin Hirschman, Thomas M. Riedhammer, June Almenoff and Jason Slakter in the US District Court for the Southern District of New York alleging that the action was brought in the right and for the benefit of Ohr seeking to remedy their various breaches of fiduciary duties, corporate waste and unjust enrichment that occurred between April 4, 2014 through January 4, 2018. Thereafter, the complaint largely summarized the allegations of the amended complaint filed in the securities class action described above. It does not quantify alleged damages. The Company and the individuals dispute these claims and intend to defend the matter vigorously. Such litigation is currently stayed pursuant to a stipulation by the parties, which has been so ordered by the court, pending a decision in the Southern District on the motion to dismiss, but that status could change. This litigation could result in substantial costs and a diversion of management’s resources and attention, which could harm the Company’s business and the value of the Company’s common stock.

Management believes that the likelihood of an adverse decision from the ongoing litigation is unlikely, however, the litigation could result in substantial costs and a diversion of management’s resources and attention, which could harm the Company’s business and the value of the Company’s common stock.

#### **NOTE 7 – RELATED PARTY TRANSACTION**

The Contract Research Organization (“CRO”) that ran the Company’s clinical trial contracted with Jason S. Slakter, M.D., P.C., d/b/a Digital Angiography Reading Center (“DARC”), a well-known digital reading center, which is owned by Dr. Jason Slakter, Ohr’s CEO, pursuant to the Company’s related party transactions policy, with the review and approval of the Audit Committee, to provide digital reading and imaging services in connection with the clinical study. During the three months ended December 31, 2018, and 2017, the Company’s CRO was invoiced or accrued \$0 and \$731,832, respectively, for pass through DARC expenses.

#### **NOTE 8 – SUBSEQUENT EVENTS**

##### *NeuBase Merger Agreement*

On January 2, 2019, the Company, Merger Sub and NeuBase entered into the Merger Agreement, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into NeuBase, with NeuBase becoming a wholly-owned subsidiary of the Company and the surviving corporation of the Merger. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the “Effective Time”), (a) each outstanding share of NeuBase capital stock, including shares of NeuBase capital stock issued in, or issued upon conversion, exercise or exchange of securities issued in, the NeuBase Financing (as defined below), will be converted into the right to receive the number of shares of the Company’s common stock equal to the exchange ratio described below; (b) each outstanding NeuBase stock option that has not previously been exercised prior to the Effective Time will be assumed by the Company and become an option to purchase the Company’s common stock; and (c) the warrant to purchase shares of common stock of NeuBase will be converted into and become a warrant to purchase shares of Company’s common stock.

Under the exchange ratio formula in the Merger Agreement, as of immediately after the Merger, the former NeuBase securityholders are expected to own approximately 80% (the “NeuBase Allocation Percentage”) of the aggregate number of shares of the Company’s common stock issued and outstanding following the consummation of the Merger (the “Post-Closing Shares”), and the stockholders of the Company as of immediately prior to the Merger are expected to own approximately 20% (the “Ohr Allocation Percentage”) of the aggregate number of Post-Closing Shares. NeuBase anticipates that it will issue and sell not less than \$4,000,000 (the gross proceeds received by NeuBase, the “NeuBase Proceeds”) of its equity securities (including securities convertible, exercisable or exchangeable into such equity securities) prior to the Effective Time (the “NeuBase Financing”). The NeuBase Allocation Percentage will be increased by 0.1% for every \$100,000 that the NeuBase Proceeds exceeds \$4,000,000, and the Ohr Allocation Percentage will be decreased by 0.1% for every \$100,000 that the NeuBase Proceeds exceeds \$4,000,000.

Immediately following the Effective Time, the name of the Company will be changed from “Ohr Pharmaceutical, Inc.” to “NeuBase Therapeutics, Inc.” The Merger Agreement contemplates that, immediately after the Effective Time, the board of directors of the Company will consist of five members, all of which will be designated by NeuBase. The executive officers of the Company immediately after the Effective Time will be designated by NeuBase with NeuBase’s Chief Executive Officer, Dietrich Stephan, being the Company’s Chief Executive Officer.

The Merger Agreement contains customary representations, warranties and covenants made by the Company and NeuBase, including covenants relating to obtaining the requisite approvals of the stockholders of the Company and NeuBase, indemnification of directors and officers, and the Company and NeuBase signing the Merger Agreement and the closing of the Merger. Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of the Company and NeuBase. The Merger Agreement contains certain termination rights for both the Company and NeuBase, and further provides that, upon termination of the Merger Agreement under specified circumstances, the Company may be required to pay NeuBase a termination fee of \$250,000 or NeuBase may be required to pay the Company a termination fee of \$250,000.

In accordance with the terms of the Merger Agreement, (i) the officers and directors of the Company have each entered into a support agreement with the Company and NeuBase (the "Ohr Support Agreements"), and (ii) the officers, directors and certain affiliated stockholders of NeuBase have each entered into a support agreement with NeuBase and the Company (the "NeuBase Support Agreements," together with the Ohr Support Agreements, the "Support Agreements"). The Support Agreements place certain restrictions on the transfer of the shares of the Company and NeuBase held by the respective signatories thereto and include covenants as to the voting of such shares in favor of approving the transactions contemplated by the Merger Agreement and against any actions that could adversely affect the consummation of the Merger.

Concurrently with the execution of the Merger Agreement, the officers and directors of the Company, and the officers, directors and certain stockholders of NeuBase, each entered into lock-up agreements (the "Lock-Up Agreements") pursuant to which they have agreed, among other things, not to sell or dispose of any shares of Company Common Stock which are or will be beneficially owned by them at the closing of the Merger until the date that is 90 days after the Effective Time.

In connection with the Merger, on January 2, 2019, the Company entered into a Retention Bonus Agreement with Dr. Jason Slakter, Ohr's Chief Executive Officer (the "Retention Bonus Agreement"). Under the Retention Bonus Agreement, Dr. Slakter is eligible for a retention bonus payment of \$75,000 upon the earliest to occur of the following: (i) Dr. Slakter's continued service with the Company in his current position through and including the closing date of the Merger, or (ii) Dr. Slakter is involuntarily separated from service without Cause (as such term is defined in the Retention Bonus Agreement) by the Company prior to the closing date of the Merger. In the event Dr. Slakter voluntarily separates from service with the Company for any reason prior to the closing of the Merger, Dr. Slakter will not receive any retention bonus payment and the Company will have no further obligation to Dr. Slakter under the Retention Bonus Agreement.

#### *Reverse Stock Split*

On January 18, 2019, following a special meeting of the Company's stockholders, the board of directors of the Company approved the Reverse Stock Split. On January 23, 2019, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation to effect the Reverse Stock Split. The Company's common stock began trading on a split-adjusted basis when the market opened on February 4, 2019. As a result of the Reverse Stock Split, the outstanding common stock has decreased from 56,466,428 shares of common stock, par value \$0.0001 per share, to 2,829,248 shares of common stock, par value \$0.0001 per share. Unless otherwise noted, impacted amounts and share information included in the financial statements and notes thereto, and elsewhere in this Form 10-Q, have been retroactively adjusted for the Reverse Stock Split as if such Reverse Stock Split occurred on the first day of the first period presented. Certain amounts in the financial statements, the notes thereto, and elsewhere in this Form 10-Q, may be slightly different than previously reported due to rounding of fractional shares as a result of the Reverse Stock Split.

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

Our discussion and analysis of the business and subsequent discussion of financial conditions may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements that are not historical in nature, including statements about beliefs and expectations, are forward-looking statements. Words such as “may,” “will,” “should,” “estimates,” “predicts,” “believes,” “anticipates,” “plans,” “expects,” “intends” and similar expressions are intended to identify these forward-looking statements, but are not the exclusive means of identifying such statements. Such statements are based on currently available operating, financial and competitive information and are subject to various risks and uncertainties as described in greater detail in Item IA, Part II, our “Risk Factors” beginning on page 16 of this Report. You are cautioned that these forward-looking statements reflect management’s estimates only as of the date hereof, and we assume no obligation to update these statements, even if new information becomes available or other events occur in the future, except as required by law. Actual future results, events and trends may differ materially from those expressed in or implied by such statements depending on a variety of factors, including, but not limited to those set forth in our filings with the Securities and Exchange Commission (“SEC”). Specifically, and not in limitation of these factors, we may alter our plans, strategies, objectives or business.

### **Company Overview**

Ohr Pharmaceutical, Inc. (“we,” “us,” “our,” “Ohr,” or the “Company”) is a pharmaceutical company which has been focused on the development of novel therapeutics and delivery technologies for the treatment of ocular disease.

### **Recent Developments**

#### *NeuBase Merger Agreement*

On January 2, 2019, the Company, Ohr Acquisition Corp., Delaware corporation and a wholly-owned subsidiary of the Company (“Merger Sub”), and NeuBase Therapeutics, Inc., a Delaware corporation (“NeuBase”), entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into NeuBase, with NeuBase becoming a wholly-owned subsidiary of the Company and the surviving corporation of the merger (the “Merger”). The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the “Effective Time”), (a) each outstanding share of NeuBase capital stock, including shares of NeuBase capital stock issued in, or issued upon conversion, exercise or exchange of securities issued in, the NeuBase Financing (as defined below), will be converted into the right to receive the number of shares of the Company’s common stock equal to the exchange ratio described below; (b) each outstanding NeuBase stock option that has not previously been exercised prior to the Effective Time will be assumed by the Company and become an option to purchase the Company’s common stock; and (c) the warrant to purchase shares of common stock of NeuBase will be converted into and become a warrant to purchase shares of Company’s common stock.

Under the exchange ratio formula in the Merger Agreement, as of immediately after the Merger, the former NeuBase securityholders are expected to own approximately 80% (the “NeuBase Allocation Percentage”) of the aggregate number of shares of the Company’s common stock issued and outstanding following the consummation of the Merger (the “Post-Closing Shares”), and the stockholders of the Company as of immediately prior to the Merger are expected to own approximately 20% (the “Ohr Allocation Percentage”) of the aggregate number of Post-Closing Shares. NeuBase anticipates that it will issue and sell not less than \$4,000,000 (the gross proceeds received by NeuBase, the “NeuBase Proceeds”) of its equity securities (including securities convertible, exercisable or exchangeable into such equity securities) prior to the Effective Time (the “NeuBase Financing”). The NeuBase Allocation Percentage will be increased by 0.1% for every \$100,000 that the NeuBase Proceeds exceeds \$4,000,000, and the Ohr Allocation Percentage will be decreased by 0.1% for every \$100,000 that the NeuBase Proceeds exceeds \$4,000,000.

Immediately following the Effective Time, the name of the Company will be changed from “Ohr Pharmaceutical, Inc.” to “NeuBase Therapeutics, Inc.” The Merger Agreement contemplates that, immediately after the Effective Time, the Board of Directors of the Company will consist of five members, all of which will be designated by NeuBase. The executive officers of the Company immediately after the Effective Time will be designated by NeuBase with NeuBase’s Chief Executive Officer, Dietrich Stephan, being the Company’s Chief Executive Officer.

The Merger Agreement contains customary representations, warranties and covenants made by the Company and NeuBase, including covenants relating to obtaining the requisite approvals of the stockholders of the Company and NeuBase, indemnification of directors and officers, and the Company and NeuBase signing the Merger Agreement and the closing of the Merger. Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of the Company and NeuBase. The Merger Agreement contains certain termination rights for both the Company and NeuBase, and further provides that, upon termination of the Merger Agreement under specified circumstances, the Company may be required to pay NeuBase a termination fee of \$250,000 or NeuBase may be required to pay the Company a termination fee of \$250,000.

In accordance with the terms of the Merger Agreement, (i) the officers and directors of the Company have each entered into a support agreement with the Company and NeuBase (the “Ohr Support Agreements”), and (ii) the officers, directors and certain affiliated stockholders of NeuBase have each entered into a support agreement with NeuBase and the Company (the “NeuBase Support Agreements,” together with the Ohr Support Agreements, the “Support Agreements”). The Support Agreements place certain restrictions on the transfer of the shares of the Company and NeuBase held by the respective signatories thereto and include covenants as to the voting of such shares in favor of approving the transactions contemplated by the Merger Agreement and against any actions that could adversely affect the consummation of the Merger.

Concurrently with the execution of the Merger Agreement, the officers and directors of the Company, and the officers, directors and certain stockholders of NeuBase, each entered into lock-up agreements (the “Lock-Up Agreements”) pursuant to which they have agreed, among other things, not to sell or dispose of any shares of Company Common Stock which are or will be beneficially owned by them at the closing of the Merger until the date that is 90 days after the Effective Time.

In connection with the Merger, on January 2, 2019, Ohr entered into a Retention Bonus Agreement with Dr. Jason Slakter, Ohr’s Chief Executive Officer (the “Retention Bonus Agreement”). Under the Retention Bonus Agreement, Dr. Slakter is eligible for a retention bonus payment of \$75,000 upon the earliest to occur of the following: (i) Dr. Slakter’s continued service with the Company in his current position through and including the closing date of the Merger, or (ii) Dr. Slakter is involuntarily separated from service without Cause (as such term is defined in the Retention Bonus Agreement) by the Company prior to the closing date of the Merger. In the event Dr. Slakter voluntarily separates from service with the Company for any reason prior to the closing of the Merger, Dr. Slakter will not receive any retention bonus payment and the Company will have no further obligation to Dr. Slakter under the Retention Bonus Agreement.

Despite devoting significant efforts to identify, evaluate and negotiate the Merger Agreement with NeuBase, the Company may not be successful in completing the Merger. Further, even if the Merger is completed, it ultimately may not deliver the anticipated benefits or enhance stockholder value. If the Merger is not completed, the Company cannot predict whether and to what extent it would be successful in consummating an alternative transaction, the timing of such a transaction or its future cash needs required to complete such a transaction, and the Company may choose or be forced to dissolve and liquidate its assets.

#### *Reverse Stock Split*

On January 18, 2019, following a special meeting of the Company’s stockholders, the board of directors of the Company approved a one-for-twenty reverse stock split of the Company’s issued and outstanding shares of common stock (the “Reverse Stock Split”). On January 23, 2019, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation to effect the Reverse Stock Split. The Company’s common stock began trading on a split-adjusted basis when the market opened on February 4, 2019. As a result of the Reverse Stock Split, the outstanding common stock has decreased from 56,466,428 shares of common stock, par value \$0.0001 per share, to 2,829,248 shares of common stock, par value \$0.0001 per share. Unless otherwise noted, impacted amounts and share information included in the financial statements and notes thereto, and elsewhere in this Form 10-Q have been retroactively adjusted for the Reverse Stock Split as if such Reverse Stock Split occurred on the first day of the first period presented. Certain amounts in the financial statements, the notes thereto, and elsewhere in this form 10-Q, may be slightly different than previously reported due to rounding of fractional shares as a result of the Reverse Stock Split.

#### **Corporate and Historical Information**

We are a Delaware corporation that was organized on August 4, 2009, as successor to BBM Holdings, Inc. (formerly Prime Resource, Inc., which was organized March 29, 2002 as a Utah corporation) pursuant to a reincorporation merger. On August 4, 2009, we reincorporated in Delaware as Ohr Pharmaceutical, Inc.

On May 30, 2014, we completed the ophthalmology assets acquisition (the “SKS Acquisition”) of the privately held SKS Ocular LLC and its affiliate, SKS Ocular 1 LLC (“SKS”). Simultaneous with the SKS Acquisition, Ohr completed a holding company reorganization in which Ohr merged with a wholly owned subsidiary and a new parent corporation succeeded Ohr as a public holding company under the same name. The business operations of Ohr did not change as a result of the reorganization. The new holding company retained the name “Ohr Pharmaceutical, Inc.” Outstanding shares of the capital stock of the former Ohr Pharmaceutical, Inc. were automatically converted, on a share for share basis, into identical shares of common stock of the new holding company.

On January 5, 2018, the Company reported topline data from the MAKO study which did not meet its primary efficacy endpoint. The MAKO study evaluated the efficacy and safety of topically administered squalamine in combination with monthly Lucentis® injections for the treatment of wet-AMD. Based on those results, the Company discontinued further development of squalamine and has been evaluating strategic alternatives to maximize stockholder value.

As part of its review of strategic alternatives, the Company formed a special committee of independent directors. The board of directors and the special committee engaged Roth Capital Markets, LLC, to advise them and management, and to assist in pursuing a range of strategic alternatives including some of the following: license, divestiture, or other monetization of current assets; license or acquisition of additional assets; merger, reverse merger, joint venture, partnership, or other business combination with another entity, public or private. On January 2, 2019, the Company, Merger Sub and NeuBase entered into a Merger Agreement, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into NeuBase, with NeuBase becoming a wholly-owned subsidiary of the Company and the surviving corporation of the Merger. Despite devoting significant efforts to identify, evaluate and negotiate the Merger Agreement with NeuBase, the Company may not be successful in completing the Merger. Further, even if the Merger is completed, it ultimately may not deliver the anticipated benefits or enhance stockholder value. If the Merger is not completed, the Company cannot predict whether and to what extent it would be successful in consummating an alternative transaction, the timing of such a transaction or its future cash needs required to complete such a transaction, and the Company may choose or be forced to dissolve and liquidate its assets.

## ASSETS AND TECHNOLOGIES

### (a) SKS SUSTAINED RELEASE OCULAR DRUG DELIVERY PLATFORM TECHNOLOGY

The SKS sustained release technology was designed to develop best-in-class drug formulations for ocular disease. The technology employs micro fabrication techniques to create nano, micro and macroparticle drug formulations that can provide sustained and predictable release of a therapeutic drug over a 3-6 month period. The versatility of this delivery technology makes it well suited to potentially deliver hydrophilic or hydrophobic small molecules, as well as proteins with complex structures.

In February 2017, the Company suspended activities at its lab facility in San Diego, CA where research regarding the SKS sustained release technology had been conducted. However, the Company continues to explore strategies and pathways for applications of its sustained release technology and potential avenues to monetize it.

### (b) CEP ASSETS

As part of the SKS acquisition, the Company acquired the exclusive rights to an animal model for dry-AMD whereby mice are immunized with a carboxyethylpyrrole (“CEP”) which is bound to mouse serum albumin (“MSA”) as well as the rights to produce and use CEP for research, clinical, and commercial applications. CEP is produced following the oxidation of docosahexaenoic acid, which is abundant in the photoreceptor outer segments that are phagocytosed by the retinal pigment epithelium (“RPE”). A number of CEP-adducted proteins have been identified in proteomic studies examining the composition of drusen and other subretinal deposits found in the eyes of patients with dry-AMD. Studies have shown that immunization of CEP-MSA can lead to an ophthalmic phenotype very similar to dry-AMD, including deposition of complement in the RPE, thickening of the Bruch’s membrane, upregulation of inflammatory cytokines, and immune cell influx into the eye. Upon immunization with CEP, a marked decrease in contrast sensitivity which precedes a loss of visual acuity, was observed, similar to what occurs in many patients with dry AMD. A collaborator of the Company is conducting research on the CEP target to understand its role in undisclosed ocular diseases and potential for use as a diagnostic agent. The Company has not yet monetized this technology.

### (c) DEPYMED JOINT VENTURE

Ohr also owns various other compounds in earlier stages of development, including the PTP1b inhibitor trodusquemine and related analogs. On February 26, 2014, the Company entered into a Joint Venture Agreement and related agreements with Cold Spring Harbor Laboratory (“CSHL”) pursuant to which a joint venture, DepYmed Inc. (“DepYmed”), was formed to further preclinical and clinical development of Ohr’s trodusquemine and analogues as PTP1B inhibitors for oncology and rare disease indications. DepYmed licenses research from CSHL and intellectual property from us. Ohr is a passive joint venturer in DepYmed.

## Liquidity and Sources of Capital

The Company has limited working capital reserves with which to fund its continuing operations. The Company is reliant, at present, upon its capital reserves for ongoing operations and has no revenues.

Net working capital reserves decreased from end of fiscal 2018 to the end of the first quarter in fiscal 2019 by \$656,878 (to \$2,616,558 from \$3,273,436) primarily due to costs incurred from operations. Our quarterly cash burn has decreased significantly compared to prior periods in calendar 2017 and 2018 due to the discontinuation of the squalamine program. We expect our cash burn to be relatively stable in the near term and potentially increase in future periods in calendar 2019, once the merger with NeuBase has been completed; however, there can be no assurance that the merger with NeuBase will be completed in calendar 2019, if at all. Management has concluded that due to the conditions described above, there is substantial doubt about the entity’s ability to continue as a going concern. We have evaluated the significance of the conditions in relation to our ability to meet our obligations and believe that our current cash balance will provide sufficient capital to continue operations, in the absence of the completion of the NeuBase merger, into the second half of calendar 2019. At present, the Company has no bank line of credit or other fixed source of capital reserves. Should the Company need additional capital in the future, it will be primarily reliant upon private or public placement of its equity or debt securities, or a strategic transaction, for which there can be no warranty or assurance that the Company may be successful in such efforts.

## Results of Operations

### Three Months Ended December 31, 2018 Compared to the Three Months Ended December 31, 2017

Results of operations for the three months ended December 31, 2018 (“2018”) reflect the following changes from the prior period (“2017”).

	2018	2017	Change
General and administrative	\$ 680,995	\$ 1,510,032	\$ (829,037)
Research and development	58,021	2,387,731	(2,329,710)
Depreciation and amortization	167,370	284,986	(117,616)
Total Operating Expenses	906,386	4,182,749	(3,276,363)
Operating Loss	(906,386)	(4,182,749)	3,276,363
Other income (expense)	8,762	31,391	(22,629)
Net Loss	\$ (897,624)	\$ (4,151,358)	\$ 3,253,734

For the quarter ended December 31, 2018, the Company had no revenues, and had operating expenses of \$906,386. The loss from operations was comprised of \$58,021 in research and development costs, \$680,995 in general and administrative expenses, \$167,370 in depreciation and amortization.

During the same period for the quarter ended December 31, 2017, the Company reported no revenues, and had operating expenses of \$4,182,749 which was comprised of \$1,510,032 in general and administrative expenses, \$2,387,731 in research and development costs, \$284,986 in depreciation and amortization.

The operating expenses of the Company decreased in 2018 compared to 2017 by \$3,276,363. General and administrative expenses decreased in 2018 as compared to 2017 by \$829,037. The decrease is primarily a result of a reduction in employee headcount and stock-based compensation. Research and development expenses decreased in 2018 as compared to 2017 by \$2,329,710. The decrease is primarily a result of significant costs paid in 2017 related to the MAKO study in wet-AMD, which was completed in the second fiscal quarter of 2018. Depreciation and amortization decreased by \$117,616 in 2018 as compared to 2017. The decrease was related to reduced amortization of long lived intangible assets due to a significant write down of such assets at September 30, 2018.

The net loss for the quarter ended December 31, 2018 was \$897,624 as compared to \$4,151,358 for the same period in 2017. Until the Company is able to generate revenues, management expects to continue to incur net losses.

**Item 3. Quantitative and Qualitative Risk.**

Market risk represents the risk of loss arising from adverse changes in interest rates and foreign exchange rates. The Company does not have any material exposure to interest rate or exchange rate risk.

**Item 4. Controls and Procedures.**

**Evaluation of Disclosure Controls and Procedures**

The Company, under the supervision and with the participation of its management, including the Chief Executive Officer and the Chief Financial Officer, evaluated the effectiveness of the design and operation of the Company's "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Report. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded the Company's disclosure controls were effective. In designing and evaluating the disclosure controls and procedures, our management, including the Chief Executive Officer and the Chief Financial Officer, recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and management was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching our desired disclosure controls objectives.

**Changes in Internal Control Over Financial Reporting**

During the period covered by this Report there has been no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings.**

The Company has become involved in certain legal proceedings and claims which arise in the normal course of business. If an unfavorable ruling were to occur, there exists the possibility of a material adverse impact on the Company's results of operations, prospects, cash flows, financial position and brand.

On February 14, 2018, plaintiff, Jeevesh Khanna, commenced an action in the Southern District of New York, against the Company and several current and former officers, alleging that they violated federal securities laws between June 24, 2014 and January 4, 2018. On August 7, 2018, the lead plaintiffs, now George Lehman and Insured Benefit Plans, Inc. filed an amended complaint, stating the class period to be April 8, 2014 through January 4, 2018. The plaintiffs did not quantify any alleged damages in their complaint but, in addition to attorneys' fees and costs, they seek to maintain the action as a class action and to recover damages on behalf of themselves and other persons who purchased or otherwise acquired our stock during the putative class period and purportedly suffered financial harm as a result. The Company and the individuals dispute these claims and intend to defend the matter vigorously. On September 17, 2018, we filed a motion to dismiss the complaint. On November 13, 2018, plaintiffs filed a motion to strike exhibits appended to the motion to dismiss. A decision on the motion to strike is pending, and the motion to dismiss will then be fully briefed based on a schedule to be determined by the court. This litigation could result in substantial costs and a diversion of management's resources and attention, which could harm the Company's business and the value of the Company's common stock.

On May 3, 2018, plaintiff Adele J. Barke, derivatively on behalf of the Company, commenced an action against Michael Ferguson, Orin Hirschman, Thomas M. Riedhammer, June Almenoff and Jason Slakter in the Supreme Court, State of New York, alleging that the action was brought in the right and for the benefit of Ohr seeking to remedy their "breach of fiduciary duties, corporate waste and unjust enrichment that occurred between June 24, 2014 and the present." It does not quantify any alleged damages. The Company and the individuals dispute these claims and intend to defend the matter vigorously. Such litigation has been stayed pursuant to a stipulation by the parties, which has been so ordered by the court, pending a decision in the Southern District case on the motion to dismiss, but that status could change. This litigation could result in substantial costs and a diversion of management's resources and attention, which could harm the Company's business and the value of the Company's common stock.



In September 2018, plaintiff John Tomson, derivatively and on behalf of the Company, commenced an action against Michael Ferguson, Sam Backenroth, Irach Taraporewala, Orin Hirschman, Thomas M. Riedhammer, June Almenoff and Jason Slakter in the US District Court for the Southern District of New York alleging that the action was brought in the right and for the benefit of Ohr seeking to remedy their various breaches of fiduciary duties, corporate waste and unjust enrichment that occurred between April 4, 2014 through January 4, 2018. Thereafter, the complaint largely summarized the allegations of the amended complaint filed in the securities class action described above. It does not quantify alleged damages. The Company and the individuals dispute these claims and intend to defend the matter vigorously. Such litigation is currently stayed pursuant to a stipulation by the parties, which has been so ordered by the court, pending a decision in the Southern District case on the motion to dismiss, but that status could change. This litigation could result in substantial costs and a diversion of management's resources and attention, which could harm the Company's business and the value of the Company's common stock.

Management believes that the likelihood of an adverse decision from the ongoing litigation is unlikely, however, the litigation could result in substantial costs and a diversion of management's resources and attention, which could harm the Company's business and the value of the Company's common stock

#### **Item 1A. Risk Factors.**

*You should carefully consider the following factors which may affect future results of operations. If any of the adverse events described below actually occur, our business, financial condition and operating results could be materially adversely affected and you may lose part or all of the value of your investment. If you choose to invest in our securities, you should be able to bear a complete loss of your investment.*

#### **Risks Relating to the Merger with NeuBase**

##### **If the Merger with NeuBase is not consummated, Ohr's business could suffer materially and Ohr's stock price could decline.**

The consummation of the Merger with NeuBase is subject to a number of closing conditions, including the approval by Ohr's stockholders, approval by the Nasdaq Stock Market of Ohr's application for initial listing of Ohr common stock in connection with the Merger, a minimum amount of financing into NeuBase, and other customary closing conditions. Ohr is targeting a closing of the Merger in the second quarter of calendar year 2019.

If the Merger is not consummated, Ohr may be subject to a number of material risks, and its business and stock price could be adversely affected, as follows:

- Ohr has incurred and expects to continue to incur significant expenses related to the Merger with NeuBase even if the Merger is not consummated.
- the Merger Agreement contains covenants relating to Ohr's solicitation of competing acquisition proposals and the conduct of Ohr's business between the date of signing the Merger Agreement and the closing of the merger. As a result, significant business decisions and transactions before the closing of the Merger require the consent of NeuBase. Accordingly, Ohr may be unable to pursue business opportunities that would otherwise be in its best interest as a standalone company. If the Merger Agreement is terminated after Ohr has invested significant time and resources in the transaction process, Ohr will have a limited ability to continue operations without obtaining additional financing to fund its operations.
- Ohr's prospective collaborators and other business partners and investors in general may view the failure to consummate the Merger as a poor reflection on its business or prospects.
- some of Ohr's suppliers, distributors, collaborators and other business partners may seek to change or terminate their relationships with Ohr as a result of the Merger.
- as a result of the Merger, current and prospective employees could experience uncertainty about their future roles within the combined company. This uncertainty may adversely affect Ohr's ability to retain its key employees, who may seek other employment opportunities.
- Ohr's management team may be distracted from day to day operations as a result of the Merger.

In addition, if the Merger Agreement is terminated and Ohr's board of directors determines to seek another business combination, it may not be able to find a third party willing to provide equivalent or more attractive consideration than the consideration to be provided by each party in the Merger. In such circumstances, Ohr's board of directors may elect to, among other things, divest all or a portion of Ohr's assets, or take the steps necessary to liquidate all of Ohr's business and assets, and in either such case, the consideration that Ohr receives may be less attractive than the consideration to be received by Ohr pursuant to the Merger Agreement.

##### **The exchange ratio in the Merger is not adjustable based on the market price of Ohr common stock so the Merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.**

The Merger Agreement has set the exchange ratio for the NeuBase common stock. Any changes in the market price of Ohr common stock before the completion of the Merger will not affect the number of shares NeuBase securityholders will be entitled to receive pursuant to the Merger Agreement. Therefore, if before the completion of the Merger the market price of Ohr common stock declines from the market price on the date of the Merger Agreement, then NeuBase securityholders could receive Merger consideration with substantially lower value. Similarly, if before the completion of the Merger the market price of Ohr common stock increases from the market price on the date of the Merger Agreement, then NeuBase securityholders could receive Merger consideration with substantially more value for their shares of NeuBase capital stock than the parties had negotiated for in the establishment of the exchange ratio. Because the exchange ratio does not adjust as a result of changes in the value of Ohr common stock, for each one percentage point that the market value of Ohr common stock rises or declines, there is a corresponding one percentage point rise or decline, respectively, in the value of the total Merger consideration issued to NeuBase securityholders.

**The market price of the combined company's common stock may decline as a result of the Merger.**

The market price of the combined company's common stock may decline as a result of the Merger for a number of reasons including:

- the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts;
- the effect of the Merger on the combined company's business and prospects is not consistent with the expectations of financial or industry analysts; or
- investors react negatively to the effect on the combined company's business and prospects from the Merger.

**Ohr's stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.**

If the combined company is unable to realize the strategic and financial benefits currently anticipated from the Merger, Ohr's stockholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. Significant management attention and resources will be required to integrate the two companies. Delays in this process could adversely affect the combined company's business, financial results, financial condition and stock price following the Merger. Even if the combined company were able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time.

**During the pendency of the Merger, Ohr may not be able to enter into a business combination with another party and will be subject to contractual limitations on certain actions because of restrictions in the Merger Agreement.**

Covenants in the Merger Agreement impede the ability of Ohr or NeuBase to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the Merger. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors. In addition, while the Merger Agreement is in effect and subject to limited exceptions, each party is prohibited from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to entering into certain extraordinary transactions with any third party, such as a sale of assets, an acquisition of Ohr common stock, a tender offer for Ohr common stock, a Merger or other business combination outside the ordinary course of business. Any such transactions could be favorable to such party's stockholders.

**Risks Relating to Our Financial Position and Need for Capital**

**Our business was substantially dependent on the success of squalamine, which failed to meet its primary efficacy endpoint in the MAKO Study. As a result of the failure of the MAKO study, we evaluated strategic alternatives and ultimately entered into a definitive Merger Agreement with NeuBase. Unless the Merger is consummated, or if we fail to execute on another strategic alternative, we may be required to liquidate, dissolve, or otherwise wind down our operations.**

Until January 5, 2018, squalamine for the treatment of wet-AMD was our lead product candidate. On January 5, 2018, we announced topline results from our MAKO Study which did not meet its primary efficacy endpoint. Based on these results, we discontinued further development of squalamine and evaluated strategic alternatives to maximize stockholder value.

On January 2, 2019, the Company, Merger Sub and NeuBase entered into the Merger Agreement, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into NeuBase, with NeuBase becoming a wholly-owned subsidiary of the Company and the surviving corporation of the Merger. Consummation of the Merger is subject to certain closing conditions, including the approval from our stockholders which may take a significant amount of time and will further decrease our cash resources. There can be no assurance that we will be able to successfully complete the Merger and investors may disagree with the new focus of our business. The Merger will result in dilution to our stockholders and could result in other restrictions that may affect our business. Further, if completed, the Merger ultimately may not deliver the anticipated benefits or enhance stockholder value.

If the Merger is not consummated, and we are not able to execute on another strategic alternative, we may be required to liquidate, dissolve or otherwise wind down our operations.

**We may not be able to monetize the non-squalamine assets, including the SKS sustained release ocular drug delivery platform technology, CEP assets, or our interest in the Depymed joint venture.**

We may not be able to monetize any or some of the non-squalamine assets, including the SKS sustained release ocular drug delivery platform technology, the CEP assets, or our interest in the Depymed joint venture. In that event, we may be constrained to write off those assets, in whole or in part. At September 30, 2018, we significantly wrote down the value of our SKS sustained release asset and there can be no assurance that we will not be required to further write down or write off this asset, or any other asset, entirely in the future.

**We are subject to securities class action litigation and derivative shareholder litigation. If an unfavorable ruling were to occur, there exists the possibility of a material adverse impact on the Company.**

As a result of our announcement of negative results from the MAKO Study, our stock price declined substantially. On February 14, 2018, a securities class action litigation was brought against the Company, Dr. Jason Slakter, Sam Backenroth, and Irach Taraporewala in federal district court in the Southern District of New York. An amended securities class action complaint was filed on August 7, 2018, by lead plaintiffs George Lehman and Insured Benefit Plans, Inc. The Company and the individuals dispute these claims and intend to defend the matter vigorously. On September 17, 2018, we filed a motion to dismiss the complaint. On November 13, 2018, plaintiffs filed a motion to strike exhibits appended to the motion to dismiss. A decision on the motion to strike is pending, and the motion to dismiss will then be fully briefed based on a schedule to be determined by the court. This litigation could result in substantial costs and a diversion of management's resources and attention, which could harm our business and the value of our common stock.

On May 3, 2018, plaintiff Adele J. Barke, derivatively on behalf of the Company, commenced an action in Supreme Court, State of New York against Michael Ferguson, Orin Hirschman, Thomas M. Riedhammer, June Almenoff and Jason Slakter alleging that the action was brought in the right and for the benefit of Ohr seeking to remedy their "breach of fiduciary duties, corporate waste and unjust enrichment that occurred between June 24, 2014 and the present." It does not quantify any alleged damages. The Company and the individuals dispute these claims and intend to defend the matter vigorously. Such litigation is currently stayed pursuant to a stipulation by the parties pending a decision on the motion to dismiss in the Southern District case, which has been so ordered by the court, but that status could change. Such litigation could result in substantial costs and a diversion of management's resources and attention, which could harm our business and the value of our common stock.

In September 2018, plaintiff John Tomson, derivatively and on behalf of the Company, commenced an action against Michael Ferguson, Sam Backenroth, Irach Taraporewala, Orin Hirschman, Thomas M. Riedhammer, June Almenoff and Jason Slakter in the US District Court for the Southern District of New York alleging that the action was brought in the right and for the benefit of Ohr seeking to remedy their various breaches of fiduciary duties, corporate waste and unjust enrichment that occurred between April 4, 2014 through January 4, 2018. Thereafter, the complaint largely summarized the allegations of the amended complaint filed in the securities class action described above. It does not quantify alleged damages. The Company and the individuals dispute these claims and intend to defend the matter vigorously. Such litigation is currently stayed, pending a decision of the Southern District on the motion to dismiss, pursuant to a stipulation by the parties, which has been so ordered by the court, but that status could change. This litigation could result in substantial costs and a diversion of management's resources and attention, which could harm the Company's business and the value of the Company's common stock.

**If we fail to continue to meet all applicable Nasdaq Capital Market requirements and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.**

On February 20, 2018, we received a written notice (the “First Notice”) from NASDAQ Stock Market LLC (“Nasdaq”) that the Company had not been in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for a period of 30 consecutive business days. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum closing bid price of \$1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days.

In accordance with Nasdaq’s Listing Rule 5810(c)(3)(A), the Company had a period of 180 calendar days, or until August 20, 2018, to regain compliance with the minimum closing bid price requirement. The Company did not regain compliance with the minimum closing bid price requirement by August 20, 2018. The Company was notified by Nasdaq that it might be afforded a second 180 calendar period to regain compliance with the minimum closing bid price requirement under certain circumstances. As a result, the Company applied for an extension of the cure period, as permitted under the notification. In order to cure the deficiency the Company indicated that, to that extent necessary, it planned to seek approval for a reverse stock split in order to meet the minimum closing bid price requirement at a special meeting of the Company’s stockholders which the Company would hold prior to the expiration of the second 180 day period and effectuate the reverse stock split immediately thereafter. On August 21, 2018, the Company received a written notice from Nasdaq that the Company had been granted an additional 180 calendar days, or until February 19, 2019, to regain compliance with the minimum \$1.00 bid price per share requirement of the Listing Rules of Nasdaq (“Second Notice”).

According to the Second Notice, if at any time before February 19, 2019, the bid price of the Company’s common stock closes at or above \$1.00 per share for a minimum of 10 consecutive business days, Nasdaq would provide written notification that the Company has achieved compliance with the minimum closing bid price requirement. If, however, compliance with the minimum closing bid price requirement cannot be demonstrated by February 19, 2018, Nasdaq would provide written notification that the Company’s common stock will be delisted, subject to the Company’s right to appeal. The Company’s stock did not close at or above \$1.00 per share for a minimum of 10 consecutive business days between the time of the Second Notice and January 18, 2019. On January 18, 2019, following a special meeting of the Company’s stockholders, the board of directors of the Company approved a Reverse Stock Split. On January 23, 2019, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to its Certificate of Incorporation to effectuate the Reverse Stock Split. The Company’s common stock began trading on a split-adjusted basis when the market opened on February 4, 2019. As a result of the Reverse Stock Split, the outstanding common stock has decreased from 56,466,428 shares of common stock, par value \$0.0001 per share, to 2,829,248 shares of common stock, par value \$0.0001 per share. Since February 4, 2019, the Company’s stock has closed at or above \$1.00 per share.

If we were unable to maintain compliance with the \$1.00 minimum bid price requirement and our common stock were delisted from Nasdaq, trading of our common stock would most likely take place on an over-the-counter market established for unlisted securities, such as the OTCQB or the Pink Market maintained by OTC Markets Group Inc. An investor would likely find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors would likely not buy or sell our common stock due to difficulty in accessing over-the-counter markets, policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules as a “penny stock,” which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to the investor of penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher-priced stock, would further limit the ability of investors to trade in our common stock. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified employees, to raise capital, and execute on a strategic alternative.

**In light of the results of the MAKO study, we began evaluating strategic alternatives, and recently entered into the Merger Agreement with NeuBase. There is no certainty that we will be able to close the Merger, or execute on any other strategic alternative if the Merger is not consummated. If we are unable to consummate the Merger or identify and execute on any other strategic alternatives if the Merger is not consummated, we may be forced to cease operations and liquidate.**

Based on the results of the MAKO study, we began a comprehensive review of strategic alternatives to maximize shareholder value. As part of its review of strategic alternatives, the Company formed a special committee of independent directors. The Board of Directors and the special committee retained Roth Capital Markets, LLC, to advise and assist in this review. The strategic alternatives that we are exploring, may include some or all of the following: license, divestiture, or monetization of current assets; license or acquisition of additional assets; merger, reverse merger, joint venture, partnership, or other business combination with another entity, public or private. On January 2, 2019, the Company, Merger Sub and NeuBase entered into the Merger Agreement, pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into NeuBase, with NeuBase becoming a wholly-owned subsidiary of the Company and the surviving corporation of the Merger. Consummation of the Merger is subject to certain closing conditions, including a concurrent financing into NeuBase and the approval from our stockholders which may take a significant amount of time and will further decrease our cash resources. There can be no assurance that we will be able to successfully complete the Merger and investors may disagree with the new focus of our business. The Merger will result in dilution to our stockholders and could result in other restrictions that may affect our business. Further, if completed, the Merger ultimately may not deliver the anticipated benefits or enhance stockholder value.

If we are unable to consummate the Merger or execute on another strategic alternative if the Merger is not consummated, we may be forced to liquidate.

**We have incurred significant losses and anticipate that we will incur additional losses. We might never achieve or sustain revenues.**

We have experienced significant net losses since our inception. As of December 31, 2018, we had an accumulated deficit of approximately \$122.2 million. We expect to continue to incur net losses. We do not expect to receive, for at least the next several years, any revenues from commercialization activities.

Our ability to generate revenues and become profitable depends, among other things, on the successful development and commercialization of our technologies and/or NeuBase's products and our ability to identify and execute on other opportunities and business combinations that will enable us to maximize stockholder value. We will need significant additional capital to pursue these objectives and sustain our operations.

**The report of our independent registered public accounting firm expresses substantial doubt about the Company's ability to continue as a going concern. Such "going concern" opinion could impair our ability to obtain financing.**

Our auditors, MaloneBailey, LLP, have indicated in their report on the Company's financial statements for the fiscal year ended September 30, 2018 and for the subsequent quarterly periods to date, that conditions exist that raise substantial doubt about our ability to continue as a going concern due to our recurring losses from operations. A "going concern" opinion could impair our ability to finance our operations through the sale of equity, incurring debt, or other financing alternatives. Our ability to continue as a going concern will depend upon the availability and terms of future funding. If we are unable to achieve this goal, our business would be jeopardized and the Company may not be able to continue. If we ceased operations, it is likely that all of our investors would lose their investment.

**We depend upon key officers and consultants in a competitive market for skilled personnel. If we are unable to retain key personnel, it could adversely affect our business. The negative result of the MAKO study and our limited financial resources may make us less successful at retaining employees.**

We are highly dependent upon the principal members of our management team, especially our Chief Executive Officer, Dr. Jason Slakter, and Vice President of Business Development and Chief Financial Officer, Sam Backenroth, as well as our directors and key consultants. A loss of any of these personnel may have a material adverse effect on aspects of our business.

The announcement that we have entered into the Merger Agreement may make it more difficult to retain qualified executive and other key personnel. The Merger and the strategic alternative process has been costly, time-consuming, and diverted the attention of management. . In addition, our stock price may experience periods of increased volatility as a result of these activities, related rumors, speculation, and our recent reverse stock split.

### **Risks Related to Our Business and Industry**

**We currently do not have, and may never have, any products that generate revenues.**

We are a development stage pharmaceutical company and currently do not have, and may never have, any products that generate revenues. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. To date, we have not generated any product revenues. Our ability to generate revenues and become profitable depends, among other things, on the successful development and commercialization of ours and/or NeuBase's products and our ability to identify and execute on other opportunities and business combinations that will enable us to maximize stockholder value.

**We are highly dependent upon our ability to raise additional capital. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies.**

Until such time, if ever, as we can generate substantial product revenues, we may finance our cash needs through a combination of equity offerings, debt financings, and partnerships. We do not have any committed external source of funds. Even if the Merger Agreement is successfully consummated, we will need to raise additional funds in order to fund our near and long-term operations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as holders of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions.

If we raise capital through a partnership, we may have to relinquish rights to our technologies or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to cease operations and liquidate.

**We are highly dependent upon our ability to enter into agreements with collaborative partners to develop, commercialize, and market any products.**

We are dependent on strategic partnerships to develop technologies and products. To date, we have not entered into any strategic partnerships for any products. We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships.

While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. We currently lack the resources to conduct clinical trials, to manufacture any product candidates on a large scale, and we have no sales, marketing or distribution capabilities. In the event we are not able to enter into a collaborative agreement with a partner or partners, on commercially reasonable terms, or at all, we may be unable to conduct clinical trials, or to develop products which would have a material adverse effect upon our business, prospects, financial condition, and results of operations.

Even if we succeed in securing a partner, the partner collaborators may fail to develop or effectively commercialize products using our technologies. Such partnership would pose a number of risks, including the following:

- partners may not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;
- collaborators may believe our intellectual property or the product candidate infringes on the intellectual property rights of others;
- partners may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
- partners may decide to pursue a competitive product developed outside of the partnership arrangement;
- partners may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals;
- partners may delay the development or commercialization of any product candidates in favor of developing or commercializing another party's product candidate; or
- partners may decide to terminate or not to renew the collaboration for these or other reasons.

Thus, should the Company ever be successful in entering into a partnership agreement, the agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. Partnership agreements are generally terminable without cause on short notice. We also face competition in seeking out collaborators. If we are unable to secure new partners that achieve the partner's objectives and meet our expectations, we may be unable to advance any product candidates and may not generate meaningful revenues.

**We have no experience selling, marketing or distributing products and no internal capability to do so.**

We currently have no sales, marketing or distribution capabilities and no experience in building a sales force and distribution capabilities. If we are ever in a position to commercialize any products, of which there can be no assurance, we must develop internal sales, marketing and distribution capabilities, which will be expensive and time consuming, or make arrangements with third parties to perform these services. If we decide to market any products directly, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Building an in-house marketing and sales force with technical expertise and distribution capabilities will require significant expenditures, management resources and time. Factors that may inhibit our efforts to commercialize any products directly and without strategic partners include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

We may not be successful in recruiting the sales and marketing personnel necessary to sell any products and even if we do build a sales force, they may not be successful in marketing any products, which would have a material adverse effect on our business and results of operations.

**If we are ever to conduct additional clinical trials, we would continue to rely on third parties to conduct any such trials for us. If such third parties do not successfully carry out their duties or if we lose our relationships with such third parties, our product development efforts could be delayed.**

We are dependent on contract research organizations, third-party vendors and independent investigators for preclinical testing, and clinical trials related to any potential drug discovery and development efforts. These parties are not our employees, and we cannot control the amount or timing of resources that they devote to any programs. If they fail to devote sufficient time and resources to any product development programs or if their performance is substandard, it would delay the development and commercialization of these product candidates. The parties with which we would contract for execution of our clinical trials would play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to achieve their research goals or otherwise meet their obligations on a timely basis could adversely affect clinical development of these product candidates.

Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other parties, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct any clinical trials and may lead to unexpected cost increases. Nevertheless, we are responsible for ensuring that each of our studies would be conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on contract research organizations would not relieve us of our regulatory responsibilities. We and our contract research organizations would be required to comply with applicable current Good Laboratory Practice ("CGLP"), current Good Manufacturing Practice ("CGMP"), and current Good Clinical Practice ("CGCP") regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these CGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our contract research organizations fail to comply with applicable CGCP, the clinical data generated in these clinical trials might be deemed unreliable and the FDA or comparable foreign regulatory authorities may require additional clinical trials before approving the marketing applications. We cannot assure that, upon inspection, the FDA or any comparable foreign regulatory authority will determine that any clinical trials would comply with CGCP. In addition, clinical trials must be conducted with product produced under CGMP regulations and would require a large number of test subjects. Our failure or the failure of our contract research organizations to comply with these regulations might require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

**If we are ever to conduct any additional trials and our contract research organizations do not successfully carry out their duties or if we were to lose relationships with contract research organizations, any product development efforts could be delayed or terminated.**

If we were to lose relationships with any one or more of these parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider might need additional time to respond to our needs and might not provide the same type or level of service as the original provider. In addition, any provider that we retain would be subject to CGLP and CGCP, other regulatory standards, and similar foreign standards, and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of any products could be delayed, and have a material adverse effect on our business.

**We may not be able to continue or fully exploit our relationships with outside advisors, which could impair our business.**

We work with advisors who are experts in their respective fields. They advise us with respect to our business and operations. These advisors are not our employees and may have other commitments that would limit their future availability to us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services, which may impair our reputation in the industry and our business efforts.

**We have no manufacturing capabilities, and, if needed, would rely completely on third-party manufacturers, which might result in delays in research, development, clinical trials, regulatory approvals and product introductions.**

We have no manufacturing facilities and do not have extensive experience in the manufacturing of drugs or in designing drug manufacturing processes. We would have to contract with third-party manufacturers to produce, in collaboration with us, any products for clinical trials. Our reliance on these third parties for development activities would reduce our control over these activities but would not relieve us of our responsibility to ensure compliance with all required regulations and study and trial protocols. If these third parties were not to successfully carry out their contractual duties, meet expected deadlines or conduct studies in accordance with regulatory requirements or our stated study and trial plans and protocols, or if there were disagreements between us and these third parties, we would not be able to initiate, or complete, or may be delayed in completing, the clinical trials required to support future approval of any products. In some such cases, we might need to locate an appropriate replacement third-party relationship, which may not be readily available or with acceptable terms, which would cause additional delay with respect to the approval of products and would thereby have a material adverse effect on our business, financial condition, results of operations and prospects.

**Contract manufacturers are subject to significant regulatory oversight with respect to manufacturing products. The manufacturing facilities on which we would need to rely may not continue to meet regulatory requirements and may have limited capacity.**

Any manufacturers of product candidates are obliged to operate in accordance with FDA-mandated CGMPs. In addition, the facilities that would be used by contract manufacturers or other third party manufacturers to manufacture product candidates must be approved by the FDA or other foreign regulatory authority pursuant to inspections that would be conducted after we request regulatory approval from the FDA or other foreign regulatory authority. A failure of any contract manufacturers to establish and follow CGMPs and to document their adherence to such practices may lead to significant delays in development, or in clinical trials or in obtaining regulatory approval of product candidates or the ultimate launch of products into the market. Furthermore, any contract manufacturers are likely to be engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes them to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of the contract manufacturers' facilities generally. Failure by third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions. Many aspects of the clinical trial and manufacturing process are outside of our control. The facilities and quality systems of third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of third-party manufacturers. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or third-party manufacturers to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a manufacturing facility. Any such remedial measures imposed upon us or third parties with whom we might contract could materially harm our business.

**Developments by competitors may render our technologies obsolete or non-competitive which would have a material adverse effect on our business and results of operations.**

We compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Any drug candidates would have to compete with existing therapies and therapies under development by competitors. In addition, the commercial opportunities may be reduced or eliminated if competitors develop and market products that are less expensive, more effective or safer. Other companies have drug candidates in various stages of preclinical or clinical development to treat diseases for which we are also seeking to develop drug products. Some of these potential competing drugs are further advanced in development. Even if we are successful in developing effective drugs, they may not compete successfully with products produced by our competitors. Most of our competitors, either alone or together with their collaborative partners, operate larger research and development programs, have larger staffing and facilities, and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals, including foreign regulatory approvals, of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.



These organizations also compete with us for mergers, acquisitions and joint venture candidates and for other collaborations.

**Our employees, partners, independent contractors, consultants, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.**

We are exposed to the risk that our employees, partners, independent contractors, consultants, and vendors may engage in fraudulent or other illegal activity with respect to our business. Such misconduct could include intentional, reckless and/or negligent conduct or unauthorized activity that violates: (1) FDA or any comparable foreign regulatory authority regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or any comparable foreign regulatory authority; (2) manufacturing standards; (3) federal, state and foreign healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA or other regulatory authority debarment could result in a loss of business from our partners and severe reputational harm. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, operating results and financial condition.

**Any future mergers or acquisitions we make of companies or technologies, including the Merger with NeuBase, may result in disruption to our business or distraction of our management.**

We may merge with, acquire, or make investments in businesses, technologies, services or products if appropriate opportunities arise, including without limitation, the Merger with NueBase. From time to time we engage in discussions and negotiations with companies regarding our acquiring or investing in such companies' businesses, products, services or technologies, in the ordinary course of our business. We cannot be assured that we will be able to identify future suitable merger, acquisition or investment candidates, or if we do identify suitable candidates, that we will be able to make such acquisitions or investments on commercially acceptable terms or at all. If we acquire or merge with another company, including NeuBase, we could have difficulty in assimilating that company's personnel, operations, technology and software. In addition, the key personnel of the acquired company, including NeuBase, may decide not to work for us. If we make other types of acquisitions, we could have difficulty in integrating the acquired products, services or technologies into our operations. These difficulties could disrupt our ongoing business, distract our management and employees, increase our expenses and adversely affect our results of operations. Furthermore, we may incur indebtedness or issue equity securities to pay for any future acquisitions. The issuance of equity securities would be dilutive to our existing stockholders.

**Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.**

We store sensitive data, including intellectual property, our proprietary business information and personally identifiable information of our employees, in our data centers and on our networks. The secure maintenance of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, and damage our reputation.

**Our business and operations would suffer in the event of system failures.**

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such an event could cause interruption of our operations. To the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of product candidates could be delayed.

**Risks Related to FDA, Comparable Foreign Regulatory Authority and Healthcare Regulations**

**We face heavy government regulation. FDA regulatory approval and/or comparable foreign regulatory authority's approval of any products is uncertain.**

The research, testing, manufacturing and marketing of drug products are subject to extensive regulation by federal, state and local government authorities, including the FDA or any comparable foreign regulatory authority. To obtain regulatory approval of a product, we would need to demonstrate to the satisfaction of the applicable regulatory agency that, among other things, the product is safe and effective for its intended use. In addition, we would need to show that the manufacturing facilities used to produce the products are in compliance with current Good Manufacturing Practices regulations.

The process of obtaining FDA and other required regulatory approvals, including foreign regulatory approvals and clearances, would require us to expend substantial time and capital. Despite the time and expense expended, regulatory approval is never guaranteed. The number of preclinical and clinical trials that would be required for FDA approval, or any comparable foreign regulatory authority's approval, varies depending on the drug candidate, the disease or condition for which the drug candidate is in development, and the requirements applicable to that particular drug candidate. The FDA or other foreign health authority can delay, limit or deny approval of a drug candidate for many reasons, including that:

- a drug candidate may not be shown to be safe or effective;
- the FDA or any comparable foreign regulatory authority may not approve the manufacturing process;
- the FDA or any comparable foreign regulatory authority may interpret data from preclinical and clinical trials in different ways; and
- the FDA may not meet, or may extend, the Prescription Drug User Fee Act date with respect to a particular NDA.

If and when products do obtain marketing approval, the marketing, distribution and manufacture of such products would remain subject to extensive ongoing regulatory requirements. Failure to comply with applicable regulatory requirements could result in:

- warning letters;
- fines;
- civil penalties;
- injunctions;
- recall or seizure of products;
- total or partial suspension of production;
- refusal of the government to grant future approvals;
- withdrawal of approvals; and
- criminal prosecution.

We have not received regulatory approval to market any product candidates in any jurisdiction.

**Following regulatory approval of any drug candidates, we would be subject to ongoing regulatory obligations and restrictions, which might result in significant expense and limit our ability to commercialize potential products.**

With regard to drug candidates, if any, approved by the FDA or by another regulatory authority, including a foreign regulatory authority, we would be held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the drug candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the drug candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we were not able to maintain regulatory compliance, we might not be permitted to market our drugs and which could have a material adverse effect on our business and competitive position.

**Healthcare policy changes, including proposals to reform the U.S. healthcare system, may harm our future business.**

Healthcare costs have risen significantly over the past decade. There have been and continue to be proposals by legislators, regulators and third-party payors to keep these costs down. Certain proposals, if passed, would impose limitations on the prices we would be able to charge for products, or the amounts of reimbursement available for these products from governmental agencies and third party payors. These limitations could in turn reduce the amount of investment into development, and the amount of revenues that we would be able to generate in the future from sales of products and licenses of our technology.

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010, together, the Healthcare Reform Act, is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges, and the expansion of the Medicaid program. This law has substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. In addition, the Healthcare Reform Act imposes an annual fee, which will increase annually, on sales by branded pharmaceutical manufacturers starting in 2011. The financial impact of these discounts, increased rebates and fees and the other provisions of the legislation on our business is unclear and there can be no assurance that our business will not be materially adversely affected. In addition, these and other ongoing initiatives in the United States have increased and will continue to increase pressure on drug pricing. The announcement or adoption of any government initiatives could have an adverse effect on potential revenues from any product that we may successfully develop.

Moreover, additional legislative or regulatory changes remain possible and appear likely. In this regard, the U.S. Tax Cuts and Jobs Act of 2017, or U.S. Tax Act, signed into law in December 2017, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Healthcare Reform Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” The nature and extent of any additional legislative or regulatory changes to the Healthcare Reform Act are uncertain at this time. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally. In addition to the Healthcare Reform Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third party payors to keep healthcare costs down while expanding individual healthcare benefits.

Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government’s role in the U.S. healthcare industry may lower the revenues for future products and adversely affect our future business, possibly materially.

**Risks Related to Our Intellectual Property**

**Our ability to compete may be undermined if we do not adequately protect our proprietary rights.**

Our commercial success depends on obtaining and maintaining proprietary rights to our product candidates and technologies and their uses, as well as successfully defending these rights against third-party challenges. We may be able to most effectively protect our product candidates, technologies, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. Nonetheless, the issued patents and patent applications covering our programs remain subject to uncertainty due to a number of factors, including:

- we may not have been the first to make one or more of the inventions covered by our pending patent applications or issued patents;
- we may not have been the first to file patent applications for one or more of our product candidates or the technologies we rely upon;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- our disclosures in a particular patent application may be determined to be insufficient to meet the statutory requirements for patentability;
- one or more of our pending patent applications may not result in issued patents;
- we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;
- one or more patents issued to us or to our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- we may fail to file for patent protection in all of the countries where patent protection will ultimately be necessary or fail to comply with other procedural, documentary, fee payment or other provisions during the patent process in any such country, and we may be precluded from filing at a later date or may lose some or all patent rights in the relevant jurisdiction;
- one or more of our technologies may not be patentable;
- others may design around one or more of our patent claims to produce competitive products which fall outside of the scope of our patents;
- others may identify prior art which could invalidate our patents; or
- changes to patent laws may limit the exclusivity rights of patent holders.

Even if we have or obtain patents or licenses covering our product candidates or technologies, we may still be barred from making, using and selling one or more of our product candidates or technologies because of the patent rights of others. Others have or may have filed, and in the future are likely to file, patent applications covering compounds, assays, therapeutic products and delivery systems, including sustained release delivery, that are similar or identical to ours. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the area of medical disorders. These could materially affect our ability to develop our product candidates or sell our products. Because patent applications can take years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our product candidates or technologies may infringe. These patent applications may have priority over one or more patent applications filed by us.

If our competitors have prepared and filed patent applications in the United States that claim technology we also claim, we may have to participate in interference proceedings required by the United States Patent and Trademark Office to determine priority of invention, which could result in substantial costs, even if we ultimately prevail. Results of interference proceedings are highly unpredictable and may result in us having to try to obtain licenses in order to continue to develop or market certain of our drug products.

**Disputes may arise regarding the ownership or inventorship of our inventions. It is difficult to determine how such disputes would be resolved. Others may challenge the validity of our patents. If one or more of our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein.**

Some of our research collaborators and scientific advisors have rights to publish data and information to which we have rights. Additionally, employees whose positions may be eliminated may seek future employment with our competitors. Each of our employees is required to sign a confidentiality agreement and invention assignment agreement with us at the time of hire. While such arrangements are intended to enable us to better control the use and disclosure of our proprietary property and provide for our ownership of proprietary technology developed on our behalf, they may not provide us with meaningful protection for such property and technology in the event of unauthorized use or disclosure. In addition, technology that we may in-license may become important to some aspects of our business. We generally will not control all of the patent prosecution, maintenance or enforcement of in-licensed technology.

**We rely on confidentiality agreements that could be breached and may be difficult to enforce which could have a material adverse effect on our business and competitive position.**

Our policy is to enter agreements relating to the non-disclosure of confidential information with third parties, including our contractors, consultants, advisors and research collaborators, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them. However, these agreements can be difficult and costly to enforce. Moreover, to the extent that our contractors, consultants, advisors and research collaborators apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we rely on trade secrets and proprietary know-how that we will seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. In addition, courts outside the United States may be less willing to protect trade secrets. Despite the protective measures we employ, we still face the risk that:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach; or
- our trade secrets or proprietary know-how will otherwise become known.

Any breach of our confidentiality agreements or our failure to effectively enforce such agreements would have a material adverse effect on our business and competitive position.

**If we infringe the rights of third parties, we could be prevented from selling products, forced to pay damages and required to defend against litigation which could result in substantial costs and may have a material adverse effect on our business and results of operations.**

We have not received to date any claims of infringement by any third parties. However, as any product candidates progress into clinical trials and commercialization, if at all, our public profile and that of these product candidates may be raised and generate such claims. Defending against such claims, and occurrence of a judgment adverse to us, could result in unanticipated costs and may have a material adverse effect on our business and competitive position. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others, which could cause us to lose the use of one or more of our drug candidates;
- defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of management resources; or
- pay damages.

Any costs incurred in connection with such events or the inability to sell our products may have a material adverse effect on our business and results of operations.

**Intellectual property litigation is increasingly common and increasingly expensive and may result in restrictions on our business and substantial costs, even if we prevail.**

Patent and other intellectual property litigation is becoming more common in the pharmaceutical industry. Litigation is sometimes necessary to defend against or assert claims of infringement, to enforce our patent rights, including those we have licensed from others, to protect trade secrets or to determine the scope and validity of proprietary rights of third parties. Currently, no third party is asserting that we are infringing upon their patent rights or other intellectual property, nor are we aware or believe that we are infringing upon any third party's patent rights or other intellectual property. We may, however, be infringing upon a third party's patent rights or other intellectual property, and litigation asserting such claims might be initiated in which we would not prevail, or we would not be able to obtain the necessary licenses on reasonable terms, if at all. All such litigation, whether meritorious or not, as well as litigation initiated by us against third parties, is time-consuming and very expensive to defend or prosecute and to resolve. In addition, if we infringe the intellectual property rights of others, we could lose our right to develop, manufacture or sell products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling products, which could harm our business, financial condition and prospects.

**A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.**

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. If any product development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from making, using or selling the patented compounds. We may need to resort to litigation to enforce a patent issued to us, protect our trade secrets or determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We also may not be able to afford the costs of litigation.

**The patent applications of pharmaceutical and biotechnology companies involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.**

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. The U.S. Patent and Trademark Office's standards are uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference or derivation proceedings, and U.S. patents may be subject to inter partes review, post grant review and ex parte reexamination proceedings in the U.S. Patent and Trademark Office (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Similarly, opposition or invalidity proceedings could result in loss of rights or reduction in the scope of one or more claims of a patent in foreign jurisdictions. Such interference, inter partes review, post grant review and ex parte reexamination and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

Changes in or different interpretations of patent laws in the United States and foreign countries may permit others to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. In particular, there have been proposals to shorten the exclusivity periods available under U.S. patent law that, if adopted, could substantially harm our business. The product candidates are protected by intellectual property rights, including patents and patent applications. If any such product candidates becomes a marketable product, we would rely on our exclusivity under patents to sell the compound and recoup our investments in the research and development of the compound. If the exclusivity period for patents is shortened, then our ability to generate revenues without competition would be reduced and our business could be materially adversely impacted. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our product candidates. In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect our products or technologies or limit the exclusivity periods that are available to patent holders. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law in 2011 and includes a number of significant changes to U.S. patent law. These include changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The U.S. Patent and Trademark Office has been in the process of implementing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

If we fail to obtain and maintain patent protection and trade secret protection of any product candidates, proprietary technologies and their uses, we could lose our competitive advantage and competition we face would increase, reducing our potential revenues and adversely affecting our ability to attain profitability.

### **Risks Related to our Common Stock**

#### **The market price and volume of our common stock fluctuate significantly and could result in substantial losses for individual investors.**

The stock market from time to time experiences significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may cause the market price and volume of our common stock to decrease. In addition, the market price and volume of our common stock is highly volatile.

Factors that may cause the market price and volume of our common stock to decrease include:

- delisting or other changes in status of Nasdaq listing (See Risk Factor entitled, “If we fail to continue to meet all applicable Nasdaq Capital Market requirements and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.”);
- changes in stock market analyst recommendations regarding our common stock or lack of analyst coverage;
- fluctuations in our results of operations, timing and announcements of our corporate news;
- developments concerning the merger with NeuBase Therapeutics;
- developments concerning discussions that we may be in, or enter into, regarding strategic alliances, partnerships, reverse mergers, mergers, acquisitions, or similar transactions;
- adverse actions taken by regulatory agencies with respect to any drug products, clinical trials, manufacturing processes or sales and marketing activities;
- any lawsuit involving us or any drug products;
- developments with respect to our patents and proprietary rights;
- announcements of technological innovations by our competitors;
- public concern as to the safety of products developed by us or others;
- regulatory developments in the United States and in foreign countries;
- the pharmaceutical industry conditions generally and general market conditions;
- failure of our results of operations to meet the expectations of stock market analysts and investors;
- sales of our common stock by our executive officers, directors and five percent stockholders or sales of substantial amounts of our common stock;
- changes in accounting principles; and
- loss of any of our key scientific or management personnel.

#### **The market for our common stock is illiquid. Our stockholders may not be able to resell their shares at or above the purchase price paid by such stockholders, or at all.**

Our common stock is listed on the NASDAQ Capital Market. The market for our securities is illiquid. This illiquidity may be caused by a variety of factors including:

- lower trading volume;
- low stock price; and
- market conditions.

There is limited trading in our common stock and our security holders may experience wide fluctuations in the market price of our securities. Such price and volume fluctuations have particularly affected the trading prices of equity securities of many pharmaceutical and biotechnology companies. These price and volume fluctuations often appear to have been unrelated to the operating performance of the affected companies. These fluctuations may have an extremely negative effect on the market price of our securities and may prevent a stockholder from obtaining a market price equal to the purchase price such stockholder paid when the stockholder attempts to sell our securities in the open market. In these situations, the stockholder may be required either to sell our securities at a market price which is lower than the purchase price the stockholder paid, or to hold our securities for a longer period of time than planned. An inactive market may also impair our ability to raise capital by selling shares of capital stock.

**As a “smaller reporting company,” the Company may avail itself of reduced disclosure requirements, which may make the Company’s common stock less attractive to investors.**

Because the market value of the Company’s common stock as of the end of its most recently completed second fiscal quarter was less than \$75 million, the Company is a “smaller reporting company” under applicable SEC rules and regulations. As a “smaller reporting company,” the Company has relied on exemptions from certain disclosure requirements that are applicable to other public companies. The Company may continue to rely on such exemptions for so long as the Company remains a “smaller reporting company.” These exemptions include reduced financial disclosure, reduced disclosure obligations regarding executive compensation, and not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. The Company’s reliance on these exemptions may result in the public finding the Company’s common stock to be less attractive and adversely impact the market price of the Company’s common stock or the trading market thereof.

**We will not pay cash dividends and investors may have to sell their shares in order to realize their investment.**

We have not paid any cash dividends on our common stock and do not intend to pay cash dividends in the foreseeable future. We intend to use our cash for reinvestment in the development and marketing of products, technologies, and services. As a result, investors may have to sell their shares of common stock to realize any of their investment.

**Our internal controls over financial reporting may not be effective which could have a significant and adverse effect on our business and reputation.**

We are subject to the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and the rules and regulations of the SEC thereunder (“Section 404”). Section 404 requires us to report on the design and effectiveness of our internal controls over financial reporting. In the past, our management has identified certain “material weaknesses” in our internal controls over financial reporting which we believe have been remediated. However, any failure to maintain effective controls could result in significant deficiencies or material weaknesses, and cause us to fail to meet our periodic reporting obligations, or result in material misstatements in our financial statements. We may also be required to incur costs to improve our internal control system and hire additional personnel. This could negatively impact our results of operations.

**Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses and divert management’s attention from operating our business, which could have a material adverse effect on our business.**

There have been other changing laws, regulations and standards relating to corporate governance and public disclosure in addition to the Sarbanes-Oxley Act, as well as new regulations promulgated by the Commission and rules promulgated by the national securities exchanges. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Our board members, Chief Executive Officer and Chief Financial Officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty retaining qualified board members and executive officers, which could have a material adverse effect on our business. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, we may incur additional expenses to comply with standards set by regulatory authorities or governing bodies which would have a material adverse effect on our business and results of operations.

**Delaware law could discourage a change in control, or an acquisition of the Company by a third party, even if the acquisition would be favorable to stockholders.**

The Delaware General Corporation Law contains provisions that may have the effect of making more difficult or delaying attempts by others to obtain control of the Company, even when these attempts may be in the best interests of stockholders. Delaware law imposes conditions on certain business combination transactions with “interested stockholders.” These provisions and others that could be adopted in the future could deter unsolicited takeovers or delay or prevent changes in our control or management, including transactions in which stockholders might otherwise receive a premium for their shares of common stock over then current market prices. These provisions may also limit the ability of stockholders to approve transactions that they may deem to be in their best interests.

**Our Board of Directors has the authority to issue Serial Preferred Stock, which could affect the rights of holders of our common stock and may delay or prevent a takeover that could be in the best interests of our stockholders.**

The Board of Directors has the authority to issue up to 9,416,664 shares of Serial Preferred Stock, \$.0001 par value per share (the “Serial Preferred Stock”) (after giving effect to the conversion and cancellation of a previous issue of 5,583,336 shares of Series B Preferred), in one or more series and to fix the number of shares constituting any such series, the voting powers, designation, preferences and relative participation, optional or other special rights and qualifications, limitations or restrictions thereof, including the dividend rights and dividend rate, terms of redemption (including sinking fund provisions), redemption price or prices, conversion rights and liquidation preferences of the shares constituting any series, without any further vote or action by the stockholders. 6,000,000 shares of the Serial Preferred Stock, designated the Series B Preferred, have been authorized, 5,583,336 were issued and, as of the date of this filing, all such shares have been converted and no Series B Preferred shares remain issued and outstanding. The issuance of additional Serial Preferred Stock could affect the rights of the holders of Common Stock. For example, such issuance could result in a class of securities outstanding that would have preferential voting, dividend, and liquidation rights over the Common Stock, and could (upon conversion or otherwise) enjoy all of the rights appurtenant to the shares of common stock. The authority possessed by the Board of Directors to issue Serial Preferred Stock could potentially be used to discourage attempts by others to obtain control of the Company through merger, tender offer, proxy contest or otherwise by making such attempts more difficult or costly to achieve. The Board of Directors may issue the Serial Preferred Stock without stockholder approval and with voting and conversion rights which could adversely affect the voting power of holders of common stock. There are no agreements or understandings for the issuance of Serial Preferred Stock and the Board of Directors has no present intention to issue any Serial Preferred Stock.

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

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

Exhibit Number

[31.1](#) [Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](#)

[31.2](#) [Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](#)

[32.1](#) [Certification of Chief Executive Officer Pursuant to 18 U.S.C Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes Oxley Act of 2002](#)

[32.2](#) [Certification of Chief Financial Officer Pursuant to 18 U.S.C Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes Oxley Act of 2002](#)

101.INS XBRL Instance Document

101.SCH XBRL Taxonomy Extension Schema Document

101.CAL XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF XBRL Taxonomy Extension Definition Linkbase Document

101.LAB XBRL Taxonomy Extension Label Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

**SIGNATURES**

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

Date: February 14, 2019

OHR PHARMACEUTICAL, INC.  
(Registrant)

By: /s/ Dr. Jason S. Slakter  
Dr. Jason Slakter  
Chief Executive Officer  
(Principal Executive Officer)

By: /s/ Sam Backenroth  
Sam Backenroth  
Chief Financial Officer  
(Principal Financial and Accounting Officer)



Certification of Principal Executive Officer  
Pursuant to Section 302 of the  
Sarbanes-Oxley Act of 2002

I, Dr. Jason S. Slakter, certify that:

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

Dated: February 14, 2019

By: /s/ Dr. Jason S. Slakter  
Dr. Jason Slakter  
Chief Executive Officer  
(Principal Executive Officer)

---

Certification of Principal Financial Officer  
Pursuant to Section 302 of the  
Sarbanes-Oxley Act of 2002

I, Sam Backenroth, certify that:

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

Dated: February 14, 2019

By: /s/ Sam Backenroth  
Title: Chief Financial Officer  
(Principal Financial and Accounting Officer)

---

Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002

Not Filed Pursuant to the Securities Exchange Act of 1934

In connection with the Quarterly Report of Ohr Pharmaceutical, Inc. (the "*Company*") on Form 10-Q for the quarterly period ending December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "*Report*"), I, Dr. Jason S. Slakter, Chief Executive Officer (Principal Executive Officer), of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 14, 2019

/s/ Dr. Jason S. Slakter

Name: Dr. Jason Slakter  
Title: Chief Executive Officer  
(Principal Executive Officer)

Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002

Not Filed Pursuant to the Securities Exchange Act of 1934

In connection with the Quarterly Report of Ohr Pharmaceutical, Inc. (the "Company") on Form 10-Q for the quarterly period ending December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sam Backenroth, Chief Financial Officer (Principal Financial Officer), of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 14, 2019

/s/ Sam Backenroth

Name: Sam Backenroth

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)