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 June 30, 2017

OR

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

For the transition period from _____ to _____ Commission File 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: 56,211,428 shares of Common Stock outstanding as of August 7, 2017.

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)

	June 30, 2017	September 30, 2016
ASSETS		
CURRENT ASSETS		
Cash	$ 18,079,406	$ 12,546,890
Prepaid expenses and other current assets	436,607	738,118
Total Current Assets	18,516,013	13,285,008
EQUIPMENT, net	79,806	198,631
OTHER ASSETS		
Security deposit	12,243	12,243
Intangible assets, net	14,369,747	15,208,219
Goodwill	740,912	740,912
TOTAL ASSETS	$ 33,718,721	$ 29,445,013
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 5,435,997	$ 4,394,068
Notes payable	158,645	87,798
Total Current Liabilities	5,594,642	4,481,866
Long-term liability	150,000	—
TOTAL LIABILITIES	5,744,642	4,481,866
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, 56,211,428 and 32,076,396 shares issued and outstanding, respectively	5,621	3,207
Additional paid-in capital	130,812,624	109,237,551
Accumulated deficit	(102,844,166)	(84,277,611)
Total Stockholders' Equity	27,974,079	24,963,147
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 33,718,721	$ 29,445,013

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 June 30,		For the Nine Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
OPERATING EXPENSES				
General and administrative	$ 1,404,287	$ 1,664,882	$ 4,554,704	$ 5,849,374
Research and development	2,233,388	5,637,602	13,158,460	11,757,741
Depreciation and amortization	288,976	296,143	879,286	889,959
Gain on Settlement of Accounts Payable	(70,757)	—	(70,757)	(710,264)
OPERATING LOSS	3,855,894	7,598,627	18,521,693	17,786,810
OTHER INCOME (EXPENSE)				
Change in fair value of contingent consideration	—	(104,844)	—	(1,356,770)
Other income	5,441		5,441	3,419
Interest income (expense), net	(50,376)	3,730	(50,303)	10,099
Total Other Income (Expense)	(44,935)	(101,114)	(44,862)	(1,343,252)
LOSS FROM OPERATIONS BEFORE INCOME TAXES	(3,900,829)	(7,699,741)	(18,566,555)	(19,130,062)
PROVISION FOR INCOME TAXES	—	—	—	—
NET LOSS	$ (3,900,829)	$ (7,699,741)	$ (18,566,555)	$ (19,130,062)
BASIC AND DILUTED LOSS PER SHARE (in dollars per share)	$ (0.07)	$ (0.24)	$ (0.45)	$ (0.61)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:				
BASIC AND DILUTED	53,986,150	31,501,540	40,916,570	31,126,656

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

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

	For the Nine Months Ended June 30,	
	2017	**2016**
OPERATING ACTIVITIES		
Net Loss	$ (18,566,555)	$ (19,130,062)
Adjustments to reconcile net loss to net cash used by operating activities:		
Common stock issued for services	783,842	1,237,064
Stock option expense	1,256,644	2,335,197
Change in fair value of contingent consideration	—	1,356,770
Depreciation	40,814	48,012
Amortization of intangible assets	838,472	841,947
Gain on settlement of accounts payable	(70,757)	(710,264)
Gain on sale of property and equipment	(5,441)	—
Changes in operating assets and liabilities		
Prepaid expenses and deposits	444,036	322,544
Accounts payable and accrued expenses	1,262,686	2,745,372
Net Cash Used in Operating Activities	(14,016,259)	(10,953,420)
INVESTING ACTIVITIES		
Purchase of property and equipment	(4,833)	(13,306)
Sale of property and equipment	88,285	—
Net Cash Provided by/ (Used in) Investing Activities	83,452	(13,306)
FINANCING ACTIVITIES		
Proceeds from issuance of common stock for cash, net	19,537,001	—
Proceeds from warrants exercised for cash	118,801	26,041
Repayments of short-term notes payable	(190,479)	(132,918)
Net Cash Provided by/ (Used in) Financing Activities	19,465,323	(106,877)
NET CHANGE IN CASH	5,532,516	(11,073,603)
CASH AT BEGINNING OF PERIOD	12,546,890	28,697,323
CASH AT END OF PERIOD	$ 18,079,406	$ 17,623,720
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
CASH PAID FOR:		
Interest	$ 5,107	$ 4,262
Income Taxes	—	—
NON CASH FINANCING ACTIVITIES:		
Settlement of contingent consideration	$ —	$ 2,061,136
Financing of insurance premiums through issuance of short term notes	261,326	215,810

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

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 June 30, 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, 2016. The results of operations for the quarterly periods ended June 30, 2017 and 2016 are not necessarily indicative of the operating results for the full years.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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 receivable, 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 June 30, 2017 and September 30, 2016, 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.

NOTE 3 – INTANGIBLE ASSETS
Intangible assets at June 30, 2017 and September 30, 2016

	June 30, 2017	September 30, 2016
License Rights	$ 17,712,991	$ 17,712,991
Patent Costs	200,000	200,000
	17,912,991	17,912,991
Accumulated Amortization	(3,543,244)	(2,704,772)
Total Intangible Assets	$ 14,369,747	$ 15,208,219

During the three and nine month periods ended June 30, 2017, the Company recognized $279,222 and $838,472 respectively, in amortization expense on the patents and license rights. The amortization expense has been included in research and development expense.

NOTE 4 – NOTES PAYABLE

On February 28, 2016, the Company entered into a premium financing arrangement for its directors' and officers' insurance policy in the amount of $215,810. The financing arrangement bears interest at a rate of 7% per annum and is payable over a period of 10 months from issuance. The outstanding balance of the note at September 30, 2016 of $87,798 was fully paid during the nine months ended June 30, 2017.

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 June 30, 2017, the Company had repaid $102,681 of principal and had paid interest of $5,477.

NOTE 5 – EQUITY

Public Offerings
On December 7, 2016, the Company entered into a securities purchase agreement with various purchasers pursuant to which the Company issued and sold to the purchasers in a registered offering an aggregate of 3,885,000 shares of its common stock, together with Series A common stock purchase warrants ("Series A Warrants") exercisable for up to an aggregate of 1,942,501 shares of common stock and Series B common stock purchase warrants ("Series B Warrants") exercisable for up to an aggregate of 3,885,000 shares of common stock. The offering closed on December 13, 2016 and the Company received net proceeds of approximately $6.8 million, after deducting placement agent fees and offering expenses payable by the Company.

The Series A Warrants have an exercise price of $2.75 per share, are immediately exercisable, and will expire on the five year anniversary of the date of issuance. The Series B Warrants were immediately exercisable and expired on the six month anniversary of the date of issuance. No Series B Warrants were exercised.

On April 5, 2017, the Company entered into a securities purchase agreement with various purchasers pursuant to which the Company issued and sold to the purchasers in a registered offering an aggregate of 20,250,032 shares of its common stock, together with warrants ("Warrants") exercisable for up to an aggregate of 14,175,059 shares of its common stock. The offering closed on April 10, 2017, and the Company received net proceeds of approximately $12.7 million, after deducting placement agent fees and offering expenses payable by the Company.

The Warrants have an exercise price of $1.00 per share. Following the one year anniversary of the date the Warrants are issued, the holders of the Warrants may exercise the Warrants through a cashless exercise, in whole or in part. The Warrants are immediately exercisable and will expire on the five year anniversary of the date of the issuance.

Common Stock Warrants

Below is a table summarizing the warrants issued and outstanding as of June 30, 2017 ("Price" reflects the weighted average exercise price per share):

	Warrants	Price
Outstanding at September 30, 2016	614,923	$ 5.08
Granted	—	—
Investor warrants	20,002,560	1.56
Stock-based compensation warrants	—	—
Exercised	—	—
Investor warrants	—	—
Stock-based compensation warrants	—	—
Forfeited or expired		
Investor warrants	(4,213,331)	3.03
Stock-based compensation warrants	(201,042)	7.92
Outstanding at June 30, 2017	16,203,110	$ 1.23
Exercisable at June 30, 2017	16,203,110	$ 1.23

As of June 30, 2017, the warrants have a weighted average remaining term of 4.72 years and have no intrinsic value.

During the nine month period ended June 30, 2017, the Company received the proceeds related to warrants exercised in July 2016 amounting to $118,801.

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.

Warrants. During the three and nine month periods ended June 30, 2017, the Company did not recognize any expense related to warrants granted as stock based compensation. As of June 30, 2017, there was no unamortized expense, and the warrants had no intrinsic value. Refer to the Common Stock Warrants table within this note for information regarding all outstanding warrants.

Options. During the three and nine month periods ended June 30, 2017, the Company recognized $410,374 and $1,256,644 of expense related to options granted. Unamortized option expense as of June 30, 2017 for all options outstanding amounted to $987,252. The Company expects to recognize this compensation cost over a weighted-average period of 1.36 years.

Below is a table summarizing the Company's activity for the nine month period ended June 30, 2017 ("Price" reflects the weighted average exercise price per share):

	Options	Price
Outstanding at September 30, 2016	2,857,468	$ 6.66
Granted	750,000	0.65
Exercised	—	—
Forfeited or expired	(991,634)	6.01
Outstanding at June 30, 2017	2,615,834	$ 5.18
Exercisable at June 30, 2017	1,795,247	$ 6.03

As of June 30, 2017, the outstanding options have a weighted average remaining term of 4.73 years and have no intrinsic value.

Restricted Stock. During the three and nine month periods ended June 30, 2017, the Company recognized $150,145 and $783,842 of expense related to restricted stock awards. As of June 30, 2017, there was $335,690 of unamortized expense. The Company expects to recognize this compensation cost over a weighted-average period of .53 years.

Below is a table summarizing the Company's activity for the nine months ended June 30, 2017:

	Shares	Weighted Average Grant Date Fair Value
Nonvested at September 30, 2016	600,358	4.80
Granted	—	—
Vested	(285,179)	4.81
Forfeited	—	—
Nonvested at June 30, 2017	315,179	4.79

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. To the best knowledge of the Company's management, at June 30, 2017, there are no legal proceedings which the Company believes will have a material adverse effect on its business, results of operations, cash flows or financial condition.

Severance Pay

As of June 30, 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 consolidated balance sheets.

NOTE 7 – RELATED PARTY TRANSACTION

Our Contract Research Organization ("CRO") running our clinical trial has 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 nine months ended June 30, 2017, and 2016, the Company's CRO was invoiced $379,347 and $0 from DARC.

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 18 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

We are a clinical stage pharmaceutical company developing novel therapies for ophthalmic diseases. Our lead clinical asset, topical Squalamine (also known as squalamine lactate ophthalmic solution, 0.2%, or OHR-102), is a novel therapeutic product which could provide a non-invasive therapy to improve vision outcomes beyond that achieved with current standard of care. We are evaluating Squalamine in combination with Lucentis® injections for the treatment of wet-AMD. This is based on the data from a Phase 2 clinical trial in wet-AMD where a positive and clinically meaningful vision benefit was seen with Squalamine combination therapy in classic containing choroidal neovascularization (classic CNV) as well as those subjects with occult neovascularization (occult CNV) less than $10mm^2$. We also have a sustained release platform technology we acquired in May 2014.

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"). Scientific evidence has shown PDGF to be an additional target for the treatment of wet-AMD and bFGF levels have been shown to be elevated in retinal vein occlusion and wet-AMD patients.

Ohr formulated squalamine lactate as a topical solution for ophthalmic indications and optimized the formulation for enhanced uptake into the back of the eye, and to potentially provide increased comfort in an elderly patient population. The Company is advancing its clinical wet-AMD program with this topical formulation. Unlike other combination therapy approaches being evaluated in clinical studies, Squalamine does not require direct injection into the eye.

We believe that Squalamine used in combination with an anti-VEGF agent may provide several potential advantages over other combination therapy approaches currently being investigated in clinical studies including:

- Potential use in combination with as-needed (PRN) anti-VEGF injections or treat-and-extend regimens as well as a monthly/bi-monthly anti-VEGF injection regimens.
- Adaptable for use in combination with future longer acting anti-VEGF agents.
- Inhibition of multiple growth factor pathways of angiogenesis.
- Cost efficiency of manufacturing a small molecule when compared to large molecule proteins and antibodies.

The Company has conducted a preclinical program which consisted of pharmacology, pharmacokinetic, and toxicology studies which support the ongoing clinical development of Squalamine.

Completed Phase 2 Trial in wet-AMD: the IMPACT Study (formerly OHR-002)

We commenced a clinical study, Study OHR-002 (or IMPACT Study), which began enrolling patients in late 2012. The IMPACT Study was a multi-center, randomized, double masked, placebo controlled Phase 2 study to evaluate the efficacy and safety of Squalamine combination therapy for the treatment of wet-AMD. The study enrolled treatment naïve wet-AMD patients at more than 20 clinical sites in the U.S. who were randomly assigned to treatment with Squalamine lactate ophthalmic solution 0.2% ("Squalamine"), or placebo eye drops for a nine month period, along with Lucentis® injections, as necessary, following an initial baseline Lucentis® injection. Full enrollment was completed in April 2014. In March 2015, we completed the IMPACT Study and announced topline results. The final data from the IMPACT Study was presented at multiple scientific conferences and forums in 2015 and 2016. In a prespecified analysis, data from the IMPACT study demonstrated that, in the intent-to-treat (ITT-LOCF) population with lesions containing classic choroidal neovascularization ("classic CNV") (Squalamine combination treatment n=38, Lucentis® monotherapy n=32), 42% of the patients receiving Squalamine achieved a ≥3 line gain at nine months, as compared to 28% in the Lucentis® monotherapy group. In patients with classic CNV (ITT-LOCF), mean gains in visual acuity were +10.5 letters for the Squalamine combination arm and +5.4 letters with Lucentis® monotherapy, a clinically meaningful benefit of +5.1 letters. The positive effect on visual acuity in classic CNV was seen early in the course of treatment and continued to increase through the end of the study. Less of a visual acuity benefit was seen in the overall population (all lesion types). The mean number of injections between the treatment arms, the primary endpoint of the study, was not meaningfully different.

Further analyses were conducted to determine the patient population most likely to benefit from combination treatment. Patients with lesions containing classic CNV are a heterogeneous population and, within the enrollment criteria of our study, could have encompassed small classic lesions with no occult component as well as lesions up to 12 disc areas (~30mm^2) in size made up almost entirely of occult CNV. These diverse lesions would both fall under the same category of "classic containing lesion" even though they would be expected to respond differently to treatment. Correlation analyses determined that the occult CNV size at baseline, regardless of whether there was a classic CNV component present, directly correlated with improved visual acuity outcomes in the Squalamine combination group (p=<0.0001), which was not seen in the Lucentis® monotherapy group. This suggests that the occult CNV size was a more important predictor of success for combination therapy than the presence of classic CNV, and a cutoff less than 10mm^2 of occult size at baseline was determined to be the optimal size to include in future clinical studies. In those patients with occult CNV less than 10mm^2 in area (n=94 of 128 completing the phase 2 study), 40% of those treated with Squalamine combination therapy achieved a gain of 3 or more lines of vision, compared with 26% of patients in the Lucentis® monotherapy arm, a 54% additional benefit. In addition, mean gains in visual acuity compared to baseline were +11.0 letters for the Squalamine combination arm and +5.7 letters with Lucentis® monotherapy, a clinically meaningful benefit of +5.3 letters (exploratory p-value, p=.033). Subjects with occult CNV <10mm^2 achieved a final mean visual acuity outcome of 71.7 letters with Squalamine combination therapy compared to 67.4 letters with Lucentis® monotherapy. The final mean visual acuity outcomes in the combination therapy group translates to approximately 20/40 vision (snellen equivalent), an important level of visual function. Importantly, this group of patients represents a larger proportion of the subjects enrolled in the IMPACT study than the classic containing group.

Status of Squalamine Program in Wet-AMD

The results of the Phase 2 clinical trial supported conducting additional clinical trials for Squalamine with enrollment criteria for a targeted population, based on the complete analysis of the Phase 2 clinical trial. We reached an agreement on a SPA with the FDA on the design of a Phase 3 trial in March 2016, initiated the clinical program and began enrolling this optimized patient population in April 2016. In February 2017, the Company announced the pause of new enrollment in its ongoing clinical trial evaluating Squalamine for the treatment of wet-AMD. More than 200 patients have been enrolled and the study remains double masked and no interim or futility analyses have been or will be conducted. The Data Safety Monitoring Committee (DSMC) has confirmed that there are no safety concerns and recommended the study continue as planned.

In April 2017, the Company amended the ongoing clinical trial to enable efficacy analyses at an earlier date than originally anticipated. The study remains a multi-center, randomized, double masked, placebo controlled clinical trial. Subjects enrolled in the study receive their assigned study treatment of monthly Lucentis® and either Squalamine or placebo twice daily, and undergo scheduled visits and assessments through nine months. The primary endpoint will be an assessment of visual acuity at nine months. We expect to report topline data from the study in early calendar 2018.

OHR–1501 Study

OHR-1501 was designed as an exploratory, double-masked, randomized, placebo-controlled study designed to assess safety and efficacy of treatment with squalamine lactate ophthalmic solution in combination with monthly anti-VEGF (both Lucentis® and Eylea®) injections in patients with wet-AMD. The study has not enrolled any subjects and we do not expect to enroll any subjects in the near term as resources have been reallocated.

Completed Trial in Proliferative Diabetic Retinopathy ("PDR") - Study 003

Study 003 was an open-label monotherapy investigator sponsored trial ("IST") evaluating Squalamine in five patients with PDR. Patients enrolled in the study received Squalamine for a six month treatment period and were then followed for an additional two months. The endpoints included regression of neovascularization, anatomical measurements, visual acuity, and safety parameters. The principal investigator of Study 003 presented a case report from the first patient to complete the protocol in February 2014. In this case report, the oral presentation discussed the case of a treatment naïve patient diagnosed with PDR. The data demonstrated that topical application of Squalamine in a monotherapy regimen, twice daily and then four times daily, was associated with regression of retinal neovascularization within two months. The retinal neovascularization remained regressed throughout the six months of four times daily Squalamine therapy. One month after cessation of treatment, the abnormal blood vessels returned in this patient's retina in the absence of Squalamine treatment, and continued to grow through the second month, the latest time point measured. Final data may be disseminated by the investigator, at his discretion, in a scientific publication.

Completed Trial in Branch and Central Retinal Vein Occlusion - Study 004

Study 004 was an IST evaluating squalamine lactate ophthalmic solution, 0.2%, in 20 patients with branch and central retinal vein occlusion. All patients in the study received Squalamine for 10 weeks, with injections of Lucentis® at weeks two and six, and a data readout at week 10. At week 10, the patients entered into the extension phase and were randomized 1:1 to either continue or discontinue taking Squalamine through week 38 ("extension phase"). During the extension phase, the patients received Lucentis® injections on a PRN basis as determined by fluid based OCT criteria. The principal investigator presented the 10 week data from the study in August 2014. The data demonstrated that, at week 10 (1) the mean gain in visual acuity was 20.3 letters for all 20 patients using the combination therapy, (2) the mean visual acuity for all 20 patients at was 20/32, (3) the average central foveal thickness for all 20 patients was reduced to 270u, and (4) only one of 20 patients qualified for an injection of Lucentis®, indicating dryness of the retina and a 95% macular deturgescence rate.

In July 2015, final data was presented demonstrating that at week 38, (1) the mean gain in visual acuity from baseline for patients randomized (at week 10) to treatment with Squalamine + Lucentis® PRN was +27.8 letters compared with +23.3 for patients randomized to treatment with Lucentis® plus PRN alone (control group), a clinically meaningful difference of +4.5 letters, (2) 80% of patients in the Squalamine + Lucentis® treated group had a gain in visual acuity, compared with 50% of patients treated with Lucentis® alone, and (3) none of the patients in the Squalamine + Lucentis® treated group lost any vision as compared to 50% of the patients receiving Lucentis® alone. After the initial combination therapy phase, the mean gain in visual acuity from week 10 to week 38 was +7.4 letters for patients who continued treatment with Squalamine + Lucentis® PRN compared with +3.1 letters in those receiving Lucentis® PRN alone. The Study was published by the investigator in the Ophthalmic Surgery, Lasers, and Imaging Retina (OSLI) journal in October 2016.

(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"). 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. 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. See "Corporate Strategy" concerning the Trodusquemine joint venture.

Competitive Factors

Competition in General

Competition in the area of biomedical and pharmaceutical research and development is intense and significantly depends on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain regulatory approval for testing, manufacturing and marketing. Our competitors include major pharmaceutical and specialized biotechnology companies, many of which have financial, technical and marketing resources significantly greater than ours. In addition, many biotechnology companies have formed collaborations with large, established companies to support research, development and commercialization of products that may be competitive with ours. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint ventures. We are aware of certain other products manufactured or under development by competitors that are used for the treatment of the health conditions that we have targeted for product development. We can provide no assurance that developments by others will not render our technology obsolete, noncompetitive or harm our development strategy, that we will be able to keep pace with new technological developments or that our technology will be able to supplant established products and methodologies in the therapeutic areas that are targeted by us. The foregoing factors could have a material adverse effect on our business, prospects, financial condition and results of operations. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants.

We will encounter competition from existing firms that offer competitive solutions in ocular diseases. These competitive companies could develop products that are superior to, or have greater market acceptance, than the products being developed by us. We will have to compete against other biotechnology and pharmaceutical companies with greater market recognition and greater financial, marketing and other resources.

Wet-AMD Market

Age-related macular degeneration ("AMD") is a medical condition which usually affects older adults and generally results in a loss of vision. AMD occurs in "dry" (non-exudative) and "wet" (exudative) forms. Wet-AMD is the advanced form of macular degeneration that involves the formation of abnormal and leaky blood vessels in the back of the eye behind the retina, through a process known as choroidal neovascularization ("CNV"). The wet form accounts for approximately 15 percent of all AMD cases, yet is responsible for 90 percent of severe vision loss associated with AMD. According to the National Eye Institute (NEI), the prevalence of wet-AMD among adults 40 years or older in the U.S. alone is estimated at 1.75 million people. In addition, more than 200,000 new cases are diagnosed annually in the U.S.

Competitive Landscape in Wet-AMD

The current FDA approved market leaders for the treatment of wet-AMD are VEGF inhibitors, including Lucentis®, Eylea® and (off-label) Avastin®. In 2016, annual revenue (worldwide) was more than $8 billion for Lucentis® and Eylea® combined, despite significant off-label use of Avastin® (estimated to be 45-60% of the overall market). Lucentis®, Eylea®, and Avastin® are administered via frequent intravitreal injections directly into the eye. We are developing Squalamine for use in combination with Lucentis® and other anti-VEGF agents to improve visual function beyond that achieved with anti-VEGF therapy alone. There is no assurance that we will receive FDA approval for Squalamine for the treatment of wet-AMD, and if we receive it, there is no assurance we will be able to displace the market leaders as a treatment in a significant percentage of patients.

There are various other companies with drugs in Phase 1, 2, and 3 trials for the treatment of wet-AMD. We cannot assure that none of them will get to market before us or that Squalamine will be a better treatment. Programs currently in Phase 2 or Phase 3 trials include, but are not limited to:

- Fovista®, a PDGF targeting aptamer being developed by Ophthotech in partnership with Novartis and Roche;
- Abicipar Pegol, a VEGF targeting DARPin molecule being developed by Allergan;
- RTH258, an anti-VEGF agent being developed by Novartis;
- X-82, an oral tyrosine kinase inhibitor being developed by Tyrogenex;

- ALG-1001, an integrin targeting peptide being developed by Allegro Ophthalmics;
- REG-910, an anti-Ang2 agent to be used with Eylea® being developed by Regeneron;
- RG7716, a bispecific antibody to both VEGF-A and Ang2 being developed by Roche;
- OPT-302, an inhibitor of VEGF-C and VEGF-D being developed by Opthea; and
- PAN-90806, a selective inhibitor of VEGF being developed by Panoptica Inc.

All of these products in clinical development, with the exception of X-82 and PAN-90806, use an intravitreal route of administration much like the current standards of care. We believe that Squalamine has potential competitive advantages through its intracellular mechanism of action, multiple growth factor inhibition, and non invasive delivery. We also believe we have reduced the risk in our clinical program by utilizing our exploratory Phase 2 trial to identify and enroll a patient population that has the greatest potential for visual acuity benefits with combination therapy. However, clinical trial data from other clinical programs may negatively impact our ability to garner future financing or business collaborations, combinations or transactions with other pharmaceutical and biotechnology companies.

Competitive Landscape in Sustained Release Drug Delivery

There are a number of companies developing various forms of sustained release drug delivery platforms for ophthalmic applications. These include, but are not limited to:

- GreyBug with a biodegradable polymer microsphere/nanoparticle matrix system;
- Envisia Therapeutics with the PRINT® technology system for microparticle and nanoparticle formulations;
- Kala Pharmaceuticals with a mucus-penetrating particle (MPP) technology; and
- Ocular Therapeutix with a proprietary hydrogel technology.

Some of these programs are in a more advanced clinical stage than us. Each of these may prove to be effective means to deliver drugs in a sustained manner and we cannot assure that none of them will get to market before us or that our technology will be a better drug delivery approach.

Corporate Strategy

We are in an ongoing business development process to seek and implement strategic alternatives with respect to Squalamine, based on the visual acuity benefit of Squalamine combination therapy seen in the Phase 2 study, including licenses, business collaborations or transactions with other pharmaceutical companies. Several third parties with whom we have been in discussions have expressed interest in a potential transaction for the Squalamine program. There can be no assurance, however, that any such discussions will result in an agreement.

As part of the Company's core ophthalmology strategy, 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 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 increased from the end of the second quarter of the Company's 2017 fiscal year to the end of the third quarter by $9,845,217 (to $12,894,560 from $3,049,343) primarily due to the public offering which closed in April 2017. We expect our cash burn to potentially increase or stabilize in the fourth fiscal quarter and stabilize or decrease in the first fiscal quarter of 2018 as our ongoing clinical study moves towards completion. 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 pharmaceutical 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 into April 2018.

Results of Operations

Three Months Ended June 30, 2017 Compared to Three Months Ended June 30, 2016

Results of operations for the three months ended June 30, 2017 ("2017") reflect the following changes from the prior period ("2016").

	2017	2016	Change
General and administrative	$ 1,404,287	$ 1,664,882	$ (260,595)
Research and development	2,233,388	5,637,602	(3,404,214)
Depreciation and amortization	288,976	296,143	(7,167)
Gain on settlement of accounts payable	(70,757)	—	(70,757)
Total Operating Expenses	3,855,894	7,598,627	(3,742,733)
Operating Loss	(3,855,894)	(7,598,627)	3,742,733
Change in fair value of contingent consideration	—	(104,844)	104,844
Other income (expense)	(44,935)	3,730	(48,665)
Net Loss	$ (3,900,829)	$ (7,699,741)	$ 3,798,912

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 $260,595 decrease when comparing 2017 to 2016.

The Company incurred $2,233,388 in research and development expenses in 2017 compared to $5,637,602 in 2016. The decrease is a result of significant upfront costs paid in 2016 related to the ongoing squalamine clinical trial in wet-AMD.

Depreciation and amortization expense remained relatively stable with $296,143 in 2016 and $288,976 in 2017.

For the three months ended June 30, 2016, the Company recognized a net loss of $7,699,741 compared to a net loss of $3,900,829 for the same period in 2017. The decrease in net loss is primarily a result of significant upfront costs paid in 2016 that were related to the ongoing squalamine trial in wet-AMD. Until the Company is able to generate revenues, management expects to continue to incur net losses.

Nine Months Ended June 30, 2017 Compared to the Nine Months Ended June 30, 2016

Results of operations for the nine months ended June 30, 2017 ("2017") reflect the following changes from the prior period ("2016").

	2017	2016	Change
General and administrative	$ 4,554,704	$ 5,849,374	$ (1,294,670)
Research and development	13,158,460	11,757,741	1,400,719
Depreciation and amortization	879,286	889,959	(10,673)
Gain on settlement of accounts payable	(70,757)	(710,264)	639,507
Total Operating Expenses	18,521,693	17,786,810	734,883
Operating Loss	(18,521,693)	(17,786,810)	(734,883)
Change in fair value of contingent consideration	—	(1,356,770)	1,356,770
Other income (expense)	(44,862)	13,518	(58,380)
Net Loss	$ (18,566,555)	$ (19,130,062)	$ 563,507

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

General and administrative expenses from operations had a decrease of $1,294,670 when comparing 2017 to 2016. The decrease is a result of stock option amortization and no annual bonuses being awarded in 2017.

The Company incurred $13,158,460 in research and development expenses in 2017 compared to $11,757,741 in 2016. The increase is a result of the ongoing squalamine clinical trial in wet-AMD. The Company expects research and development expenses to continue to rise as development of its products continues.

Depreciation and amortization expense remained relatively flat with $879,286 expensed in 2017 and $889,959 in 2016.

In 2016, the Company had a gain on settlement of $710,264 in 2016 compared to a gain on settlement of $70,757 in 2017. The decrease in gain in 2017 is due to settlement agreements made with vendors who had outstanding invoices with the Company.

In 2016, the Company had a change in fair value of contingent consideration of $1,356,770 compared to none in 2017. The contingent consideration was removed during 2016 because management did not expect to achieve the milestone associated with the consideration.

For the nine months ended June 30, 2017, the Company recognized a net loss of $18,566,555 compared to net loss of $19,130,062 for the same period in 2016. Until the Company is able to generate revenues, management expects to continue to incur such 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.

None.

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 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 currently in development. We cannot guarantee that any of our product candidates currently in development will ever become marketable products.

We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA, and other regulatory authorities in the European Union and elsewhere approve our product for commercialization. Because of the modifications we made to the current trial in 2017, there is a risk that the FDA will rescind the current SPA, and require additional clinical trials be performed. Significant additional research, preclinical testing and clinical testing is required before we can file applications with the FDA or other regulatory authorities for premarket approval of our drug candidates. In addition, to compete effectively, our drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. We cannot be certain that the clinical development of this or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

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 June 30, 2017, we had an accumulated deficit of approximately $102.8 million. We expect to incur net losses over the next several years. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We do not expect to receive, for at least the next several years, any revenues from the commercialization of our product candidates.

We will need to raise substantial additional capital to further our clinical program for Squalamine in wet-AMD as well as future trials and may not be able to raise additional capital on favorable terms, if at all. If additional capital is not available, we may not be able to continue operations or complete the necessary clinical and preclinical trials to complete the development of Squalamine or any other products.

We will need substantial additional capital to further our drug and delivery platform development programs. Specifically, we will require significant additional funds to complete our clinical development program. In our capital-raising efforts, we may seek to sell additional equity or debt securities, or seek a strategic commercial partner or do a combination. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. However, we may not be able to raise additional funds on acceptable terms, or at all. If we raise capital through a strategic commercial partner, 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 secure sufficient capital to fund our research and development activities, we may have to delay, reduce or cease operations.

As of June 30, 2017, we had cash and cash equivalents of $18.1 million. We believe that our cash and cash equivalents should be sufficient to fund our operating expenses into April 2018. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. At this time, we cannot reasonably estimate the remaining costs necessary to complete development of any product candidate.

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 strategic 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.

Our strategy with respect to Squalamine 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 products. Several third parties with whom we have been in discussions have expressed interest in a potential licensing or partnering transaction for the Squalamine program, but, to date, such discussions have not resulted in any transactions. Accordingly, there is no assurance that the Company will enter into a definitive agreement with respect to such a transaction. If we raise capital through such strategic commercial partner, 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 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 complete our clinical trials, or 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 complete our 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 may be unsuccessful in monetizing existing assets, acquiring additional assets or entering into joint development programs.

We are seeking development partners for our existing products. Several third parties with whom we have been in discussions have expressed interest in a potential licensing or partnering transaction for the Squalamine program. However, there is no assurance that the Company will enter into a definitive agreement with respect to such a transaction.

We are substantially dependent on the success of our lead product candidate Squalamine in wet-AMD, which is in a later stage of development than our other product candidates. There is no guarantee that clinical trials for Squalamine in wet-AMD will be completed, completed in the anticipated timeframe or that they will be successful.

The results of the Phase 2 clinical trial supported conducting additional clinical trials for Squalamine with enrollment criteria for a targeted population, based on the complete analysis of the Phase 2 clinical trial. We reached an agreement on a SPA with the FDA on the design of a Phase 3 trial in March 2016, initiated the clinical program and began enrolling patients in April 2016. In February 2017 we paused enrollment, and in April 2017 we modified the trial to enable a top-line efficacy data readout by early 2018. Because of the modifications we made to the ongoing squalamine study, there is a serious risk that the FDA will rescind the current SPA, and require additional clinical trials be performed. Our business and future success is substantially dependent on our ability to successfully develop, obtain regulatory approval for, and successfully commercialize our lead product candidate Squalamine in wet-AMD. Any delay or setback in the development or regulatory approval of any of our product candidates, but particularly Squalamine in wet-AMD, would likely adversely affect our business and cause our stock price to decline. Should the on-going or planned Squalamine clinical development program not be completed or be delayed or be insufficient to support regulatory approval, we may be forced to rely on other product candidates, or to cease operations. We cannot assure you that our on-going or planned clinical development program for Squalamine will be completed in a timely manner, or at all, or that we will be able to obtain approval for Squalamine in wet-AMD from the FDA or any foreign regulatory authority.

The historical rate of failures for product candidates in clinical development and late-stage clinical trials is high.

There can be no assurance that we will meet the goals of our clinical trials or that we will have the same level of success in the clinical trials as we have in our prior clinical trials, or that we will be successful at all.

If we do not successfully complete clinical development of Squalamine, we will be unable to market and sell products derived from it and to generate product revenues. Even if we do successfully complete clinical trials for Squalamine in patients with wet-AMD, we may not achieve or complete the other requirements that may be needed before we may submit a New Drug Application, or NDA, to the FDA for the initial or other future indications. Of the vast number of drugs in development, only a small percentage result in the submission of an NDA to the FDA, and even fewer result in the NDA ultimately being approved by the FDA or other foreign regulatory authority for commercialization.

Results from early clinical trials for Squalamine in wet-AMD are not necessarily predictive of the results of later clinical trials for Squalamine in wet-AMD. If we cannot replicate the results from our earlier clinical trials for Squalamine in wet-AMD in our later clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize Squalamine in wet-AMD.

Results from our Phase 2 clinical trial for Squalamine in wet-AMD may not necessarily be predictive of the results from required later clinical trials. We may not be able to complete our ongoing clinical program for Squalamine in wet-AMD. Similarly, even if we are able to complete clinical trials for Squalamine in wet-AMD according to our current development timeline, the results from our Phase 2 clinical trial for Squalamine in wet-AMD may not be replicated in our future clinical trial results. Many companies in the pharmaceutical and biotechnology industries, including companies developing combination therapies for wet-AMD, have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, pre-clinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events, aberrant results in the control group in earlier stage clinical trials, and expansion of enrollment eligibility criteria from phase 2 to later studies. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials nonetheless failed to obtain FDA or foreign regulatory approval. If we fail to produce positive results in our clinical trials for Squalamine in wet-AMD, the development timeline and regulatory approval and commercialization prospects for our leading product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Delays, suspensions and terminations in our clinical trials could result in increased costs to us, delay our ability to generate product revenues and therefore may have a material adverse effect on our business, results of operations and future growth prospects.

The commencement of clinical trials can be delayed for a variety of reasons, including:

- delays in demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- manufacturing sufficient quantities of a product candidate;
- obtaining clearance from the FDA to commence clinical trials pursuant to an Investigational New Drug application (or IND);
- obtaining clearance from foreign regulatory authorities to commence clinical trials;
- financial or strategic considerations;
- obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site; and
- patient enrollment, which is a function of many factors, including the size of the patient population, the sufficiency of funds, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.
- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

Once a clinical trial has begun, it may be delayed, suspended, modified or terminated due to a number of factors, including:

- inability to raise funding necessary to continue a clinical trial;
- ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;
- failure to conduct clinical trials in accordance with regulatory requirements;
- lower than anticipated screening or retention rates of patients in clinical trials;
- serious adverse events or side effects experienced by participants;
- financial or strategic considerations; and
- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

Many of these factors may also ultimately lead to the rescinding of an SPA or denial of regulatory approval of a current or potential product candidate. If we experience delays, suspensions or terminations in a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed and our business and financial prospects would be materially affected.

Even if we successfully complete the clinical trials of one or more of our product candidates, the product candidates may fail for other reasons.

Even if we successfully complete the clinical trials for one or more of our product candidates, the product candidates may fail for other reasons, including the possibility that the product candidates will:

- fail to receive the U.S. and foreign regulatory approvals required to market them as drugs;
- be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;
- be difficult or expensive to manufacture on a commercial scale;
- have adverse side effects that make their use less desirable; or
- fail to compete with product candidates or other treatments commercialized by our competitors.

In addition, our clinical trials may involve a specific patient population. Because of the small sample size, the results of these early clinical trials may not be indicative of future results. Adverse or inconclusive results may cause us to abandon a drug candidate and may delay development of other drug candidates. Any delay in, or termination of, our clinical and preclinical studies will delay the filing of our NDAs with the FDA and, ultimately, significantly impair our ability to commercialize our drug candidates and generate product revenues which would have a material adverse effect on our business and results of operations. If we are unable to receive the required U.S. and foreign regulatory approvals, secure our intellectual property rights, minimize the incidence of any adverse side effects or fail to compete with our competitors' products, our business, financial condition, and results of operations could be materially and adversely affected. Additionally, even if we receive FDA approval for Squalamine for the treatment of wet-AMD, there is no assurance we will be able to displace the market leaders as a treatment in a significant percentage of patients.

If we find it difficult to enroll patients in our clinical trials, it will cause significant delays in the completion of such trials and may cause us to abandon one or more clinical trials.

For the diseases or disorders that our product candidates are intended to treat, we expect only a subset of the patients with these diseases to be eligible for our clinical trials. Given that each of our product candidates is in preclinical or clinical development, we may not be able to initiate or continue clinical trials for each or all of our product candidates if we are unable to enroll a sufficient number of eligible subjects to participate in the clinical trials required by the FDA or other foreign regulatory authorities. The requirements of our clinical testing mandate that a patient cannot be involved in another clinical trial for the same indication. We are aware that our competitors have ongoing clinical trials for products that are competitive with our product candidates and subjects who would otherwise be eligible for our clinical trials may be involved in such testing, rendering them unavailable for testing of our product candidates. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether, which would have a material adverse effect on our business.

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. Our CRO running our clinical trial has also 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, our 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 our clinical trial. We are advised that DARC has implemented a standard operating procedure (SOP) to firewall interactions between DARC employees and Dr. Slakter. It is possible that in the future the Company may contract directly with DARC for the same or similar services. It is possible that the FDA will investigate and that this related party transaction may impact adversely on its approval of the trials. The parties with which we contract for execution of our clinical trials 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 entities, 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.

Although we do design our clinical trials for Squalamine in wet-AMD and other drug candidates, contract research organizations conduct all of the clinical trials. As a result, many important aspects of our drug development programs are outside of our direct control. In addition, the contract research organizations may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements, but we remain responsible and are subject to enforcement action that may include civil penalties up to and including criminal prosecution for any violations of FDA or comparable foreign laws and regulations during the conduct of our clinical trials. If the contract research organizations do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of Squalamine in wet-AMD and other drug candidates may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these contract research organizations devote to our program. If we are unable to rely on clinical data collected by our contract research organizations, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures, and have a material adverse effect on our business.

If our contract research organizations do not successfully carry out their duties or if we lose our relationships with contract research organizations, our drug development efforts could be delayed or terminated.

If we lose our relationship 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 our 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 clinical trials. 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 our 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 have contracted with third-party manufacturers to produce, in collaboration with us, our product candidates, including Squalamine, 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 our current 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 our current 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.

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

The manufacturers of our product candidates are obliged to operate in accordance with FDA-mandated CGMPs. In addition, the facilities used by our 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 of our current or future 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 contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers 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 our contract manufacturers' facilities generally. Failure by our current or future 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. In addition, the third-party manufacturers may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If a third-party manufacturer breaches its obligations to us or fails to comply with regulatory requirements, the commercialization of Squalamine in wet-AMD and other drug candidates may be delayed or irreversibly harmed.

The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our 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 and clinical development and regulatory programs.

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.

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 completed or ongoing 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.

The potential U.K. exit from the European Union as a result of the recent U.K. referendum could harm our business, financial condition or results of operations.

On June 23, 2016, the U.K. affirmatively voted for a non-binding referendum in favor of the exit of the U.K. from the European Union (commonly referred to as the "Brexit") and it has been approved by vote of the British legislature. Negotiations have commenced to determine the future terms of the U.K.'s relationship with the European Union, including the terms of trade between the U.K. and the European Union. The effects of Brexit will depend on any agreements the U.K. makes to retain access to European Union markets either during a transitional period or more permanently. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which European Union laws to replace or replicate.

The announcement of Brexit also created (and the actual exit of the U.K. from the European Union may create future) global economic uncertainty. The actual exit of the U.K. from the European Union could cause disruptions to and create uncertainty surrounding our business. Any of these effects of Brexit (and the announcement thereof), and others we cannot anticipate, could harm our business, financial condition or results of operations.

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 pending legislation recently adopted and further proposals still pending 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 or 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 will require 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. While at the present time, the future of the 2010 legislation is uncertain, 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 primary 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 any strategic alliances or acquisitions we are in discussion regarding or we may enter into;

- 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;
- our shares of common stock trading in five- rather than one-cent increments under the SEC's Tick Size Pilot program;
- 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 accounting principles; and
- loss of any of our key scientific or management personnel.

If we fail to meet the continued listing standards of Nasdaq, our common stock may be delisted, which may adversely affect the market price and liquidity of our common stock.

Our common stock is currently traded on the Nasdaq Capital Market. Nasdaq has requirements we must meet in order to remain listed on the Nasdaq, including that we maintain a minimum closing bid price of $1.00 per share of our common stock. 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 have been provided a period of 180 calendar days, or until October 3, 2017, to regain compliance. The letter states that the Nasdaq staff will provide written notification that we have regained compliance if at any time before October 3, 2017, the bid price of our common stock closes at $1.00 per share or more for a minimum of ten consecutive business days. If the Company is unable to regain compliance with the continued listing standards of Nasdaq, our common stock may be delisted from Nasdaq. 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.

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. Additionally, under the SEC's Tick Size Pilot program, in October 2016, shares of our common stock began trading in five cent rather than one cent increments. The change to five cent increments may result in greater fluctuations in the market price of our common stock and could result in higher trading costs for investors.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years and increased litigation. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and the value of our common stock.

If we do not raise additional funds, we will not be able to continue operations or complete the necessary clinical and preclinical trials to complete development of Squalamine and our sustained release ophthalmological platform or our other products and will not be able to sell them anywhere.

We will not be able to sell Squalamine and our sustained release ophthalmological platform products or our other products in the United States or other territories unless we submit, and the FDA or foreign regulatory authority approves, an application for approval for each such product. We must conduct clinical trials of each of our products in humans before we submit such application. We currently do not have sufficient capital to complete the necessary trials to complete the development of Squalamine and our sustained release ophthalmological platform or any of our other therapeutic drug products.

It is possible that the results of clinical and preclinical studies of Squalamine and our sustained release ophthalmological platform products or our other products will not prove that they are safe and effective. It is also possible that the FDA or foreign regulatory authority will not approve the sale of any of our products if we submit an application for such product. Even if the data show that any of our products are safe and effective, obtaining approval of the application could take years and require financing of amounts not presently available to us.

Conducting the clinical and preclinical studies of each of our products will require significant cash expenditures and we do not have the funds necessary to complete the clinical program for Squalamine and our sustained release ophthalmological platform products or any other products. Our products may never be approved for commercial distribution by any country. Because our research and development expenses and clinical and preclinical study expenses will be charged against earnings for financial reporting purposes, we expect that losses from operations will continue to be incurred for the near future. If we do not raise enough money to complete the Squalamine development program, it could significantly hurt our business and the value of our common stock.

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, and our independent auditors may not be able to certify as to their effectiveness, 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.

Section 404 also requires an independent registered public accounting firm to test our internal controls over financial reporting and report on the effectiveness of such controls. For future reporting periods, there can be no assurance that our auditors will issue an unqualified report attesting to our internal controls over financial reporting at that time. As a result, there could be a negative reaction in the financial markets due to a loss of confidence in the reliability of our financial statements or our financial statements could change.

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.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On August 7, 2017, Avner Ingerman, M.D. resigned as Chief Clinical Officer of the Company, effective September 5, 2017, to pursue other career interests.

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: August 8, 2017

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 Chief 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: August 8, 2017

/s/ Dr. Jason 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: August 8, 2017

/s/ Sam Backenroth
Sam Backenroth (Principal Financial and Chief 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 June 30, 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: August 8, 2017

/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 June 30, 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: August 8, 2017

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