UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington , D.C. 20549

FORM 10-Q

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

For the quarterly period ended December 31, 2014

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			

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: 25,392,387 shares of Common Stock outstanding as of February 9, 2015.

OHR PHARMACEUTICAL, INC.
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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

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OHR PHARMACEUTICAL, INC.
Consolidated Balance Sheets
Unaudited

	December 31, 2014	September 30, 2014
ASSETS		
CURRENT ASSETS		
Cash	$ 10,441,190	$ 13,220,494
Prepaid expenses and other current assets	579,050	133,527
Total Current Assets	11,020,240	13,354,021
EQUIPMENT, net	96,789	104,425
OTHER ASSETS		
Security deposit	12,243	12,243
Investment in joint venture	—	3,143
Intangible assets, net	17,512,414	17,810,400
Goodwill	740,912	740,912
TOTAL ASSETS	$ 29,382,598	$ 32,025,144
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 1,192,314	$ 351,864
Due to Joint Venture	23,507	—
Notes payable	—	43,899
Contingent consideration	5,560,745	4,877,359
Total Current Liabilities	6,776,566	5,273,122
TOTAL LIABILITIES	6,776,566	5,273,122
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred stock, Series B; 6,000,000 shares authorized, $0.0001 par value, zero shares issued and outstanding	—	—
Common stock; 180,000,000 shares authorized, $0.0001 par value, 25,266,142 and 25,254,190 shares issued and outstanding, respectively	2,527	2,525
Additional paid-in capital	70,515,390	70,063,045
Accumulated deficit	(47,911,885)	(43,313,548)
Total Stockholders' Equity	22,606,032	26,752,022
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 29,382,598	$ 32,025,144

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

OHR PHARMACEUTICAL, INC.
Consolidated Statements of Operations
Unaudited

	For the Three Months Ended December 31,	
	2014	**2013**
OPERATING EXPENSES		
General and administrative	$ 163,516	$ 57,777
Professional fees	175,243	384,215
Research and development	2,839,801	1,352,356
Salaries and wages	745,427	227,145
Total Operating Expenses	3,923,987	2,021,493
OPERATING LOSS	(3,923,987)	(2,021,493)
OTHER INCOME (EXPENSE)		
Interest expense	(433)	(513)
Change in fair value of contingent consideration	(683,386)	—
Share in losses on investment in joint venture	(26,650)	—
Interest income	306	81
Royalty income	35,813	—
Total Other Income (Expense)	(674,350)	(432)
LOSS FROM OPERATIONS BEFORE INCOME TAXES	(4,598,337)	(2,021,925)
PROVISION FOR INCOME TAXES	—	—
NET LOSS	$ (4,598,337)	$ (2,021,925)
BASIC AND DILUTED LOSS PER SHARE	$ (0.18)	$ (0.10)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:		
BASIC AND DILUTED	25,259,154	19,872,539

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

OHR PHARMACEUTICAL, INC.
Consolidated Statements of Cash Flows
Unaudited

	For the Three Months Ended December 31,	
	2014	**2013**
OPERATING ACTIVITIES		
Net loss	$ (4,598,337)	$ (2,021,925)
Adjustments to reconcile net loss to net cash used by operating activities:		
Common stock issued for services	28,760	—
Warrants issued for services	8,559	700,393
Stock option expense	362,028	146,303
Change in fair value of contingent consideration	683,386	—
Share in losses on investment in joint venture	26,650	—
Depreciation	7,636	2,921
Amortization of intangible assets	297,986	19,608
Changes in operating assets and liabilities		
Prepaid expenses and deposits	(445,523)	25,533
Accounts payable and accrued expenses	890,450	(165,455)
Net Cash Used in Operating Activities	(2,738,405)	(1,292,622)
INVESTING ACTIVITIES		
Net Cash Used in Investing Activities	—	—
FINANCING ACTIVITIES		
Proceeds from warrants exercised for cash	3,000	200,002
Repayments of short-term notes payable	(43,899)	(14,051)
Net Cash Provided by (Used in) Financing Activities	(40,899)	185,951
NET CHANGE IN CASH	(2,779,304)	(1,106,671)
CASH AT BEGINNING OF PERIOD	13,220,494	5,122,895
CASH AT END OF PERIOD	$ 10,441,190	$ 4,016,224
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
CASH PAID FOR:		
Interest	$ 433	$ 513
Income Taxes	—	—
NON CASH FINANCING ACTIVITIES:		
Conversion of preferred for common stock	$ —	$ 50
Common stock issued to settle accounts payable	50,000	50,000

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

NOTE 1 – CONDENSED FINANCIAL STATEMENTS

The accompanying consolidated financial statements have been prepared by the Company without audit. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at December 31, 2014, and for all periods presented herein, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. It is suggested that these condensed consolidated financial statements be read in conjunction with the consolidated financial statements and notes thereto included in the Company's September 30, 2014 audited consolidated financial statements. The results of operations for the periods ended December 31, 2014 and 2013 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 accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates. Estimates subject to change in the near term include impairment (if any) of long-lived assets and fair value of derivative liabilities.

Fair Value of Financial Instruments

In accordance with ASC 820, the carrying value of cash and cash equivalents, accounts receivable, accounts payable, notes payable and contingent consideration 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.

The following table presents assets and liabilities that are measured and recognized at fair value as of December 31, 2014 and September 30, 2014, on a recurring basis:

Assets and liabilities measured at fair value on a recurring basis at December 31, 2014	Level 1	Level 2	Level 3	Total Carrying Value
Contingent Stock Consideration	$ —	$ —	$ 5,560,745	$ 5,560,745
	$ —	$ —	$ 5,560,745	$ 5,560,745

Assets and liabilities measured at fair value on a recurring basis at September 30, 2014	Level 1	Level 2	Level 3	Total Carrying Value
Contingent stock consideration	$ —	$ —	$ 4,877,359	$ 4,877,359
	$ —	$ —	$ 4,877,359	$ 4,877,359

The following tables present the change in fair value of financial instruments as of December 31, 2014, by caption on the balance sheet and by ASC 820 valuation hierarchy described above.

Level 3 Reconciliation:	Contingent Stock Contsideration
Total level 3 assets and liabilities at September 30, 2014	4,877,359
Purchases, sales, issuances and settlements (net)	—
Mark to market adjustments	683,386
Total level 3 assets and liabilities at December 31, 2014	$ 5,560,745

Recent Accounting Pronouncements

The Company has implemented all new accounting pronouncements that are in effect and that may impact its financial statements and does not believe that there are any other new pronouncements that have been issued that might have a material impact on its financial position or results of operations.

NOTE 3 – INTANGIBLE ASSETS

Intangible assets at December 31, 2014 and September 30, 2014, consist of:

	December 31, 2014	September 30, 2014
License Rights	$ 17,712,991	$ 17,712,991
Patent Costs	800,000	800,000
	18,512,991	18,512,991
Accumulated Amortization	(1,000,577)	(702,591)
Total Intangible Assets	$ 17,512,414	$ 17,810,400

During the quarter ended December 31, 2014, the Company recognized $297,986 in amortization expense on the patent and license rights. The amortization expense has been included in research and development expense.

NOTE 4 – NOTES PAYABLE

On February 28, 2014, the Company entered into a premium financing arrangement for its directors and officers insurance in the amount of $194,000. The financing arrangement was subject to annual interest of 6.75% and was fully repaid as of December 31, 2014.

NOTE 5 – CAPITAL STOCK

On October 17, 2014, the Company issued 2,000 common shares in connection with the exercise of warrants at an exercise price of $1.50 for total proceeds of $3,000.

On October 29, 2014, the Company issued 4,000 common shares with a fair value of $7.19 per share for consulting services and recognized stock-based compensation expense of $28,760.

On December 23, 2014, the Company issued 5,952 common shares as settlement of accounts payable in the amount of $50,000.

NOTE 6 – COMMON STOCK WARRANTS

During the three months ended December 31, 2014, the Company has recorded $8,559 in consulting expense related to warrants that have vested to date including warrants granted in prior years.

Below is a table summarizing the warrants issued and outstanding as of December 31, 2014:

	Number Outstanding	Weighted-Average Exercise Price
Outstanding at September 30, 2014	1,947,008	$ 3.64
Granted	—	—
Exercised	(2,000)	1.50
Forfeited	(32,834)	1.50
Outstanding at December 31, 2014	1,912,174	$ 3.67

The outstanding warrants as of December 31, 2014 have an intrinsic value of approximately $8.5 million.

NOTE 7 – COMMON STOCK OPTIONS

During the three months ended December 31, 2014, the Company recognized $362,028 of expense related to vested options that were granted in prior years. Unamortized option expense as of December 31, 2014 for all options outstanding amounted to approximately $2,542,130.

Below is a table summarizing the options issued and outstanding as of December 31, 2014:

	Number Outstanding	Weighted-Average Exercise Price
Outstanding at September 30, 2014	2,048,335	$ 5.43
Granted	—	—
Exercised	—	—
Forfeited	(20,000)	8.39
Outstanding at December 31, 2014	2,028,335	$ 5.37

As of December 31, 2014, the outstanding options have an intrinsic value of approximately $6.9 million.

NOTE 8 – OBLIGATION TO FUND INVESTMENT

During 2014, the Company committed to fund DepYmed, Inc. As of December 31, 2014, the Company owed $23,507 to fulfill its commitment.

NOTE 9 – 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 December 31, 2014, 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.

In June 2012, the Company was named, along with other parties, as a defendant in a putative class action lawsuit brought, as amended, by Alan Schmidt, individually, and on behalf of Genaera Corporation and the Genaera Liquidating Trust. We purchased biotechnology assets from the Trust in 2009. On August 12, 2013, the court dismissed each of the plaintiff's claims against the Company. The litigation has ended with respect to claims against the Company, and management believes that it is unlikely that the litigation continuing against other parties will have a material adverse impact on the Company's financial condition.

Contingent Stock Consideration

On May 30, 2014, the Company completed the acquisition of certain assets of SKS Ocular, LLC ("SKS Parent"), and SKS Ocular 1, LLC ("SKS 1" and SKS Parent referred to herein as "SKS"), including licenses, patents and contracts relating to micro-fabrication polymer-based sustained delivery platforms related to ocular therapeutics and dry age-related macular degeneration animal models, together with biomarkers to support such models.

The purchase price consisted of: (a) Cash in the amount of $3,500,000; (b) 1,194,862 shares of the Company's common stock (valued at $10,180,224 based on the trading price on May 30, 2014 of the Company's common stock) and (c) an additional 1,493,577 shares (the "contingent shares") that will be issued contingent to achievement of certain milestones. This contingent consideration has been recorded as a liability of the Company and is reviewed by management for probability and likelihood of the milestones being achieved at each reporting period. The fair value of the liability is adjusted in each reporting period according to management's assessment (see Note 2).

NOTE 10 – SUBSEQUENT EVENTS

In January 2015, the Company issued 34,548 common shares in connection with the exercise of warrants for total proceeds of $77,005.

In January 2015, the Company issued 54,659 common shares to a member of the Company's board of directors pursuant to a cashless exercise of 66,667 warrants.

On January 6, 2015, the Company issued 17,095 and 19,943 restricted common shares to two consultants and a member of the Company's board of directors, respectively, as a bonus for performance and meeting key milestones in fiscal year 2014.

On January 6, 2015, the Company issued 140,000 common stock options to two employees of the Company. The options have a term of five years and an exercise price of $8.19 per share. The options vest 25% immediately and 25% thereafter on the next three anniversaries of the grant date.

On February 6, 2015, the Company announced the sale of 4,259,259 shares of common stock, inclusive of the over allotment, in an underwritten public offering at a price per share of $6.75. The Company expects to issue the shares of common stock at the closing of the transaction on February 11, 2015, and receive gross proceeds of approximately $28.8 million.

On February 8, 2015, the Company agreed to issue 10,714 restricted shares of common stock to a consultant, subject to vesting throughout calendar 2015, for $75,000 of services to be provided in calendar year 2015.

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

Certain statements contained in this report, including, without limitation, statements containing the words "believes," "anticipates," "expects," "intends," and words of similar import, constitute "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 or by the Securities and Exchange Commission in its rules, regulations and releases, regarding the Company's financial and business prospects. These forward-looking statements are qualified in their entirety by these cautionary statements, which are being made pursuant to the provisions of such Act and with the intention of obtaining the benefits of the "safe harbor" provisions of such Act. The Company cautions investors that any forward-looking statements it makes are not guarantees of future performance and that actual results may differ materially from those in the forward-looking statements. We assume no obligation to update any forward-looking statements contained in this report, whether as a result of new information, future events or otherwise. Any investment in our common stock involves a high degree of risk. For a general discussion of some of these risks in greater detail, see our "Risk Factors" in the Company's Annual Report on Form 10-K (the "*Form 10-K"*) for the fiscal year ended September 30, 2014, as filed with the Securities and Exchange Commission on December 22, 2014.

Company Overview

Ohr Pharmaceutical, Inc. ("we", "Ohr", the "Company" or the "Registrant") is a pharmaceutical company focused on the development of novel therapeutics and delivery technologies for the treatment of ocular disease. Our development pipeline consists of multiple development programs and indications at various stages of development. Our lead clinical program, OHR-102 eye drops, is a novel therapeutic product which could provide a non-invasive therapy to improve vision outcomes without requiring multiple injections per office visit. We are evaluating OHR-102 eye drops, given in combination with Lucentis injections, in multiple Phase II studies for the treatment of retinal diseases including wet-AMD, retinal vein occlusion, proliferative diabetic retinopathy, and diabetic macular edema. To date, the Phase II results have shown a beneficial effect in visual acuity and anatomical parameters when compared to Lucentis monotherapy.

Our preclinical stage pipeline is focused on the development of sustained release therapeutics utilizing the platform technology we acquired in May 2014. There are several active programs evaluating molecules and approaches for the treatment of glaucoma, steroid induced glaucoma, ocular allergy, and retinal disease. These programs have been specifically identified by Ohr as large markets with unmet medical needs or where sustained release therapeutics can greatly improve upon the way ocular disease is currently being treated, including increased compliance rates and reduction in treatment burden.

Corporate and Historical Information

Ohr Pharmaceutical, Inc. is a Delaware corporation that was organized on May 30, 2014, as successor to Ohr Pharmaceutical, Inc. (formerly BBM Holdings, Inc, which was organized on August 4, 2009, and Prime Resource, Inc., which was organized March 29, 2002) pursuant to a holding company merger.

On June 3, 2013, the Company effected a 3:1 reverse stock split on its shares of common stock (with related adjustments to its outstanding preferred stock, options and warrants). Unless otherwise noted, impacted amounts and share information included in this document have been retroactively adjusted for the stock split as if such stock split occurred on the first day of the first period presented. Certain amounts may be slightly different than previously reported due to rounding of fractional shares as a result of the reverse stock split.

On May 30, 2014, the Company 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 agreement, in exchange for substantially all the assets of SKS, Ohr made an upfront payment of $3.5 million in cash and 1,194,862 shares of Ohr common stock. In addition, SKS will be eligible to receive up to 1,493,577 additional shares of Ohr common stock in contingent milestone payments. The transaction provided Ohr with a proprietary, patent protected, sustained release technology platform under development as well as a pipeline of pre-clinical sustained release drug product candidates that address ocular indications including glaucoma, ocular allergy, retinal disease and other ophthalmic indications. As part of the SKS Acquisition, Ohr retained the ten SKS employees and continued the SKS operations at the SKS research laboratory facility in San Diego, CA.

Simultaneous with the SKS Acquisition described above, 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 retains 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.

Recent Developments

On February 6, 2015, the Company announced the sale of 4,259,259 shares of common stock, inclusive of the over allotment, in an underwritten public offering at a price per share of $6.75. The Company expects to issue the shares of common stock at the closing of the transaction on February 11, 2015, and receive gross proceeds of approximately $28.8 million.

Product Pipeline

(a) OHR-102

OHR-102 (Squalamine Lactate Ophthalmic Solution 0.2%), formerly known as Squalamine Eye Drops.

Squalamine 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. Recent clinical evidence has shown PDGF to be an additional target for the treatment of Wet Age-related Macular Degeneration ("wet-AMD") and bFGF levels have been shown to be elevated in retinal vein occlusion and wet-AMD patients as well.

Ohr formulated Squalamine as a topical solution (OHR-102 or Squalamine lactate ophthalmic solution 0.2%) for ophthalmic indications and optimized the formulation for enhanced uptake into the back of the eye, and increased comfort in an elderly patient population. Preclinical testing has demonstrated that the eye drop formulation is both safe to ocular tissues and achieves in excess of target anti-angiogenic concentrations in the tissues of the back of the eye. The Company is advancing its clinical wet-AMD program with this topical formulation. Unlike other combination therapy approaches being evaluated in clinical studies, OHR-102 does not require direct injection into the eye.

In May 2012, the U.S. Food and Drug Administration awarded Fast Track Designation to the Squalamine eye drop program for the potential treatment of wet-AMD. After discussions with the FDA in September 2014, we expect to begin Phase III studies in the first half of calendar 2015

The Company conducted preclinical testing on the novel topical formulation with the following results:

- Ocular Tolerance and Toxicity: In a dose escalation safety study involving daily eye drop treatment in Dutch belted rabbits over a 28 day period, the formulation proved safe, and exhibited no signs of ocular toxicity or changes in intraocular pressure. Importantly, no macroscopic or histopathological changes to the ocular tissues were noted.

- Single Dose Biodistribution study: A single eye drop was administered to the front of the eye in Dutch belted rabbits. At all evaluated timepoints, drug concentrations in the posterior sclera-choroid region behind the retina at the back of the eye exceeded the targeted tissue concentrations of Squalamine.

- Multi Dose Biodistribution Study: Squalamine eye drops were administered once or twice daily in both eyes for up to 14 days in Dutch belted rabbits. The eyes were examined one full dosing interval (12 hours when given twice daily, 24 hours when given once daily) after the last administration of Squalamine eye drops to determine concentrations of Squalamine in the posterior ocular tissues ("Trough" level). At all time points and dosing regimens, Trough Squalamine concentrations exceeded the targeted tissue concentrations of Squalamine.

- Long Term Ocular Tolerance and Toxicity: In a 26-week safety and toxicity study in male and female Dutch belted rabbits, Squalamine or placebo eye drops were administered via topical instillation twice a day in both eyes. Ophthalmoscopic examinations were conducted throughout the study period to assess ocular irritation (redness, swelling, discharge). Blood and urine samples for clinical pathology evaluations were collected, and blood samples for determination of the Squalamine plasma concentrations and toxicokinetic evaluations were collected from all animals at designated time points. At study termination, necropsy examinations were performed, and organs and optical tissues were microscopically examined. No adverse effects of treatment were observed for any of the parameters evaluated including clinical findings, body weights, food consumption, ocular irritation, hematology, coagulation, clinical chemistry, urinalysis and macroscopic pathology examinations. Importantly, ophthalmoscopic examinations indicated no signs of clouding of the lens, no corneal opacities or deposits, and no increase in intraocular pressure. In addition, microscopic histopathology evaluations on ocular tissues were normal. Squalamine also did not build up in plasma over long term administration, indicating reduced potential for systemic side effects.

In previous Phase II clinical trials using the intravenous formulation of Squalamine, stabilization or improvement in visual activity was observed in the vast majority of patients, with both early and advanced lesions responding and few adverse drug-related ocular or systemic effects observed. In a number of patients whose wet-AMD had progressed to an advanced stage, the administration of Squalamine produced beneficial effects and significant improvement in best corrected visual acuity.

OHR-102 (Squalamine eye drops) used in combination with an anti-VEGF agent may provide several potential advantages over combination therapy approaches currently being investigated in clinical studies including:

- Daily eye drop therapy compared to an additional monthly intravitreal injection
- Potential for use in combination with an as-needed anti-VEGF injection (PRN) regimen instead of a monthly anti-VEGF injection
- Inhibition of multiple growth factor pathways
- Cost advantage of manufacturing a small molecule when compared to large molecule proteins and antibodies

Ongoing Phase II 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 is a randomized, double masked, placebo controlled Phase II study to evaluate the efficacy and safety of OHR-102 for the treatment of wet-AMD. The study enrolled treatment naïve wet-AMD patients at more than twenty clinical sites in the U.S., who will be treated with OHR-102 eye drops or placebo eye drops for a nine month period. Full enrollment was completed in April 2014, with final data on the study expected by the end of the first quarter of calendar 2015.

A planned interim analysis was conducted on the first 62 patients (29 treated in the OHR-102 arm, 33 treated in the placebo arm), who completed the nine month treatment protocol (representing approximately 50 percent of the targeted study population). All patients in the study received an initial Lucentis injection followed by Lucentis as needed ("PRN") based on clinical response. The two treatment arms were OHR-102 eye drops administered twice daily plus Lucentis PRN ("OHR-102" arm or group) versus standard-of-care treatment: placebo eye drops administered twice daily plus Lucentis PRN ("Lucentis monotherapy" arm or group).

Visual Acuity Benefit of OHR-102 Combination Arm

The data demonstrated a positive benefit in clinically relevant visual function in the OHR-102 arm across multiple key secondary endpoints. In the interim analysis group, 48.3 percent of OHR-102 treated patients showed best corrected visual acuity ("BCVA") gains of ≥15 letters (≥3 lines) on a standard early treatment diabetic retinopathy study eye-chart, compared with 21.2 percent in the Lucentis monotherapy arm at the end of the study (p=0.025). A three line gain is a clinically relevant improvement of vision as this translates into a patient being able to see a letter half the size of what they could see at baseline. In addition, patients receiving OHR-102 drops were more than twice as likely to gain ≥4 and ≥5 lines of vision compared with patients in the Lucentis monotherapy arm (≥4 lines p=0.022, ≥5 lines p=0.059). Mean change in visual acuity at the end of study was +10.4 letters with OHR-102 eye drops plus Lucentis PRN versus +6.3 letters in the placebo eye drops plus Lucentis PRN arm, a 65 percent additional relative benefit (p=0.18). The visual acuity improvements were seen as early as four weeks and the relative difference in visual acuity between the two treatment arms continued to increase throughout the study. There were no significant differences in the frequency of Lucentis injections, which was the primary endpoint of this initial study.

Data presented at the American Society of Retina Specialists meeting ("ASRS") on August 12, 2014, showed that mean change in central subfield thickness was -139um in the OHR-102 arm versus -117um in the Lucentis monotherapy arm. Representative cases were shown at ASRS demonstrating that the combination of OHR-102 and Lucentis resulted in the resolution of sub-retinal hyper reflective material as well as intra-retinal and subretinal edema. Given that previous combination therapy trials have focused on classic lesions, a subgroup analysis was performed on this patient population. In the group of patients with a lesion containing a classic component and a size of up to 12 disc areas, 67 percent of OHR-102 treated patients (n=18) demonstrated BCVA gains of ≥3 lines on a standard ETDRS eye-chart, compared with 20 percent in the Lucentis monotherapy arm (n=15) at the end of the study (p=0.007). In addition, patients receiving OHR-102 drops were more than three times as likely to gain ≥4 and ≥5 lines of vision compared with patients in the Lucentis monotherapy arm (≥4 lines p=0.05, ≥5 lines p=0.12). Mean change in visual acuity was +13.8 letters in the OHR-102 arm as compared to +6.7 letters in the Lucentis monotherapy arm (p=0.15). The OHR-102 patients with classic CNV also saw an improvement in visual function, with 61% of patients achieving a 20/40 vision outcome and 39% achieving a 20/32 outcome as compared to 40% and 20%, respectively, in the Lucentis monotherapy group. OHR-102 eye drops were well tolerated and had a comparable safety profile to the Lucentis monotherapy arm.

Anatomic Analysis of Subretinal Hyperreflective Material ("SHRM")

On October 18, 2014, anatomic data was presented in a podium presentation during the late breaker session at the American Academy of Ophthalmology, demonstrating that the combination of OHR-102 plus Lucentis resulted in a marked improvement in subretinal hyperreflective material, an anatomical biomarker for wet-AMD. SHRM, which is visualized using OCT, is an important biomarker of neovascular AMD and is believed to represent a combination of neovascular tissue, pre-fibrotic material and other subretinal exudative and inflammatory debris. A quantitative analysis of the SHRM biomarker was conducted at a large independent reading center in the U.S. Two masked readers reviewed and measured the area of SHRM on the spectral domain optical coherence tomography (OCT) scans at baseline and the final visit. Only patients with measurable SHRM at baseline were included in the analysis (overall: OHR-102 arm n=27, Lucentis monotherapy n=27, Classic containing lesions: OHR-102 n=18, Lucentis monotherapy n=13).

In the IMPACT Study overall population, patients receiving OHR-102 combination therapy demonstrated a 75% mean reduction in the area of SHRM as compared to 56% in the Lucentis monotherapy group. In addition, 59% of patients in the OHR-102 combination arm achieved a complete resolution of SHRM versus 44% in the monotherapy arm. The mean reduction in SHRM directly correlated with the visual acuity improvements seen in each vision outcome category, with a greater reduction of SHRM in each consecutive vision gain category up to more than 90% reduction of SHRM in patients achieving ≥4 lines (≥20 letters) of visual acuity gains. Given that previous combination therapy trials in wet-AMD focused on classic containing lesions, and SHRM is seen more often in classic choroidal neovascularization (CNV), a subgroup analysis was performed on this patient population. In these patients, greater differences in SHRM reductions were observed. Patients receiving OHR-102 combination therapy demonstrated a 74% mean reduction in the area of SHRM as compared to 43% in the Lucentis monotherapy group. In addition, 56% of patients in the OHR-102 combination arm achieved a complete resolution of SHRM versus 31% in the monotherapy arm. As with the overall analysis, the mean reduction in SHRM in these patients directly correlated with the visual acuity improvements seen in each vision outcome category, with a greater reduction of SHRM in each consecutive vision gain category up to more than 90% reduction of SHRM in patients achieving ≥4 lines (≥20 letters) of visual acuity gains.

We anticipate completing the IMPACT Study and announcing topline data by the end of the first calendar quarter of 2015, with additional presentations of the detailed final data to be made at scientific conferences in calendar year 2015.

Regulatory Guidance from FDA on OHR-102 Program in wet-AMD

At an end of Phase II meeting with the U.S. Food and Drug Administration ("FDA") in September 2014, the FDA agreed with the Company on a 9 month primary efficacy endpoint for the Phase III trials based on the proportion of patients achieving a ≥3 line improvement in visual acuity. The Phase III trials for Squalamine eye drops are being designed to measure the efficacy of combination therapy with OHR-102 eye drops plus Lucentis injections compared with Lucentis monotherapy in treatment naïve patients with wet-AMD. All patients will be followed for safety for 2 years. Two identical confirmatory studies will be required and we expect to begin these studies in the first half of calendar 2015.

Phase III Trials in wet-AMD

The Company plans to commence two Phase III trials in the first half of calendar year 2015 to evaluate the efficacy and safety of OHR-102 given in combination with Lucentis for newly diagnosed, treatment naïve patients with wet-AMD. Each Phase III study will be a randomized, double masked, placebo controlled trial and will enroll approximately 325 patients per arm. As with the phase II IMPACT study, we expect to enroll patients with classic or occult only choroidal neovascularization and patients with a diagnosis of diabetes. During the first year of the study, patients will be randomized 1:1 to receive monthly Lucentis plus OHR-102 (Squalamine eye drops) twice a day or Lucentis plus placebo. During the second year they will receive Lucentis PRN (as needed) plus OHR-102 or placebo twice a day. The primary endpoint will be the proportion of patients achieving a ≥3 line (≥15 letters) improvement in visual acuity at nine months, as measured by a standard ETDRS visual acuity chart.

Ongoing ISTs - OHR-102 (Squalamine Lactate Ophthalmic Solution 0.2%)

We have commenced three investigator sponsored trials ("ISTs") in ophthalmic indications where a molecule that possesses anti-angiogenic properties may provide therapeutic benefit. These indications include branch retinal vein occlusion, central retinal vein occlusion, proliferative diabetic retinopathy, and diabetic macular edema.

OHR-102 in Proliferative Diabetic Retinopathy ("PDR") - Study 003

Study 003 is an open-label monotherapy IST evaluating OHR-102 eye drops in five patients with PDR. Patients enrolled in the study receive OHR-102 for a six month treatment period and are then followed for an additional two months. The endpoints include 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 at the Macula Society meeting on February 19, 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 OHR-102 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 OHR-102 eye drop therapy. One month after cessation of treatment, the abnormal blood vessels returned in this patient's retina in the absence of OHR-102 treatment, and continued to grow through the second month, the latest time point measured. The study has completed enrollment and we expect the final data from the study to be available for presentation at a scientific conference or forum in the first half of calendar 2015.

OHR-102 in Branch and Central Retinal Vein Occlusion -Study 004

Study 004 is an IST evaluating OHR-102 eye drops in 20 patients with branch and central retinal vein occlusion. All patients in the study received OHR-102 for ten weeks, with injections of Lucentis at week 2 and 6, and a data readout at week 10. At week 10, the patients entered into the extension phase and have been randomized 1:1 to either continue or discontinue taking OHR-102 eye drops through week 38 ("extension phase") During the extension phase, the patients will receive Lucentis injections on a PRN basis based on fluid based OCT criteria. The principal investigator presented the ten week data from the study at the American Society of Retina Specialists on August 9, 2014. The data demonstrated that, at week 10, the mean gain in visual acuity was 20.3 letters for all 20 eyes using the combination therapy. In addition, the mean visual acuity for all 20 eyes at week 10 was 20/32. At week 10, the average central foveal thickness for all 20 eyes was reduced to 270u. One of 20 eyes qualified for an injection of ranibizumab at week 10, indicating dryness of the retina and a 95% macular deturgescence rate. Study 004 has completed enrollment and we expect data from the extension phase including visual acuity parameters and injection frequency to be available in the first half of calendar 2015 for presentation by the investigator at a scientific forum or conference.

OHR 102 in Diabetic Macular Edema (“DME”) - Study 005

Study 005 is a multi-center, randomized, masked, placebo controlled IST that is evaluating OHR-102 eye drops in patients with DME. Based on the clinical findings from the IMPACT Study in wet-AMD, we have increased the amount of patients originally planned for enrollment in this study and have modified the design of the trial to focus on visual acuity using a combination therapy approach. Patients will be randomized in a 2:1:2:1 randomization schedule (OHR-102 BID: placebo drops BID: OHR-102 QID: placebo drops QID). All patients will receive OHR-102 or placebo drops, given in combination with Lucentis monthly injections for the first six months. For months six through twelve, patients will receive OHR-102 or placebo drops, and Lucentis PRN (as needed). The primary endpoint will be the improvement in visual acuity. The study is expected to begin enrolling patients in the first quarter of calendar year 2015 and enroll a total of approximately 90 patients. We anticipate releasing topline data from the visual acuity primary endpoint at week 24 by the middle of calendar year 2016.

(b) SKS Sustained Release Ocular Drug Delivery Platform Technology

The SKS sustained release technology employs a hydrogel template approach to prepare nano or microparticles of predefined size and shape and with homogeneous size distribution. The size of the particles can be adjusted, providing flexibility in controlling the size and release rate in drug delivery formulations. The drug loading capacity is much higher than that achieved by conventional methods (30% or higher), with a controlled initial burst release of drug that is minimal. Simplicity in processing makes the hydrogel template method useful for scale-up manufacturing of particles. We believe the technology has significant advantages over currently available microparticle drug delivery systems prepared by emulsion methods. The limits of emulsion technology include low drug loading capacity (usually much less than 10% of the total weight) and often significant initial burst release of a drug. This technology platform is adaptable to multiple routes of ocular delivery.

We are using the sustained release technology platform to develop best-in-class drug formulations for ocular disease. The SKS Ocular sustained release technology acquired by Ohr employs micro fabrication techniques to create nano and microparticle drug formulations that can provide sustained and predictable release of a therapeutic drug over a 3 – 6 month period. The technology was designed to circumvent many of the challenges associated with current drug delivery technologies to deliver drugs, including small molecules and biologics, for extended durations.

Lead Sustained Release Preclinical Development Program in Glaucoma

The Company is working on several molecules and approaches for sustained release delivery in glaucoma, and has a research agreement with Alcon Research, Ltd. (“Alcon”), to develop a sustained release formulation in glaucoma. If successful with any of these approaches, this could potentially result in a significant improvement in glaucoma treatment, where the current standard of care is frequent topical, patient administered medications. It has been well established from multiple studies that the single greatest reason for treatment failure in glaucoma today is lack of compliance with medication due to the nature of the disease. Unlike retinal disease where patients, due to clearly evident visual symptoms and vision loss, are highly motivated to be compliant with therapy, glaucoma is typically asymptomatic until late in the disease process and thus compliance is a significant issue. A physician-administered drug with a requirement for injections at intervals of several months would potentially improve patient compliance and may have an impact on reducing loss of vision from glaucoma.

Additional Sustained Release Preclinical Development Programs

Ohr’s preclinical pipeline of sustained release programs include sustained release formulations of small molecule and protein therapeutics for the treatment of ocular diseases, including steroid induced glaucoma, allergies, and retinal disease. Ohr has several molecules under development for these indications and anticipates expanding the pipeline during fiscal year 2015 to include additional molecules and indications in ocular disease. We also anticipate potentially filing an investigational new drug application with the FDA on one sustained release program in the first half of calendar 2016.

(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 to examine 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 molecules in the RPE, thickening of the Bruch’s membrane, upregulation of inflammatory cytokines, and immune cell influx into the eye. Ohr licenses the intellectual property rights to this model, and EyeCRO, a development partner of the Company, has obtained exclusive rights to provide contracted screening services in the CEP model. EyeCRO is a contract research organization specializing in preclinical services to the ophthalmology industry. In addition, we have optimized the induction parameters to create disease pathology within 60 days. 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. Under the terms of the license agreement, we may receive royalties from EyeCRO during fiscal 2015.

(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.

In January 2015, the Company ceased development of the OHR/AVR118 program and discontinued maintenance and prosecution of the intellectual property portfolio.

Competitive Factors

The pharmaceutical industry is characterized by intense competition and confidentiality. We may not be aware of the other biotechnology companies, pharmaceutical companies or public institutions that are developing pharmaceuticals that compete with our potential products. We also may not be aware of all the other competing products our known competitors are pursuing. In addition, these biotechnology companies, pharmaceutical companies and public institutions compete with us in recruiting for research personnel and subjects, which may affect our ability to complete our research studies. Lucentis® (Genentech/Roche) and Eylea® (Regeneron) are currently approved by the FDA and are the market leaders for the treatment of wet-AMD. Ophthotech is developing a combination therapy (Fovista™) used with an additional intravitreal agent to improve vision outcomes. There is no assurance that we can get FDA approval for Squalamine eye drops for the treatment of wet-AMD, and if we get it, there is no assurance we will be able to displace the market leaders as a treatment in a significant amount of patients. In addition there are various other companies with drugs in Phase I, II, and III trials for the treatment of wet-AMD. We cannot assure that none of them will get to market before us or that Squalamine eye drops will be a better treatment. See “Risk Factors” below.

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 yearly 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 2013, annual revenue (worldwide) was more than $3 billion for Lucentis, despite significant cannibalization by the off-label use of Avastin (estimated to be 45-60% of the overall market). Eylea®, was approved for use in wet-AMD in the U.S. in November 2011 and achieved 2013 revenues of approximately $1.4 billion. Both Lucentis and Eylea are administered via frequent intravitreal injections directly into the eye. We believe our primary competition is Fovista ^{TM} , a PDGF targeting pegylated aptamer being developed by Ophthotech and Novartis, which is currently enrolling three Phase III clinical studies to evaluate Fovista in combination with anti-VEGF agents, including Lucentis®, Eylea®, and Avastin®. To date, Fovista and OHR-102 are the only combination therapy approaches we are aware of that have demonstrated a visual acuity benefit when used in combination with an anti-VEGF intravitreal injection. The Fovista clinical trials are designed for patients to receive two intravitreal injections per month for a period of 24 months. Other programs that have completed or are currently in Phase II trials include MP0112, a VEGF targeting DARPin molecule being developed by Allergan, iSonep, a sphingosine-1-phosphate targeting agent being developed by LPath Inc and Pfizer, X-82, a tyrosine kinase inhibitor being developed by Xcovery Vision, ALG-1001, an integrin targeting peptide being developed by Allegro Ophthalmics, and AVA-101, a gene therapy being developed by Avalanche Biotechnologies. All of these products in clinical development, with the exception of X-82, use an intravitreal route of administration much like the current standards of care.

Corporate Strategy

The Company is currently actively developing its pipeline products for applications in ophthalmology. During the 2014 fiscal year, we transitioned Ohr to a core focus on ophthalmology indications and building an ophthalmology-focused pipeline, for instance, through our acquisition of SKS Ocular in May 2014.

After the recent presentations of the interim results from the Phase II IMPACT Study with OHR-102, we began an initiative to seek and implement strategic alternatives with respect to our products, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. We are currently in discussions and will continue to engage in discussions with third parties regarding the licensure, sale or acquisition of our products and technologies or a merger or sale of the Company; however, we currently do not have any agreement to enter into such a transaction, and there is no assurance that the Company will complete such a transaction.

On February 26, 2014, the Company entered into a Joint Venture Agreement and related agreements with Cold Spring Harbor Laboratory ("CSHL") pursuant to which a joint venture, DepYmed Inc. ("DepYmed"), was formed to further preclinical and clinical development of Ohr's Trodusquemine and analogues as PTP1B inhibitors for undisclosed indications. PTP1B is non-receptor phospho-tyrosine protein phosphatase. PTP1B plays a role in many biological processes and may have potential uses in indications including cancer, diabetes, and obesity. The initial clinical focus of DepYmed will be in oncology applications, and DepYmed anticipates initiating a Phase I dose escalation study evaluating Trodusquemine in breast cancer patients by the end of the first calendar quarter of 2015; however, there can be no assurance that DepYmed will be able to design and support clinical trials or otherwise determine the efficacy or commercial potential of Trodusquemine for commercial use, or that regulatory authorities will approve final testing or marketing of any pharmaceutical product. DepYmed is jointly owned by CSHL and the Company, and licenses research from CSHL and intellectual property from the Company. In December 2014, DepYmed hired a full time CEO to run the operations of DepYmed and intends to seek private investment to fund the ongoing operations of DepYmed.

Liquidity and Sources of Capital

To continue development of its pharmaceutical products and continuing operation, the Company is reliant, at present, upon its capital reserves. The Company has no revenues. The Company announced the sale of 4,259,259 shares of common stock, inclusive of the over allotment, in an underwritten public offering on February 6, 2015, and expects to issue the shares and receive gross proceeds of approximately $28.8 million at the closing on February 11, 2015. With this additional capital, management believes the Company has sufficient capital to meet its planned operating needs through July 2016. At present, the Company has no bank line of credit or other fixed source of positive net working capital reserves. Should it need additional capitalization in the future, it will be primarily reliant upon private or public placement of its equities, and there can be no assurance that the Company will be successful in such efforts.

Results of Operations

Three Months Ended December 31, 2014

Three months ended December 31, 2014 ("2014") compared to the three months ended December 31, 2013 ("2013"). Results of operations for the three months ended December 31, 2014 reflect the following changes from the prior period.

	2014	2013	Change
Operating Expenses			
General and administrative	$ 163,516	$ 57,777	$ 105,739
Professional fees	175,243	384,215	(208,972)
Research and development	2,839,801	1,352,356	1,487,445
Salaries and wages	745,427	227,145	518,282
Total Operating Expenses	3,923,987	2,021,493	1,902,494
Operating Loss	(3,923,987)	(2,021,493)	(1,902,494)
Change in fair value of contingent consideration	(683,386)	—	(683,386)
Share in losses on investment in joint venture	(26,650)	—	(26,650)
Royalty and other income (expenses)	35,686	(432)	36,118
Net Loss	$ (4,598,337)	$ (2,021,925)	$ (2,576,412)

The Company had no net revenues from operations in 2014. Accordingly, the Company also had no cost of revenue from operations in 2014.

General and administrative expenses from operations increased from $57,777 in 2013 to $163,516 in 2014. Professional fees decreased from $384,215 in 2013 to $175,243 in 2014. Salaries and wages increased from 2013 to 2014 due to salaries, option grants and bonuses that were higher in 2014 than in 2013. The Company expects salaries and wages, professional fees, and general and administrative expenses to increase in future periods as development of its products continues.

The Company incurred $2,839,801 in research and development expenses in 2014 compared to $1,352,356 in 2013. The increase is a result of the ongoing clinical trials in ophthalmic indications and increased costs associated with the acquisition of SKS Ocular, as well as maintenance and development of the products that it acquired in 2009. The Company expects research and development expenses to continue to rise as development of its products continues.

The Company had salaries and wages expenses in 2014 of $745,427 as compared to $227,145 in the same period in 2013. The increase was primarily the result of the increase of employees from the acquisition of SKS Ocular.

The Company had royalty and other income and expenses in 2014 of $35,686 as compared to ($432) in the same period in 2013. The increase was primarily the result of royalty income received during 2014. The Company also had a change in fair value of contingent consideration in 2014 of $683,386 and a share in losses on investment in joint venture of $26,650, compared to no expenses in these areas for 2013.

For the three months ended December 31, 2014, the Company recognized a net loss of $4,598,337 compared to a net loss of $2,021,925 for the same period in 2013. 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

Management's Quarterly Report on Internal Control Over Financial Reporting

We have carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer ("CEO") and the Chief Financial Officer ("CFO"), of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this report.

In designing and evaluating the disclosure controls and procedures, our management, including the CEO and CFO, 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 necessarily 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. Based on an evaluation under the supervision and with the participation of the Company's management, including the CEO and CFO, have concluded that the Company's disclosure controls and procedures were effective as of December 31, 2014 to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms and (ii) accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

As a result of material weakness of our internal controls over financial reporting identified during the period covered by our Annual Report on Form 10-K for year ended September 30, 2014, management implemented changes to our internal controls that are both organizational and process-focused in an effort to improve the control environment, including as it relates to our application of accounting principles regarding our fair-value process and review and approval of certain non-routine valuation calculations. We made changes to our control environment which include, among others:

- Identification of technical accounting resources for complex transactions on an ad hoc basis;
- Re-evaluation of key processes that support our financial reporting and technical accounting function; and
- Hiring of additional resources for assistance in these areas.

We will continue our efforts to improve our control environment and to focus on improving our processes and systems to help ensure that our financial reporting, operational and business requirements are met in a timely manner going forward.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

In June 2012, the Company was named, along with other parties, as a defendant in a putative class action lawsuit being brought, as amended, on behalf of the Genaera Liquidating Trust ("Trust"). We purchased biotechnology assets from the Trust in 2009. On August 12, 2013, the court dismissed each of the plaintiff's claims against the Company. An appeal of the dismissal is pending; however, the plaintiff, on April 25, 2014, agreed to dismiss the Company from that appeal. The court approved the dismissal stipulation by order entered on May 7, 2014, dismissing the Company from the appeal with prejudice. The litigation has ended with respect to the Company, and management believes that it is unlikely that the litigation continuing with other parties will have a material adverse impact on the Company's financial condition.

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 significant revenues.

We are a development stage pharmaceutical company and currently do not have, any may never have, any products that generate significant 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 United States, the European Union and elsewhere. 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. OHR-102, our most advanced drug candidate, is currently in Phase II clinical trials. 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 September 30, 2014, we had an accumulated deficit of approximately $43.3 million. We expect to incur net losses over the next several years as we advance our programs and incur significant clinical development costs. 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.

There is no guarantee that our currently ongoing Phase II or our future Phase III clinical trial for OHR-102 in wet-AMD will be successful.

We commenced a clinical study, Study OHR-002 (or IMPACT Study), which began enrolling patients in late 2012. The IMPACT Study is a randomized, double masked, placebo controlled Phase II study to evaluate the efficacy and safety of OHR-102 for the treatment of wet-AMD. The study enrolled treatment naïve wet-AMD patients at 23 clinical sites in the U.S., who were treated with OHR-102 eye drops or placebo eye drops for a nine month period. Full enrollment was completed in April 2014, with final data on the study expected by the end of the first quarter of calendar 2015.

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

At an end of Phase II meeting with the U.S. Food and Drug Administration (“FDA”) in September 2014, the FDA agreed with the Company on a 9 month primary efficacy endpoint for the Phase III trials based on the proportion of patients achieving a ≥3 line improvement in visual acuity. The Phase III trials for Squalamine eye drops are being designed to measure the efficacy of combination therapy with OHR-102 eye drops plus Lucentis injections compared with Lucentis monotherapy in treatment naïve patients with wet-AMD. All patients will be followed for safety for 2 years. Two identical confirmatory studies will be required and we expect to begin these studies in the first half of calendar 2015.

The Company plans to commence two Phase III trials in the first half of calendar year 2015 to evaluate the efficacy and safety of OHR-102 given in combination with Lucentis for newly diagnosed, treatment naïve patients with wet-AMD. Each Phase III study will be a randomized, double masked, placebo controlled trial and will enroll approximately 325 patients per arm. As with the Phase II IMPACT study, we expect to enroll patients with classic or occult only choroidal neovascularization and patients with a diagnosis of diabetes. During the first year of the study, patients will be randomized 1:1 to receive monthly Lucentis plus OHR-102 (Squalamine eye drops) twice a day or Lucentis plus placebo. During the second year they will receive Lucentis PRN (as needed) plus OHR-102 or placebo twice a day. The primary endpoint will be the proportion of patients achieving a ≥3 line (≥15 letters) improvement in visual acuity at nine months, as measured by a standard ETDRS visual acuity chart.

While we are currently conducting our Phase II clinical trial and plan to conduct Phase III clinical trials in accordance with the end of Phase II meeting, there is no guarantee that we will have the same level of success in these trials as we have in our earlier clinical trials, or be successful at all.

We believe that OHR-102 may also have clinical utility in indications other than wet-AMD. We have commenced three investigator sponsored trials ("ISTs") in ophthalmic indications where a molecule that possesses anti-angiogenic properties may provide therapeutic benefit. These indications include branch retinal vein occlusion, central retinal vein occlusion, proliferative diabetic retinopathy, and diabetic macular edema.

If we do not successfully complete clinical development of OHR-102, 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 OHR-102 in patients with wet-AMD, those results are not necessarily predictive of results of future pivotal trials 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 for commercialization.

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 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 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.

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

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 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 and small 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 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.

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 the early stages of 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 locate 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.

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.

We are dependent on contract research organizations, third-party vendors and independent investigators for preclinical testing, clinical trials and ISTs related to our drug discovery and development efforts, and we will likely continue to depend on them to assist in our future discovery and development efforts. These parties are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If they fail to devote sufficient time and resources to our drug development programs or if their performance is substandard, it will delay the development and commercialization of our product candidates. The parties with which we contract for execution of our clinical trials and ISTs 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.

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 Good Laboratory Practices, 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.

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, 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 at academic and other institutions 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.

Relying on third-party manufacturers 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 OHR-102, for clinical trials. If any of our product candidates are approved by the FDA or other 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. While we believe that there are alternative sources available to manufacture our product candidates, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts. 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 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.

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 pursuant to inspections that will be conducted after we request regulatory approval from the FDA. 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. 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.

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 either 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.

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, staff 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 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 ventures 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.

Risks associated with the SKS Acquisition could cause us to fail to realize the anticipated benefits of the SKS Acquisition and harm our business generally.

We recently completed the acquisition of the ophthalmology assets of SKS Ocular LLC and its affiliate, SKS Ocular 1 LLC ("SKS"). In the SKS Acquisition, we retained ten SKS employees and continued the SKS operations at the SKS research laboratory facility in San Diego, CA.

The SKS Acquisition could lead to unforeseen operating difficulties and expenditures, including:

- Reallocation of management time and focus from operating core ophthalmology business to integration challenges related to the SKS Acquisition;
- Implementation of controls, procedures, and policies at research laboratory facility in San Diego, CA;
- Integration of the SKS' accounting, human resource, and other administrative systems, and coordination of product development functions;
- Transition of SKS personnel into our existing platforms;
- Challenges associated with integrating employees from SKS into our organization, and retention of employees from the businesses we acquire;
- Liability for activities of the SKS before the SKS Acquisition, including patent and trademark infringement claims, violations of laws, commercial disputes, tax liabilities, and other known and unknown liabilities; and
- Litigation or other claims in connection with SKS, including claims from terminated employees, customers, former stockholders, or other third parties.

Our failure to address these risks or other problems encountered in connection with the SKS Acquisition could cause us to fail to realize the anticipated benefits of the SKS Acquisition and harm our business generally.

Risks associated with the research collaboration with a large global pharmaceutical company.

We entered into a research agreement with Alcon, a large global pharmaceutical company, in a glaucoma application using our sustained release platform; however, there can be no assurance that such collaboration will continue or that the research program will result in commercially useful products.

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. Irach Taraporewala, our Vice President of Business Development and CFO, Sam Backenroth, and our Chief Medical Officer, Dr. Jason Slakter, as well as our directors. 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 have employment agreements with Dr. Taraporewala and Mr. Backenroth and a consulting agreement with Dr. Slakter. Although these agreements include a non-competition covenant, the applicable noncompetition provisions can be difficult and costly to monitor and enforce. The loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals.

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.

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 biotech 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.

We may be unsuccessful in monetizing existing assets, acquiring additional assets or entering into joint development programs.

We will continue to seek to acquire or make investments in complementary businesses, technologies, services or products and plan to seek development partners for our existing products. We are currently in discussions and will continue to engage in discussions with third parties regarding the licensure, sale or acquisition of our products and technologies or a merger or sale of the Company; however, we currently do not have any agreement to enter into such a transaction, and there is no assurance that the Company will complete such a transaction.

Risk Factors Related to FDA Regulation

We face heavy government regulation, and FDA regulatory 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. 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 (cGMP).

The process of obtaining FDA and other required 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 varies depending on the drug candidate, the disease or condition that the drug candidate is in development for, and the requirements applicable to that particular drug candidate. The FDA 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 may not approve our manufacturing process;
- the FDA 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 New Drug Application ("NDA").

For example, if certain of our methods for analyzing our trial data are not accepted by the FDA, 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
- 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, 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 our business could suffer.

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 patents and patent applications US 7981876, 8716270, 6262283, 7728157,6962909, and 20130281420 to cover the Squalamine formulations, composition of matter, methods of manufacture and synthesis 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 prepare and file 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 in connection with restructurings may seek future employment with our competitors. Although each of our employees is required to sign a confidentiality agreement with us at the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of such future employment. In addition, technology that we may license in 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 ex parte review and 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, ex parte review, 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 or maintain 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 or delays in our 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 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;
- 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.

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 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.

We will need additional financing to further our drug and delivery platform development programs as well as future trials and may not be able to raise additional capital on favorable terms, if at all.

We will need additional financing to further our drug and delivery platform development programs as well as future trials. In our capital-raising efforts, we may seek to sell additional equity or debt securities or obtain a bank credit facility. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. 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 are unable to secure sufficient capital to fund our research and development activities, we may not be able to continue operations, or we may have to enter into collaboration agreements that could require us to share commercial rights to our products to a greater extent or at earlier stages in the drug development process than is currently intended. These collaborations, if consummated prior to proof-of-efficacy or safety of a given product candidate, could impair our ability to realize value from that product candidate. If our business does not generate the cash needed to finance our ongoing operations, we will likely need to continue to raise additional capital.

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 or our other products in the United States unless we submit, and the FDA approves, an NDA for each such product. We must conduct clinical trials of each of our products in humans before we submit an NDA. 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 or our other products will not prove that they are safe and effective. It is also possible that the FDA will not approve the sale of any of our products in the United States if we submit an NDA for such product. It is not known at this time how later stage clinical trials will be conducted, if at all. Even if the data show that any of our products are safe and effective, obtaining approval of the NDA 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 all phases of clinical trials for Squalamine and our sustained release ophthalmological platform 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. We currently do not have sufficient funds to complete all phases of clinical and preclinical testing of any of our products which are required to permit the commercial sale of such products.

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.

We have identified a material weakness in our internal control over financial reporting which could, if not remediated, result in material misstatements in our financial statements. In addition, current and potential stockholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of our common stock.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our results of operation could be harmed.

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal controls over financial reporting. We continuously monitor our existing internal controls over financial reporting systems to confirm that they are compliant with Section 404, and we may identify deficiencies that we may not be able to remediate in time to meet the deadlines imposed by the Sarbanes-Oxley Act. This process may divert internal resources and will take a significant amount of time and effort to complete.

In our Quarterly Report on Form 10-Q for our third fiscal quarter of 2014, we concluded that the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, were not effective in reaching the required level of reasonable assurance in achieving the desired control objectives, primarily due to lack of staff. To remediate this deficiency, we hired additional accounting personnel to improve the controls over our financial reporting process and to ensure the effectiveness of our disclosure controls for future filings.

As disclosed in Item 9A of our Annual Report on Form 10-K for the year ended September 30, 2014, management identified a material weakness in our internal control over financial reporting related to fair value accounting for non-recurring items. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As a result of this material weakness, our management concluded that our internal control over financial reporting was not effective based on criteria set forth by the Committee of Sponsoring Organization of the Treadway Commission in Internal Control—An Integrated Framework. We are actively engaged in implementing a remediation plan designed to address this material weakness. If our remedial measures are insufficient to address the material weakness, or if additional material weaknesses or significant deficiencies in our internal control are discovered or occur in the future, our consolidated financial statements may contain material misstatements and we could be required to restate our financial results. We expect to experience higher than anticipated operating expenses as well as increased independent auditor and consultant fees during the implementation of these changes and thereafter. Further, we may need to hire additional qualified personnel. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to maintain an effective internal control environment could also cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of our common stock.

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.

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.

On October 17, 2014, the Company issued 2,000 common shares in connection with the exercise of warrants for total proceeds of $3,000.

On October 29, 2014, the Company issued 4,000 common shares with a fair value of $7.19 per share for consulting services and recognized stock-based compensation expense of $28,760.

On December 23, 2014, the Company issued 5,952 common shares as settlement of accounts payable in the amount of $50,000.

The issuances of the shares were made in reliance on the exemption from registration provided under Section 4(2) of the Securities Act of 1933, as amended.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Removed and Reserved.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit	Number
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

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

Date: February 9, 2015

OHR PHARMACEUTICAL, INC.

(Registrant)

By: /s/ Irach Taraporewala
Irach Taraporewala
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, Irach Taraporewala, certify that:

1. I have reviewed this report on Form 10-Q of Ohr Pharmaceutical, Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b . Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 9, 2015

/s/ Irach Taraporewala
Irach Taraporewala
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 registrants other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant 's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant 's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant 's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 9, 2015

/s/ Sam Backenroth
Sam Backenroth
Principal Financial 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 period ending December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the *"Report"*), I, Irach Taraporewala, Principal Executive Officer, of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 9, 2015

/s/ Irach Taraporewala
Name: Irach Taraporewala
Title: 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 period ending December 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the *"Report"*), I, Sam Backenroth, Principal Financial Officer, of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 9, 2015

/s/ Sam Backenroth
Name: Sam Backenroth
Title: Principal Financial Officer