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, 2017

OR

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

For the transition period from _____ to _____ Commission File Number: 333-88480

OHR PHARMACEUTICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	46-5622433
(State or other jurisdiction of incorporation or organization)	(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	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒

Do not check if smaller reporting company

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 56,466,428 shares of Common Stock outstanding as of February 13, 2018.

OHR PHARMACEUTICAL, INC.

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Part I FINANCIAL INFORMATION

Item 1. Financial Statements.

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OHR PHARMACEUTICAL, INC.
Consolidated Balance Sheets
(Unaudited)

	December 31, 2017	September 30, 2017
ASSETS		
CURRENT ASSETS		
Cash and Cash Equivalents	$ 8,724,057	$ 12,801,085
Prepaid expenses and other current assets	100,722	223,278
Total Current Assets	8,824,779	13,024,363
EQUIPMENT, net	60,890	63,757
OTHER ASSETS		
Security deposit	—	12,243
Intangible assets, net	13,805,484	14,087,602
Goodwill	740,912	740,912
TOTAL ASSETS	$ 23,432,065	$ 27,928,877
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 3,598,471	$ 4,827,525
Notes payable	—	106,387
Total Current Liabilities	3,598,471	4,933,912
Long-term liabilities	150,000	150,000
TOTAL LIABILITIES	3,748,471	5,083,912
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, 56,421,428 and 56,196,428 shares issued and outstanding, respectively	5,642	5,619
Additional paid-in capital	131,917,917	130,927,953
Accumulated deficit	(112,239,965)	(108,088,607)
Total Stockholders' Equity	19,683,594	22,844,965
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 23,432,065	$ 27,928,877

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

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

	For the Three Months Ended December 31,	
	2017	**2016**
OPERATING EXPENSES		
General and administrative	$ 1,510,032	$ 1,746,356
Research and development	2,387,731	4,931,144
Depreciation and amortization	284,986	298,435
TOTAL OPERATING LOSS	4,182,749	6,975,935
OTHER INCOME (EXPENSE)		
Other income (expense)	31,391	281
Total Other Income (Expense)	31,391	281
LOSS FROM OPERATIONS BEFORE INCOME TAXES	(4,151,358)	(6,975,654)
PROVISION FOR INCOME TAXES	—	—
NET LOSS	$ (4,151,358)	$ (6,975,654)
BASIC AND DILUTED LOSS PER SHARE (in dollars per share)	$ (0.07)	$ (0.21)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING: BASIC AND DILUTED	56,203,765	32,836,505

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

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

	For the Three Months Ended December 31,	
	2017	**2016**
OPERATING ACTIVITIES		
Net loss	$ (4,151,358)	$ (6,975,654)
Adjustments to reconcile net loss to net cash used by operating activities:		
Common stock issued for services	135,701	440,052
Stock option expense	629,286	566,573
Depreciation	2,867	15,736
Amortization of intangible assets	282,118	282,699
Changes in operating assets and liabilities		
Prepaid expenses and deposits	122,556	247,926
Accounts payable and accrued expenses	(1,229,054)	(507,793)
Security Deposit used	12,243	—
Net Cash Used in Operating Activities	(4,195,641)	(5,930,461)
INVESTING ACTIVITIES		
Purchase of property and equipment	—	(4,833)
Net Cash Provided by/ (Used in) Investing Activities	—	(4,833)
FINANCING ACTIVITIES		
Proceeds for issuance of common stock for cash	—	6,846,483
Proceeds from warrants exercised for cash	225,000	118,801
Repayments of short-term notes payable	(106,387)	(87,798)
Net Cash Provided by/ (Used in) Financing Activities	118,613	6,877,486
NET CHANGE IN CASH	(4,077,028)	942,192
CASH AT BEGINNING OF PERIOD	12,801,085	12,546,890
CASH AT END OF PERIOD	$ 8,724,057	$ 13,489,082
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
CASH PAID FOR:		
Interest	$ 1,770	$ 1,320

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

OHR PHARMACEUTICAL, INC.
Notes to Unaudited Consolidated Financial Statements
December 31, 2017

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, 2017, 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, 2017. The results of operations for the quarterly periods ended December 31, 2017 and 2016 are not necessarily indicative of the operating results for the full years.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND GOING CONCERN

Use of Estimates

The preparation of financial statements in conformity with GAAP 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.

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.

There are no assets and liabilities that are measured and recognized at fair value as of December 31, 2017 and September 30, 2017, on a recurring basis.

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.

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 expects to seek additional funds through equity or debt financings or through collaboration, licensing transactions or other sources. The Company may be unable to obtain equity or debt financings or enter into collaboration 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.

NOTE 3 – INTANGIBLE ASSETS

Intangible assets at December 31, 2017 and September 30, 2017:

	December 31, 2017	September 30, 2017
License Rights	$ 17,712,991	$ 17,712,991
Patent Costs	200,000	200,000
	17,912,991	17,912,991
Accumulated Amortization	(4,107,507)	(3,825,389)
Total Intangible Assets	$ 13,805,484	$ 14,087,602

During the three month period ended December 31, 2017, the Company recognized $282,118 in amortization expense on the patents and license rights.

NOTE 4 – NOTES PAYABLE

On February 28, 2017, the Company entered into a premium financing arrangement for its directors' and officers' insurance policy in the amount of $261,326. The financing arrangement bears interest at 7.5% per annum. As of December 31, 2017, the Company had repaid the note in full in the amount of $261,326 of principal and had paid total interest of $9,067.

NOTE 5 – EQUITY

Common Stock Warrants

In December 2017, 225,000 shares of common stock were issued in connection with the exercise of warrants issued and sold to various purchasers as part of a registered offering that closed on April 10, 2017. The warrants were exercised at a price of $1.00 per share, and $225,000 in cash was received during the quarter ended December 31, 2017.

Below is a table summarizing the warrants issued and outstanding as of December 31, 2017 ("Price" reflects the weighted average exercise price per share):

	Warrants	Price
Outstanding at September 30, 2017	16,178,110	$ 1.23
Granted		
Investor warrants	—	—
Stock-based compensation warrants	250,000	1.00
Exercised		
Investor warrants	(225,000)	1.00
Stock-based compensation warrants	—	—
Forfeited or expired		
Investor warrants	—	—
Stock-based compensation warrants	—	—
Outstanding at December 31, 2017	16,203,110	$ 1.23
Exercisable at December 31, 2017	16,078,108	$ 1.23

As of December 31, 2017, the warrants have a weighted average remaining term of 4.19 years and have an intrinsic value of $12,212,051.

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.

The following assumptions were used to calculate the fair value of the Company's warrants and options issued during the three months ended December 31, 2017:

	Warrants	Options
Expected term	2 years	3.25 to 5 years
Expected volatility	73%	101%
Expected dividends	0%	0%
Risk-free rates	1.73%	1.68%

Warrants. In October 2017, the Company issued a warrant to purchase 250,000 shares of common stock to a consultant for services to be rendered. The warrant vests in six equal consecutive monthly amounts at the end of each calendar month starting October 31, 2017, at an exercise price of $1.00 per share, for a term of two years from the date of issuance.

During the three month period ended December 31, 2017, the Company recognized $152,192 of expense related to warrants granted as stock based compensation. Unamortized expense as of December 31, 2017 for outstanding warrants issued as stock based compensation amounted to $73,569. Refer to the Common Stock Warrants table within this note for information regarding all outstanding warrants.

Options. In October 2017, the Company granted nonqualified stock options to purchase an aggregate of 1,640,000 shares of common stock to certain directors, employees, executive officers and key consultants. Other than the issuance of a stock option to purchase 80,000 shares of common stock issued to one key consultant, one third of the shares of common stock subject to the stock options became exercisable immediately, and one third of the shares of common stock subject to the stock options will become exercisable on each of October 16, 2018 and October 16, 2019. With respect to the stock option to purchase 80,000 shares of common stock issued to one key consultant, one quarter of the shares of common stock subject to the stock option vested immediately, and the remaining three quarters of the shares of common stock subject to the stock option are exercisable upon the achievements of certain milestones in connection with the Company's MAKO clinical study. All but one milestone has been achieved. As such, the 20,000 shares of common stock associated with this unmet performance condition have been accounted for as forfeitures and 60,000 shares have vested as of December 31, 2017. The stock options have an exercise price of $0.67 per share and expire on October 15, 2022.

During the three month period ended December 31, 2017, the Company recognized $477,094 of expense related to options granted. Unamortized option expense as of December 31, 2017 for all options outstanding amounted to $599,557. The Company expects to recognize this compensation cost over a weighted-average period of 1.48 years.

Below is a table summarizing the Company's activity for the three month period ended December 31, 2017 ("Price" reflects the weighted average exercise price per share):

	Options	Price
Outstanding at September 30, 2017	2,250,500	$ 5.58
Granted	1,640,000	$ 0.67
Exercised	—	—
Forfeited or expired	(210,666)	$ 6.38
Outstanding at December 31, 2017	3,679,834	$ 3.34
Exercisable at December 31, 2017	2,174,576	$ 4.51

As of December 31, 2017, the outstanding options have a weighted average remaining term of 4.25 years and an intrinsic value of $2,532,800.

Restricted Stock. During the three month period ended December 31, 2017, the Company recognized $135,701 of expense related to restricted stock awards. As of December 31, 2017, there was $59,400 of unamortized expense. The Company expects to recognize this compensation cost over a weighted-average period of .03 years.

Below is a table summarizing the Company's activity for the three months ended December 31, 2017:

	Shares	Weighted Average Grant Date Fair Value
Nonvested at September 30, 2017	270,179	$ 4.53
Granted	—	—
Vested	—	—
Forfeited	—	—
Nonvested at December 31, 2017	270,179	$ 4.53

NOTE 6 – COMMITMENTS AND CONTINGENCIES

Legal Proceedings

The Company may 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, alleging that several current and former officers violated federal securities laws between June 24, 2014 and 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 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. We dispute these claims and intend to defend the matter vigorously.

Severance Pay

As of December 31, 2017, the Company agreed to pay a former director severance pay in the amount of $250,000 over a five year period. The non-current portion of the liability is reported as long-term liability in the amount of $150,000 in the consolidated balance sheets.

NOTE 7 – RELATED PARTY TRANSACTION

The Contract Research Organization ("CRO") that ran our 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 our 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, 2017, and 2016, the Company's CRO was invoiced or accrued $731,832 and $152,405 from DARC.

NOTE 8 – SUBSEQUENT EVENTS

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 age-related macular degeneration ("wet-AMD"). The primary efficacy endpoint was the mean visual acuity gain at nine months, using a mixed-effects model for repeated measures (MMRM) analysis. Subjects receiving squalamine combination therapy (n=119) achieved a mean gain of 8.33 letters from baseline versus 10.58 letters from baseline with Lucentis® monotherapy (n=118). There were no differences in the safety profile between the two treatment groups. Based on these results, we have discontinued further development of squalamine and are evaluating strategic alternatives to maximize shareholder value.

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 13 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 focused on the development of novel therapeutics and delivery technologies for the treatment of ocular disease.

Recent Developments

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. The primary efficacy endpoint was the mean visual acuity gain at nine months, using a mixed-effects model for repeated measures (MMRM) analysis. Subjects receiving squalamine combination therapy (n=119) achieved a mean gain of 8.33 letters from baseline versus 10.58 letters from baseline with Lucentis® monotherapy (n=118). There were no differences in the safety profile between the two treatment groups. Based on these results, we have discontinued further development of squalamine and are evaluating strategic alternatives to maximize shareholder value.

The Board of Directors has engaged Roth Capital Markets, LLC, to advise the Board of Directors 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, joint venture, partnership, or other business combination with another entity, public or private. The Board has not set a definitive timetable for completion of this process. There can be no assurance that this process will result in a strategic alternative of any kind. The Company does not intend to disclose developments or provide updates on the progress or status of this process unless it deems further disclosure is appropriate or required.

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"). Under the terms of the acquisition agreement, in exchange for substantially all the assets of SKS, Ohr made an upfront payment of $3.5 million in cash and issued 1,194,862 shares of Ohr common stock to SKS. In addition, SKS is eligible to receive up to an aggregate of 1,493,577 additional shares of Ohr common stock in three contingent milestone payments, each milestone resulting in the issuance of 497,859 shares of Ohr common stock. Milestone 1 required Ohr to demonstrate a consistent long-term release of a therapeutic agent above threshold therapeutic levels in the targeted ocular tissues of an animal model. Ohr met this milestone in December 2015. Milestone 2 required the completion of a pharmacodynamic study in an animal model showing clinically relevant efficacy from a drug substance released from SKS microparticles within 24 months of the date of the closing of the SKS Acquisition. Ohr achieved the study results in May 2016, and the Board reviewed and approved Milestone 2 in July 2016. Milestone 3 requires, among other things, the approval of an Investigational New Drug Application ("IND") within three years of the date of the closing of the SKS Acquisition. We did not achieve Milestone 3.

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.

PRODUCT PIPELINE

(a) SQUALAMINE LACTATE OPHTHALMIC SOLUTION 0.2%

Squalamine Lactate Ophthalmic Solution 0.2% ("Squalamine", also known as OHR-102)

Squalamine lactate is a small molecule anti-angiogenic drug with a novel intracellular mechanism of action. The drug acts against the development of aberrant neovascularization by inhibiting multiple protein growth factors of angiogenesis, including vascular endothelial growth factor ("VEGF"), platelet-derived growth factor ("PDGF") and basic fibroblast growth factor ("bFGF").

In April 2016, we commenced enrollment in the MAKO study. The study was a multi-center, randomized, double-masked, placebo-controlled clinical trial to evaluate the efficacy and safety of squalamine combination therapy for the treatment of wet-AMD. Subjects were randomized 1:1 to receive topical squalamine lactate ophthalmic solution, 0.2%, ("squalamine") twice daily ("BID") and monthly Lucentis® injections ("squalamine combination") or topical placebo BID and monthly Lucentis® injections ("Lucentis monotherapy"). Eligibility criteria for the study eye included: newly diagnosed with wet-AMD and no previous treatment, occult neovascularization, if present, measured less than $10mm^2$ as assessed by fluorescein angiography, and visual acuity between 20/40 and 20/320. A total of 237 subjects were randomized. Visual acuity was measured monthly using the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. The primary efficacy endpoint was the mean visual acuity gain at nine months, using a mixed-effects model for repeated measures (MMRM) analysis.

On January 5, 2018, the Company reported topline data from the study which did not meet its primary efficacy endpoint. The study evaluated the efficacy and safety of topically administered squalamine in combination with monthly Lucentis® injections for the treatment of wet-AMD. The primary efficacy endpoint was the mean visual acuity gain at nine months, using a mixed-effects model for repeated measures (MMRM) analysis. Subjects receiving squalamine combination therapy (n=119) achieved a mean gain of 8.33 letters from baseline versus 10.58 letters from baseline with Lucentis® monotherapy (n=118). There were no differences in the safety profile between the two treatment groups. Based on the results of the study, we are no longer moving squalamine forward in clinical development.

(b) 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 applications of its sustained release technology and potential avenues to monetize it.

(c) ANIMAL MODEL FOR DRY-AMD

As part of the SKS acquisition, we 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 and clinical 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 currently 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.

(d) NON-OPHTHALMOLOGY ASSETS

Ohr also owns various other compounds in earlier stages of development, including the PTP1b inhibitor trodusquemine and related analogs. On February 26, 2014, we 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 other undisclosed 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 continue development of its pharmaceutical products and 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 the end of the Company's 2017 fiscal year to the end of the first quarter in fiscal year 2018 by $2,864,143 (to $5,226,308 from $8,090,451) primarily due to costs related to the clinical trial. We expect our cash burn to significantly decrease in the remainder of fiscal 2018 as compared to the same periods in 2017 as a result of the completion of the MAKO study. Management has concluded that due to the conditions described above, there is substantial doubt about the Company's ability to continue as a going concern. The Company does not have a bank line of credit or other fixed source of capital reserves. When it will need additional capital in the future, the Company will be primarily reliant upon private or public placement of its equity or debt securities, or a transaction with a partner, but presently there can be no assurance that the Company will be successful in such efforts. In April 2017, the Company closed a public offering for net proceeds of approximately $12.7 million, and management believes the Company has sufficient capital to meet its planned operating needs through the end of calendar 2018.

Results of Operations

Three Months Ended December 31, 2017 Compared to Three Months Ended December 31, 2016

Results of operations for the three months ended December 31, 2017 ("2017") reflect the following changes from the prior period ("2016").

	2017	2016	Change
General and administrative	$ 1,510,032	$ 1,746,356	$ (236,324)
Research and development	2,387,731	4,931,144	(2,543,413)
Depreciation and amortization	284,986	298,435	(13,449)
Total Operating Expenses	4,182,749	6,975,935	(2,793,186)
Operating Loss	(4,182,749)	(6,975,935)	2,793,186
Other income (expense)	31,391	281	31,110
Net Loss	$ (4,151,358)	$ (6,975,654)	$ 2,824,296

The Company had no net revenues from operations in 2016 or 2017. Accordingly, the Company had no cost of revenue from operations in 2016 or 2017.

General and administrative expenses from operations remained relatively flat, with a $236,324 decrease when comparing 2017 to 2016.

The Company incurred $2,387,731 in research and development expenses in 2017 compared to $4,931,144 in 2016. The decrease is a result of significant upfront costs paid in 2016 related to the MAKO study in wet-AMD.

Depreciation and amortization expense remained relatively stable with $298,435 in 2016 and $284,986 in 2017.

For the three months ended December 31, 2017, the Company recognized a net loss of $4,151,358 compared to a net loss of $6,975,654 for the same period in 2016. The decrease in net loss is primarily a result of significant upfront costs paid in 2016 that were related to the MAKO study in wet-AMD. 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.

On February 14, 2018, plaintiff, Jeevesh Khanna, commenced an action in the Southern District of New York, alleging that several current and former officers violated federal securities laws between June 24, 2014 and 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 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. We dispute these claims and intend to defend the matter vigorously.

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 Our Financial Position and Need for Capital

Our business was substantially dependent on the success of squalamine, which recently failed to meet its primary efficacy endpoint in the MAKO Study. We are unable to identify a viable path forward for continued development of this product candidate.

To date, we have devoted a substantial portion of our research, development, clinical efforts and financial resources toward the development of squalamine for the treatment of wet-AMD. Squalamine 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. We are unable to identify a viable plan for continued clinical development of this product candidate. Because our business was substantially dependent on the success of squalamine, we have curtailed all of our activities on this program and may be required to liquidate, dissolve or otherwise wind down our operations if we are unable to consummate a strategic alternative.

We may not be able to monetize the non squalamine assets, including the SKS sustained release ocular drug delivery platform technology or the non-ophthalmology assets.

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 animal model for dry AMD or the non-ophthalmology assets, including the PTP1b inhibitor trodusquemine and related analogs. In that event, we may be constrained to write off those assets, in whole or in part.

We are subject to securities class action litigation.

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 us. 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.

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.

Our common stock is listed on the Nasdaq Capital Market. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital, a minimum price per share and continued business operations so that we are not characterized as a “public shell company.” If we are unable to comply with Nasdaq’s listing standards, Nasdaq may determine to delist our common stock from the Nasdaq Capital Market. In the event that our common stock is delisted from the Nasdaq Capital Market and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Markets. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

On April 6, 2017, we received a notification letter from Nasdaq indicating that the bid price of our common stock for the last 30 consecutive business days had closed below the minimum $1.00 per share required for continued listing under Nasdaq Listing Rule 5550(a). We were provided a period of 180 calendar days, or until October 3, 2017, to regain compliance. At the end of September 2017, the Company determined that it would not be in compliance with the minimum closing bid price requirement by October 3, 2017, which would subject the Company’s common stock to delisting from Nasdaq. As a result, the Company notified Nasdaq and applied for an extension of the cure period, as permitted under the original notification. In the application, the Company indicated that it met the continued listing requirement for market value of publicly-held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the minimum closing bid price, and provided written notice of its intention to cure the deficiency during the second compliance period of an additional 180 days. On October 4, 2017, we received a written notice from Nasdaq that we were granted an additional 180 calendar days, or until April 2, 2018, to regain compliance with the minimum $1.00 bid price per share requirement of the Listing Rules of Nasdaq. On December 15, 2017, the Company received notice from Nasdaq confirming that for the last 10 consecutive business days, from December 1, 2017 to December 14, 2017, the closing bid price of the Company’s common stock had been at $1.00 per share or greater. Accordingly, Nasdaq determined that the Company had regained compliance with Nasdaq Listing Rule 5550(a)(2). Although we have regained Nasdaq compliance, there can be no assurance that we will be able to maintain compliance with the requirements for listing our common stock on the Nasdaq. The failure to maintain our listing on the Nasdaq could have an adverse effect on the market price and liquidity of our shares of common stock.

There is no certainty that we will be able to execute on any strategic alternatives to maximize shareholder value. If we are unable to identify and execute such strategic alternatives, we may be forced to cease operations.

Based on the results of the MAKO study, we began a comprehensive review of strategic alternatives to maximize shareholder value. We have retained Roth Capital Markets, LLC, to advise and assist us 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, joint venture, partnership, or other business combination with another entity, public or private. There can be no assurance that this review process will result in a transaction, or that if a transaction does occur, that it will successfully enhance stockholder value. Our expected cash position, net of all liabilities, limits our attractiveness to potential merger candidates and the value that we may receive in such merger, joint venture, partnership, or other business combination scenarios may be less than the current market value of the Company.

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, 2017, we had an accumulated deficit of approximately $112 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 the commercialization of our product candidates.

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, 2017 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.

As a result of the negative results from the MAKO Study and our limited financial resources, we may not be successful in retaining key employees.

Our cash conservation activities may yield unintended consequences, such as reduced employee morale and unwanted attrition. Competition among biotechnology companies for qualified employees is intense, and the ability to retain our key employees is critical to our ability to effectively manage our resources while we seek to identify and implement strategic alternatives. Loss of any of our key employees could have a material adverse effect on our business.

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 from our product candidates. We cannot guarantee that any of our product candidates will ever become marketable products.

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 or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, and partnerships. We do not have any committed external source of funds. 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, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise capital through a partnership, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates 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 delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves, or cease operations and liquidate.

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

Our strategy is to seek a strategic commercial partner, or partners, such as large pharmaceutical companies, with extensive experience in the development, commercialization, and marketing of ophthalmic and non-ophthalmic products. To date, we have not entered into any strategic partnerships for any of our 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 of our 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 commercialize our 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 product candidates or technologies. A partnership involving our product candidates 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 our 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 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 our product candidates and may not generate meaningful revenues.

If we are ever in a position to commercialize our product candidates, of which there can be no assurance, 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 our product candidates, 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 of our 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 our 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 our 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 our products and even if we do build a sales force, they may not be successful in marketing our products, which would have a material adverse effect on our business and results of operations.

We rely, and expect that we will continue to rely, on third parties to conduct any future clinical 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 drug 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 our drug discovery and development efforts, and we will likely continue to depend on them to assist in our future discovery and development efforts. These parties are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If they fail to devote sufficient time and resources to our drug development programs or if their performance is substandard, it will delay the development and commercialization of our product candidates. The parties with which we contract for execution of our clinical trials will 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 our 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 our clinical trials and may subject us to unexpected cost increases that are beyond our control. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on contract research organizations does not relieve us of our regulatory responsibilities. We and our contract research organizations are 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 our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that, upon inspection, the FDA or any comparable foreign regulatory authority will determine that any of our clinical trials comply with CGCP. In addition, our clinical trials must be conducted with product produced under current CGMP, regulations and will require a large number of test subjects. Our failure or the failure of our contract research organizations to comply with these regulations may 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 our contract research organizations do not successfully carry out their duties or if we were to lose relationships with contract research organizations, our drug 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 may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to current 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 our product candidates could be delayed, and have a material adverse effect on our business.

Our product candidates may not gain acceptance among physicians, patients, or the medical community, thereby limiting our potential to generate revenues, which will undermine our future growth prospects.

Even if our product candidates are approved for commercial sale by the FDA or other regulatory authorities, including foreign regulatory authorities, the degree of market acceptance of any approved product candidate by physicians, healthcare professionals and third-party payors, and our profitability and growth will depend on a number of factors, including:

- the ability to provide acceptable evidence of safety and efficacy;
- pricing and cost effectiveness, which may be subject to regulatory control;
- our ability to obtain sufficient third-party insurance coverage or reimbursement;

- effectiveness of our or our collaborators' sales and marketing strategy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects; and
- availability of alternative treatments.

If any product candidate that we develop does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide some additional patient benefit over the current standard of care, that product will not achieve market acceptance and we will not generate sufficient revenues to achieve profitability.

We may not be able to continue or fully exploit our partnerships with outside scientific and clinical advisors, which could impair the progress of clinical trials and our research and development efforts.

We work with scientific and clinical advisors who are experts in the field of ocular disorders. They advise us with respect to our programs. 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 delay the development or commercialization of our product candidates.

We rely completely on third-party manufacturers which may result in delays in 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 will have to contract with third-party manufacturers to produce, in collaboration with us, our product candidates for clinical trials. If any of our product candidates are approved by the FDA or other regulatory agencies, including foreign regulatory agencies for commercial sale, we may need to amend our contract with the manufacturer or contract with another third party to manufacture them in larger quantities. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on these third parties for development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study and trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study and trial plans and protocols, or if there are disagreements between us and these third parties, we will not be able to initiate, or complete, or may be delayed in completing, the clinical trials required to support future approval of our product candidates. In some such cases, we may 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 our product candidates and would thereby have a material adverse effect on our business, financial condition, results of operations and prospects.

We have not entered into long-term agreements with third-party manufacturers or with any alternate suppliers. Although we intend to do so prior to any commercial launch of a product that is approved by the FDA or any comparable foreign regulatory authorities in order to ensure that we maintain adequate supplies of commercial drug product, we may be unable to enter into such agreements or do so on commercially reasonable terms, which could delay a product launch or subject our commercialization efforts to significant supply risk. In addition, reliance on third-party manufacturers entails risks to which we would not be subject to if we manufactured the product candidates ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of manufacturers or suppliers of products and services that are vital to our clinical program caused by conditions unrelated to our business or operations, including regulatory enforcement actions, and bankruptcy of the manufacturer or supplier.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize future product candidates. Some of these events could be the basis for FDA or any comparable foreign regulatory authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

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

Any manufacturers of our 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 our product candidates must be approved by the FDA or other foreign regulatory authority pursuant to inspections that will 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 clinical trials or in obtaining regulatory approval of product candidates or the ultimate launch of products based on our product candidates into the market. Furthermore, all of our future 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 our 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 our third-party manufacturers. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our 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 our 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 contract could materially harm our business.

Developments by competitors may render our products or 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. Our drug candidates will have to compete with existing therapies and therapies under development by our competitors. In addition, our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our drug products. 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 than our drug candidates and may be commercialized earlier. Even if we are successful in developing effective drugs, our products 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 to attract qualified personnel, acquisitions and joint venture candidates and for other collaborations. Activities of our competitors may impose unanticipated costs on our business which would have a material adverse effect on our business and results of operations.

We depend upon key officers and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

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.

We also depend in part on obtaining the service of scientific personnel and our ability to identify, hire and retain additional personnel. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

In addition, the announcement that we have commenced a review of strategic alternatives may create uncertainty about our prospects as an independent business entity, and make it more difficult to attract and retain qualified executive and other key personnel. The review process may also be costly, time-consuming, divert the attention of management and our employees or result in changes in our management team or our board of directors, all of which could materially and adversely affect our business. In addition, our stock price may experience periods of increased volatility as a result of these activities or related rumors and speculation.

Our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations 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, principal investigators, consultants, vendors and contract research organizations may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees 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 employee 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 acquisitions we make of companies or technologies may result in disruption to our business or distraction of our management, due to difficulties in assimilating acquired personnel and operations.

We may acquire or make investments in complementary businesses, technologies, services or products which complement our pharmaceutical operations if appropriate opportunities arise. 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 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 invest in another company, we could have difficulty in assimilating that company's personnel, operations, technology and software. In addition, the key personnel of the acquired company 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. However, we currently do not have any agreement to enter into any material investment or acquisition transaction.

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. For example, the loss of data from clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs. 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 our 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 our products is uncertain.

The research, testing, manufacturing and marketing of drug products such as those that we are developing 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 must 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 must 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, will 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 will 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 our manufacturing process;
- the FDA or any comparable foreign regulatory authority may interpret data from preclinical and clinical trials in different ways than we do; and
- the FDA may not meet, or may extend, the Prescription Drug User Fee Act date with respect to a particular NDA.

For example, if certain of our methods for analyzing our trial data are not accepted by the FDA or foreign regulatory authority, we may fail to obtain regulatory approval for our product candidates. Moreover, if and when our 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.

Any delay or failure by us to obtain regulatory approvals for our product candidates could diminish competitive advantages that we may attain and would adversely affect the marketing of our products. We have not received regulatory approval to market any of our product candidates in any jurisdiction.

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

With regard to our drug candidates, if any, approved by the FDA or by another regulatory authority, including a foreign regulatory authority, we are 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 are 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 will be able to charge for the products that we are developing, or the amounts of reimbursement available for these products from governmental agencies third-party payors. These limitations could in turn reduce the amount of investment into development, and the amount of revenues that we will be able to generate in the future from sales of our products and licenses of our technology.

In March 2010, the U.S. Congress enacted healthcare reform legislation that may significantly impact the pharmaceutical industry. In addition to requiring most individuals to have health insurance and establishing new regulations on health plans, this legislation requires discounts under the Medicare drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the legislation 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.

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 future revenues for the products we are developing 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 will 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. For example, we have rights under U.S. patents and patent applications 7981876, 8716270, 6262283, 7728157, 20130281420 and 21050342874 to cover the Squalamine formulations, composition of matter, use in combination with other agents, methods of manufacture, and uses. Nonetheless, the issued patents and patent applications covering our technology 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 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 ocular 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 our product candidates progress into clinical trials and commercialization, if at all, our public profile and that of our 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 our 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 our 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 our 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 our drug development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. If our products 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 use our discoveries or 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 that we are developing are protected by intellectual property rights, including patents and patent applications. If any of our product candidates becomes a marketable product, we will 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 will 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 recently signed into law 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 our 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:

- adverse results, termination, reduction, changes or delays in our or our competitors clinical trials;
- fluctuations in our results of operations, timing and announcements of our bio-technological innovations or new products or those of our competitors;
- developments concerning discussions that we may be in, or enter into, regarding strategic alliances, partnerships, mergers, acquisitions, or similar transactions;
- announcements of FDA non-approval of our drug products, or delays in the FDA or other foreign regulatory review process or actions;
- adverse actions taken by regulatory agencies with respect to our drug products, clinical trials, manufacturing processes or sales and marketing activities;
- any lawsuit involving us or our drug products;
- developments with respect to our patents and proprietary rights;
- announcements of technological innovations or new products 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;
- changes in stock market analyst recommendations regarding our common stock or lack of analyst coverage;
- 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 status of Nasdaq listing;
- 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 quoted 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; 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 or to recruit and retain managers with equity-based incentive plans.

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 our products and services. As a result, investors may have to sell their shares of common stock to realize 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 attracting and 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.

In October 2017, the Company issued a warrant to purchase 250,000 shares of common stock to a consultant for services to be rendered. The warrant vests in six equal consecutive monthly amounts at the end of each calendar month starting October 31, 2017, at an exercise price of $1.00 per share, for a term of two years from the date of issuance. The warrant was issued pursuant to the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

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, 2018

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)

Exhibit 31.1

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, 2018

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

Exhibit 31.2

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, 2018

/s/ Sam Backenroth
Sam Backenroth
(Principal Financial and Accounting Officer)

Exhibit 32.1

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, 2017, 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, 2018

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

Exhibit 32.2

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, 2017, 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, 2018

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