

Ohr Pharmaceutical Inc
Form 10-K
December 22, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended September 30, 2014

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

For the transition period from _____ to _____.

Commission File No: 333-88480

OHR PHARMACEUTICAL, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware **46-5622433**
(State or Other Jurisdiction of (I.R.S. Employer Identification No.)
Incorporation or Organization)

800 Third Ave, 11th Floor

New York, NY 10022

(Address of Principal Executive Offices)

212-682-8452

Registrant's telephone number, including area code

Securities registered under Section 12(b) of the Exchange Act: Common Stock, par value \$0.0001 per share

Name of each exchange on which registered: NASDAQ Capital Market

Securities registered under to Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☐

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 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 ☐

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. 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.

(Check One): Large accelerated filer Accelerated filer Non-accelerated Smaller reporting company

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates at March 31, 2014 based on the closing price of the registrant's common stock on the NASDAQ Capital Market on such date was \$219,484,196. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such person might be deemed to be an affiliate. This determination of affiliate status might not be conclusive for other purposes.

At December 22, 2014, the registrant had 25,260,190 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The Company's definitive Proxy Statement for its 2015 Annual Meeting of Stockholders expected to be held March 31, 2015, is incorporated by reference into Part III of this Form 10-K to the extent described herein.

TABLE OF CONTENTS

Part I

<u>Item 1</u>	<u>Description of Business</u>	1
<u>Item 1A</u>	<u>Risk Factors</u>	9
<u>Item 2</u>	<u>Description of Property</u>	16
<u>Item 3</u>	<u>Legal Proceedings</u>	16
<u>Item 4</u>	<u>Reserved</u>	16

Part II

<u>Item 5</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	16
<u>Item 6</u>	<u>Selected Financial Data</u>	19
<u>Item 7</u>	<u>Managements' Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>Item 7A</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
<u>Item 8</u>	<u>Financial Statements and Supplementary Data</u>	22

Part III

<u>Item 9</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	24
<u>Item 9A</u>	<u>Controls and Procedures</u>	24
<u>Item 9B</u>	<u>Other Information</u>	26
<u>Item 10</u>	<u>Directors, Executive Officers and Corporate Governance</u>	26
<u>Item 11</u>	<u>Executive Compensation</u>	29
<u>Item 12</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	29
<u>Item 13</u>	<u>Certain Relationships, Related Transactions, and Director Independence</u>	29
<u>Item 14</u>	<u>Principal Accountant Fees and Services</u>	29

Part IV

<u>Item 15</u>	<u>Exhibits</u>	30
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Certification pursuant to Section 302 of the Sarbanes Oxley Act of 2002	Exhibit 31
Certification pursuant to Section 906 of the Sarbanes Oxley Act of 2002	Exhibit 32

Part I

ITEM 1 BUSINESS

Our discussion and analysis of the business and subsequent discussion of financial conditions may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements that are not historical in nature, including statements about beliefs and expectations, are forward-looking statements. Words such as “may,” “will,” “should,” “estimates,” “predicts,” “believes,” “anticipates,” “plans,” “expects,” “intends” and similar expressions are intended to identify forward-looking statements, but are not the exclusive means of identifying such statements. Such statements are based on currently available operating, financial and competitive information and are subject to various risks and uncertainties as described in greater detail in our “Risk Factors” on page 9 of this Annual Report. You are cautioned that these forward-looking statements reflect management’s estimates only as of the date hereof, and we assume no obligation to update these statements, even if new information becomes available or other events occur in the future. Actual future results, events and trends may differ materially from those expressed in or implied by such statements depending on a variety of factors, including, but not limited to those set forth in our filings with the Securities and Exchange Commission (“SEC”). Specifically, and not in limitation of these factors, we may alter our plans, strategies, objectives or business.

We are a reporting company and file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any reports, proxy statements or other information that we file at the SEC’s public reference room at 100 F Street N.E., Room 1580, Washington, D.C., 20549. You can also request copies of these documents by writing to the SEC and paying a fee for the copying costs. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. Our public filings with the SEC are also available on the web site maintained by the SEC at <http://www.sec.gov>.

On June 3, 2013, the Company effected a 3:1 reverse stock split on its shares of common stock. Unless otherwise noted, impacted amounts and share information included in the financial statements and notes thereto 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 in the notes to the financial statements may be slightly different than previously reported due to rounding of fractional shares as a result of the reverse stock split.

GENERAL AND HISTORICAL

Summary

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.

Until the Company is able to generate significant revenue from its principal operations, it will remain classified as a development stage company. The Company can give no assurance that it will be successful in such efforts or that its limited operating funds will be adequate to continue the Company as a public company, nor is there any assurance of any additional funding being available to the Company. Our website address is www.ohrpharmaceutical.com. Information on our website is not incorporated herein by reference. We make available free of charge through our website press releases, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after we have electronically filed with, or furnished to, the Securities and Exchange Commission.

Historical

The Company is a Delaware corporation that was organized on August 4, 2009, as successor to BBM Holdings, Inc. (formerly Prime Resource, Inc., which was organized March 29, 2002) pursuant to a reincorporation merger. On August 4, 2009 the Company reincorporated in Delaware as Ohr Pharmaceutical, Inc. (“Ohr”).

On June 13, 2013, the Company’s common shares were approved for listing and began trading on The NASDAQ Capital Market.

On April 8, 2014, the Company sold 1.8 million shares of common stock at a price per share of \$10.00, for net proceeds of approximately \$16.9 million.

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.

Prior Business - The Company was originally formed under the name Prime Resource, Inc., a Utah corporation. After disposing of its prior insurance business, on March 30, 2007, the Company merged with Broadband Maritime Inc., a broadband maritime service supplier. No goodwill was recognized in the merger since Broadband Maritime was treated as the acquirer for accounting purposes and the Company was a “shell company.” On June 5, 2007, after cancellations of key contracts, the Company announced that it had ceased broadband maritime operations and reduced employment to a small residual force. Accordingly, the Company ceased broadband maritime operations effective September 30, 2007 and was reclassified as a development stage enterprise, from the date of cessation forward.

Acquisition of Pharmaceutical Business

On March 19, 2009, the Company acquired in a secured party sale all the patents, related intellectual property, clinical data and other assets related to AVR118 (renamed OHR/AVR118). OHR/AVR118 has completed a Phase II trial for the treatment of cachexia.

On August 19, 2009, the Company completed the acquisition of Squalamine, Trodusquemine and related compounds from Genaera Liquidating Trust. The Company paid \$200,000 in cash for the compounds.

On May 30, 2014, the Company completed the ophthalmology assets 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.

Recent Developments

On June 26, 2014, the Company announced topline data from the interim analysis of the Phase II study evaluating OHR-102 in combination with Lucentis for the treatment of wet-AMD. Additional data was presented at scientific conferences in the third calendar quarter of 2014 demonstrating a visual acuity and anatomical benefit of OHR-102 combination therapy.

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 planned 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.

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 toxicity (irritation, redness, swelling, discharge). Blood and urine samples for clinical pathology evaluations were collected, and blood samples for determination of the plasma concentrations of squalamine eye drops 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 in 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 in 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 in the first calendar quarter of 2015, with additional presentations of the detailed final data to be made at scientific conferences in the first half of 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 300-350 patients per arm. As with the phase II IMPACT study, we expect to enroll patients with classic or occult only chroidal 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, and continued to grow through the second month, the furthest 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 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 early in calendar year 2015 and enroll a total of approximately 90 patients.

We may also initiate an additional IST to further evaluate OHR-102 eye drops for the treatment of DME in combination with monthly Lucentis® injections for DME patients that have been sub-responders to monthly intravitreal Lucentis injections. The trial would enroll approximately 20 patients and be randomized, masked, and placebo controlled.

(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.

(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 owns 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/AVR118

OHR/AVR118, a molecule acquired in 2009, is a novel immunomodulator with a singular chemical structure that is terminally sterilized and endotoxin-free. The compound is composed of two small peptides, Peptide A, which is 31 amino acids long, and Peptide B, which is 21 amino acids long. Peptide B is unique in that the dinucleotide, diadenosine, is covalently attached to serine at position 18 through a phosphodiester bond. OHR/AVR118 is stable at room temperature and has a favorable safety profile both in animal toxicity studies and in human clinical trials.

The Company completed a Phase IIa study evaluating OHR/AVR118 in patients with cancer cachexia. In December 2013, the data was presented at the 7th International Cachexia Conference in Kobe, Japan. The data were selected for podium presentation of late breaking clinical trials and were presented by principal investigator Dr. Martin Chasen, Medical Director, Palliative Care, Ottawa Hospital Cancer Centre, Canada.

In a Phase IIa trial with OHR/AVR118, 29 patients with advanced cancer and cachexia were enrolled. 18 patients, three with stage III and 15 with stage IV cancers, completed the treatment protocol. This included five patients with pancreatic cancer, five with lung cancer, two with prostate cancer and one each with colon, stomach, esophageal, liver cancers, head and neck cancer and multiple myeloma. While the primary trial end point of weight gain was not met, at the completion of treatment, patients achieved stabilization of body weight, body fat and muscle mass with a significant increase in appetite ($p < .005$). Additionally, patient generated subjective global assessment scores ($p = .025$) demonstrated improvement, indicating an enhanced quality of life.

After completing the initial 28 day treatment period, patients had the option to continue receiving study drug if they felt it was in their best interest. 11 of the 18 patients (61%) elected to do so, being treated with the drug for a total of between 42 to 153 days. Sustained body weight stabilization was maintained even on prolonged therapy with the drug in this sub-group of patients. These results were seen despite the fact that seven of the 18 patients were receiving concomitant chemotherapy, and one was receiving concomitant radiotherapy during the trial treatment period with OHR/AVR118. Chemotherapy and radiation frequently exacerbate the symptoms of cachexia. Overall, the drug appeared well tolerated with minimal side effects. The Company is not currently conducting clinical trials of OHR/AVR118.

The Company plans to monetize OHR/AVR118 through a license agreement, partnership, joint venture, or sale; 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.

Ohr also owns various other compounds in earlier stages of development, including the PTP1b inhibitor Trodusquemine and related analogs. See “Corporate Strategy” concerning the Trodusquemine joint venture.

COMPETITIVE FACTORS

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™, a PDGF targeting 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 calendar year 2014 or 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, we hired a full time CEO to run the operations of DepYmed and intend to seek private investment to fund the ongoing operations of DepYmed.

The Company plans to monetize OHR/AVR118, a non ophthalmology asset, through a license agreement, partnership, joint venture, or sale; 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.

NUMBER OF PERSONS EMPLOYED

At present, the Company has 13 full-time employees. In addition, the Company uses numerous high level scientific consultants and Contract Research Organizations, on an as needed basis, to augment our internal resources and provide a cost efficient alternative to a large infrastructure build out to support our ongoing preclinical and clinical development programs. The Company anticipates hiring additional staff during fiscal 2015 to support the upcoming Phase III trials for OHR-102 and the expansion of the sustained release platform programs.

ENVIRONMENTAL COMPLIANCE

The Company is not aware of any environmental claims or liabilities.

GOVERNMENTAL COMPLIANCE

Ohr will continue to be subject to various SEC and state securities rules and regulations. Its Nasdaq listing will also be subject to various rules and regulations by the Nasdaq Capital Market (“Nasdaq”). The foregoing is not meant to be exclusive, and the Company will continue to be subject to various generic governmental regulations, such as tax filing and reporting requirements, OSHA compliance, etc. See “Risk Factors” below.

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.

We 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.

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.

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:

- o a drug candidate may not be shown to be safe or effective;
- o the FDA may not approve our manufacturing process;
- o the FDA may interpret data from preclinical and clinical trials in different ways than we do; and
- o 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:

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

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 do not have sufficient capital currently 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.

If the results of our clinical and preclinical studies do not support our claims relating to any drug candidate or if serious side effects are identified, the completion of development of such drug candidate may be significantly delayed or we may be forced to abandon development altogether, which will significantly impair our ability to generate product revenues.

The results of our clinical and preclinical studies with respect to any drug candidate might not support our claims of safety or efficacy, the effects of our drug candidates may not be the desired effects or may include undesirable side effects or the drug candidates may have other unexpected characteristics. Further, success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our drug candidates are safe for humans and effective for indicated uses. 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 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.

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:

- o developing drugs;
- o undertaking preclinical testing and human clinical trials;
- o obtaining FDA and other regulatory approvals of drugs;
- o formulating and manufacturing drugs; and
- o 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 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. 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.

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.

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.

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.

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.

We plan to monetize OHR/AVR118, a non ophthalmology asset, through a license agreement, partnership, joint venture, or sale. However, we currently do not have any agreement to enter into an acquisition, investment, development, license, partnership, joint venture, or sale transaction, and there is no assurance that the Company will complete such a transaction.

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 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, 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 developing 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.

Issuance of Serial Preferred Stock.

The Board of Directors has the authority to issue up to 9,444,444 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 5,555,556 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, 5,555,556 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 PROPERTIES

We currently lease a lab facility in San Diego, where most of our employees operate from and conduct preclinical research on our compounds and platform technology.

Our New York offices are provided to us by BFK Law LLC, a related person of Mr. Backenroth. On October 2, 2013, we issued BFK Law LLC warrants to purchase 25,000 shares of common stock as compensation for the use of the office facilities and receptionist. Such warrants have an exercise price of \$7.96 and will be exercisable for a period of three years.

ITEM 3 LEGAL PROCEEDINGS

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 (“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.

ITEM 4 RESERVED

Part II

ITEM 5 MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Ohr’s shares of common stock are quoted on the Nasdaq Capital Market (“Nasdaq”). Its trading symbol is OHRP. Following is a table of the quotation ranges (high and low trading prices) for its shares for the last two years.

FY 2014

High Low FY 2013

High Low

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October 1 – December 31, 2013	\$8.26	\$6.61	October 1 – December 31, 2012	\$5.70	\$3.21
January 1 – March 31, 2014	\$19.65	\$7.85	January 1 – March 31, 2013	\$5.40	\$4.32
April 1 – June 30, 2014	\$14.03	\$6.82	April 1 – June 30, 2013	\$8.25	\$4.68
July 1 – September 30, 2014	\$9.98	\$7.23	July 1 – September 30, 2013	\$8.17	\$5.91

Performance Graph

The following graph compares our cumulative total stockholder return from October 1, 2009, with those of the NASDAQ Capital Market Composite Index (RCMP) and the NASDAQ Biotechnology Index (NBI). The graph assumes that U.S. \$100 was invested on October 1, 2009 in (1) our common stock, (2) the NASDAQ Capital Market Composite Index and (3) the NASDAQ Biotechnology Index. The measurement points utilized in the graph closely approximates the last day of the respective fiscal year of the Company. The historical stock performance presented below is not intended to and may not be indicative of future stock performance.

	9/30/2009	9/30/2010	9/30/2011	9/30/2012	9/30/2013	9/30/2014	12/16/2014
OHRP	\$ 100	\$ 179	\$ 536	\$ 721	\$ 1,931	\$ 1,726	\$ 1,888
Nasdaq Capital Market Composite Index	\$ 100	\$ 100	\$ 85	\$ 109	\$ 135	\$ 129	\$ 123
Nasdaq Biotech Index	\$ 100	\$ 107	\$ 115	\$ 177	\$ 261	\$ 341	\$ 366

Holdings

As of December 22, 2014 there were 181 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers. On December 19, 2014 the closing price for the common stock as reported on the NASDAQ Capital Market was \$8.74.

Dividends

We have never declared or paid cash dividends on our common stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of the business and do not anticipate paying any cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities

On December 16, 2011, the Company completed a private placement offering pursuant to which the Company sold 611,114 shares of its common stock at a price of \$1.80 per share for gross proceeds of \$1,100,000. Purchasers of the shares also received an aggregate of 305,560 Class J Warrants to purchase common stock at an exercise price of \$1.95 per share and exercisable for a period of 5 years.

On December 21, 2011, the Company issued a total of 1,042 warrants for services rendered to the Company. In conjunction with this issuance, the Company recognized \$1,967 in consulting expense. The warrants are exercisable for five years at an exercise price of \$1.95 per share.

On February 15, 2012, the Company issued 55,556 shares of common stock as a deposit on a service contract. The shares were valued at \$1.80 per share based on the fair market value of the services to be provided. The Company recorded the corresponding \$100,000 fair market value as research and development expense.

On March 3, 2012, the Company issued a total of 116,667 fully-vested warrants with a fair market value of \$220,422 as a retainer for services to be rendered to the Company. In accordance with ASC 505-50-25, the Company recorded the fair market value of the warrants as professional fees.

On March 9, 2012, the Company agreed to grant 566,667 options to board members and executives. The Company calculated a fair value of \$1.89 per option. Of the 566,667 options issued, 141,667 vested upon issuance and the remaining 425,000 vest in 25 percent tranches on each anniversary. As of September 30, 2014, an additional 141,667 options have vested.

On March 18, 2012, the Company issued 43,334 shares of common stock as a deposit on a service contract. The shares were valued at \$2.52 per share based on the fair market value of the stock on the date of issuance. The Company recorded the corresponding \$109,200 fair market value professional fees.

On April 10, 2012 14,464 warrants were exercised through a cashless exercise. Accordingly, the Company issued 4,221 shares of common stock.

On April 12, 2012, the Company issued a total of 5,000 fully-vested warrants with a fair market value of \$12,775 as a retainer for services to be rendered to the Company. In accordance with ASC 505-50-25, the Company recorded the fair market value of the warrants as professional fees.

Between May 18, 2012 and July 11, 2012, the Company issued a total of 133,334 warrants with a fair market value of \$357,394 for services yet to be rendered to the Company. The 116,667 warrants vest in two equal amounts three and six months from the date of issuance while the remaining 16,667 warrants vest over four quarters effective October 11, 2012. As of September 30, 2013, the Company has recorded \$357,394 in professional fees related to the warrants that have vested to date.

On June 28, 2012, the Company issued 1,766,334 shares of common stock for total proceeds of \$2,914,452 to investors who elected to exercise their Series H warrants at an exercise price of \$1.65. As an incentive to exercise the options, the Company agreed to issue 0.6 replacement warrants for each full Series H warrant exercised. The Company issued 1,059,804 replacement warrants under the incentive provision. The warrants were valued at

\$2,663,204. As the original Series H warrants were issued as part of cash financing, the value of these warrants has been included as an offsetting entry within additional paid-in capital.

On July 9, 2012, 10,000 warrants were exercised at an exercise price per share of \$1.50 to purchase Company common stock through a cashless exercise. Accordingly, the Company issued 4,445 shares of common stock on July 17, 2012.

On September 7, 2012, the Company issued warrants to a related party to purchase 25,000 shares of common stock as compensation for the use of the office facilities and receptionist. Such warrants have an exercise price of \$3.00 and will be exercisable for a period of five years. We have been using the office space since April 2010 and will continue to do so in the future.

On September 12, 2012, the Company issued 33,334 shares of common stock as a deposit on a service contract. The shares were valued at \$2.97 per share based on the fair market value of the stock on the date of issuance. The Company recorded the corresponding \$99,000 fair market value as professional fees.

On September 19, 2012, the Company issued 367 shares of common stock to a consultant for services. The shares were valued at \$3.06 per share based on the market price of the shares on the date of issuance. The Company recorded the corresponding \$1,122 expense to general and administrative expense.

On October 5, 2012, two holders of its Series B preferred shares converted an aggregate of 138,889 preferred shares into common shares. Accordingly, the Company issued 46,296 shares of common stock.

On October 24, 2012, the Company issued 66,667 shares of common stock for total proceeds of \$100,000 upon exercise of warrants at an exercise price per share of \$1.50.

On November 30, 2012, a former director exercised 53,624 options at an exercise price per share of \$1.95 using the cashless exercise feature in the option. Accordingly, the Company issued 30,842 shares of common stock.

On March 7, 2013, the Company issued 6,996 shares of common stock for total proceeds of \$24,976 upon exercise of warrants at an exercise price per share of \$3.57.

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On March 11, 2013, the Company issued 1,679 shares of common stock for total proceeds of \$5,994 upon exercise of warrants at an exercise price per share of \$3.57.

On March 22, 2013, the Company issued 3,704 shares of common stock for total proceeds of \$6,112 upon exercise of warrants at an exercise price per share of \$1.65.

On March 27, 2013, a director exercised 128,698 options at an exercise price per share of \$1.50 using the cashless exercise feature in the option. Accordingly, the Company issued 79,140 shares of common stock.

On March 27, 2013, 816,000 warrants were exercised at an exercise price per share of \$1.65 by cashless exercise. Accordingly, the Company issued 554,943 shares of common stock. On that same day, the Company issued 24,000 shares of common stock for total proceeds of \$39,600 upon exercise of warrants at an exercise price per share of \$1.65.

On April 1, 2013, the Company issued 43,333 shares of common stock in exchange for consulting services. These services were valued at \$214,500.

On April 5, 2013, the Company notified holders of the Company's Series B Warrants, exercisable at \$3.57 per warrant (the "Series B Warrants"), that it had accelerated the date of expiration of the Series B Warrants in accordance with their terms to April 18, 2013 at 4:00pm EDT. The letter also outlined an offer to Series B Warrant holders that exercise at least 33% of their Series B Warrant holdings to amend the terms of such holders' unexercised Series B Warrants (the "Qualified Warrants") to provide for (i) an extension of the expiration date of the Qualified Warrants to September 30, 2013 ("New Warrant Expiration Date"), (ii) increase of the exercise price to \$6.75, (iii) acceleration of the New Warrant Expiration Date at the option of the Company following a period of 5 consecutive trading days where the market price per share exceeds 200% of the exercise price then in effect, and (iv) exercise via a net exercise feature (the Qualified Warrants, as amended, referred to as the "Amended Series B Warrants"). Between March 1 and the April 18, 2013, 4:00 pm EDT expiration deadline, the Company received notices for the exercise of 1,414,995 Series B Warrants and gross proceeds of approximately \$5.06 million dollars. Accordingly, the Company issued 1,414,995 shares of Company common stock, and 2,253,531 Qualified Warrants were converted to 2,253,531 Amended Series B Warrants. 326,597 Series B Warrants were not exercised and have expired.

On April 16, 2013, 138,888 Series B preferred shares were converted into common shares. Accordingly, the Company issued 46,296 shares of common stock.

On May 15, 2013, several holders of its Series B preferred shares converted an aggregate of 3,911,112 preferred shares into common shares. Accordingly, the Company issued 1,303,704 shares of common stock.

On June 7, 2013, the Company issued 6,519 shares of common stock for total proceeds of \$10,756 upon exercise of warrants at an exercise price per share of \$1.65.

On June 14, 2013, two holders of its Series B preferred shares converted an aggregate of 894,450 preferred shares into common shares. Accordingly, the Company issued 298,150 shares of common stock.

On June 14, 2013, 1,000 warrants were exercised at an exercise price per share of \$1.50 using cashless exercise. Accordingly, the Company issued 730 common shares.

On July 2, 2013, 50,000 warrants were exercised at an exercise price per share of \$1.50 using cashless. Accordingly, the Company issued 40,458 common shares.

On July 24, 2013, the Company issued 9,100 shares of common stock to a consultant for services. The shares were valued at \$6.12 per share based on the market price of the shares on the date of issuance. The Company recorded the

corresponding \$55,667 expense to research and development for trial expense.

On September 20, 2013, the Company issued 13,889 shares of common stock for total proceeds of \$27,084 upon exercise of warrants at an exercise price per share of \$1.95.

On October 2, 2013, the Company issued 6,282 shares of common stock to a legal firm to settle \$50,000 in accounts payable. These shares were valued at \$7.96 which was the price of the stock at the close of business on the previous trading day.

On October 31, 2013, 55,556 Series A Warrants with an exercise price of \$3.60 were exercised. Accordingly, the Company issued 55,556 common shares for proceeds of \$200,002.

On November 13, 2013, two holders of its Series B preferred shares converted an aggregate of 500,000 preferred shares into 166,667 common shares. As of the date of this filing, there are no Series B Preferred shares outstanding.

On February 26, 2014, 30,741 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 10,634 common shares.

On February 28, 2014, 23,867 warrants were exercised at an exercise price per share of \$3.60 using cashless exercise. Accordingly, the Company issued 18,408 common shares.

On March 18, 2014, 28,000 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 14,959 common shares.

On March 19, 2014, 1,616,667 warrants were exercised at an exercise price per share of \$1.50 using cashless exercise. Accordingly, the Company issued 1,468,765 common shares.

On March 20, 2014, 19,723 warrants were exercised at an exercise price per share of \$1.95 using cashless exercise. Accordingly, the Company issued 17,672 common shares.

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On March 24, 2014, 13,889 warrants were exercised at an exercise price per share of \$1.95 using cashless exercise. Accordingly, the Company issued 12,448 common shares.

On March 24, 2014, 33,267 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 19,123 common shares.

On March 26, 2014, 27,778 warrants were exercised at an exercise price per share of \$1.95 using cashless exercise. Accordingly, the Company issued 24,660 common shares.

On March 26, 2014, 500 warrants with an exercise price of \$1.50 were exercised. Accordingly, the Company issued 500 common shares for proceeds of \$750.

On March 28, 2014, 34,723 warrants were exercised at an exercise price per share of \$1.95 using cashless exercise. Accordingly, the Company issued 30,826 common shares.

On March 28, 2014, 339,841 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 198,165 common shares.

On March 31, 2014, 16,204 warrants were exercised at an exercise price per share of \$1.95 using cashless exercise. Accordingly, the Company issued 14,332 common shares.

On April 10, 2014, 14,815 warrants were exercised at an exercise price per share of \$3.60 using cashless exercise. Accordingly, the Company issued 11,068 common shares.

On April 16, 2014, 3,334 warrants were exercised at an exercise price per share of \$3.60 using cashless exercise. Accordingly, the Company issued 2,978 common shares.

On April 16, 2014, 5,652 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 3,199 common shares.

On June 25, 2014, 50,000 warrants were exercised at an exercise price per share of \$1.20. Accordingly, the Company issued 50,000 common shares and received gross proceeds of \$60,000.

On September 3, 2014, 14,418 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 3,147 common shares.

On September 11, 2014, 1,434,166 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 304,707 common shares.

On September 12, 2014, 330,122 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 67,802 common shares.

On September 16, 2014, 13,889 warrants were exercised at an exercise price per share of \$1.95 using cashless exercise. Accordingly, the Company issued 10,362 common shares.

On September 25, 2014, 28,837 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 5,527 common shares.

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.

Stock Repurchase

Ohr has not engaged in any stock repurchase transactions, and no stock repurchase plan is currently in place.

ITEM 6 SELECTED FINANCIAL DATA

The tables below set forth selected historical financial information of the Company that has been derived from the audited financial statements as of September 30, 2010, 2011, 2012, 2013 and 2014, and for the five years in the period ended September 30, 2014. The selected historical financial data should be read in conjunction with the consolidated financial statements and related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, included elsewhere in this Form 10-K.

Consolidated Statements of Operations Data:

	Year Ended September 30,				
	2010	2011	2012	2013	2014
Operating expenses					
General and administrative	\$96,414	\$104,348	\$135,552	\$312,541	\$555,735
Professional fees	362,603	338,055	875,868	608,408	1,780,657
Research and development	302,553	521,969	1,625,695	2,610,120	3,990,875
Salaries and wages	254,021	279,029	649,293	1,089,847	2,795,657
Total operating expenses	1,015,591	1,243,401	3,286,408	4,620,916	9,122,924
Operating loss	(1,015,591)	(1,243,401)	(3,286,408)	(4,620,916)	(9,122,924)
Other income (expenses)					
Interest expense	(21,493)	(2,433)	(1,817)	(4,689)	(5,576)
Change in derivative liability	1,480,586	(3,977,041)	1,812,224	(1,117,642)	—
Share in loss on investment in joint venture	—	—	—	—	(10,643)
Gain on sale of assets	—	70,500	—	—	—
Gain on settlement of debt	19,410	49,179	21,005	—	—
Other income and expense	31,465	1,677	112	90,759	8,479
Total other income (expense)	1,509,968	(3,858,118)	1,831,524	(1,031,572)	(7,740)
Loss from operations	494,377	(5,101,519)	(1,454,884)	(5,652,488)	(9,130,664)
Provision for income taxes	—	—	—	—	—
Net loss	\$494,377	\$(5,101,519)	\$(1,454,884)	\$(5,652,488)	\$(9,130,664)
Net loss per basic and diluted share	\$0.05	\$(0.40)	\$(0.10)	\$(0.30)	\$(0.41)
Weighted-average shares used to compute net loss per basic and diluted share:	10,940,626	12,888,915	14,242,792	18,707,759	22,141,538

Combined and Consolidated Balance Sheet Data:

	As of September 30,				
	2010	2011	2012	2013	2014
Total assets	\$1,412,025	\$1,412,846	\$3,517,420	\$5,743,865	\$32,025,144
Total liabilities	1,794,482	6,194,599	1,091,195	479,737	5,273,122
Total shareholders' equity	(382,457)	(4,781,753)	2,426,225	5,264,128	26,752,022

ITEM 7 MANAGERMENTS' DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Safe Harbor Statement

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” on page 9 of this Annual Report.

On June 3, 2013, the Company effected a 3:1 reverse stock split on its shares of common stock. Unless otherwise noted, impacted amounts and share information included in the financial statements and notes thereto 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 in the notes to the financial statements may be slightly different than previously reported due to rounding of fractional shares as a result of the reverse stock split.

General

The Company is a pharmaceutical company focused on the development of the Company’s previously acquired compounds and technologies with a focus on the clinical and preclinical development of ophthalmology products. Our lead clinical program, Squalamine eye drops (OHR-102), is being evaluated in multiple clinical trials for the treatment of back-of-the-eye disorders including the wet form of age-related macular degeneration, and we are also developing a recently acquired sustained release ocular drug delivery platform technology.

The Company will continue to incur ongoing operating losses, which are expected to increase substantially as it funds development and clinical testing of its pharmaceutical compounds. In addition, losses will be incurred in paying ongoing reporting expenses, including legal and accounting expenses, as necessary to maintain the Company as a public entity. No projected date for potential revenues can be made, and the Company is undercapitalized at present to completely develop, test and market any pharmaceutical product.

Until the Company is able to generate significant revenue from its principal operations, it will remain classified as a development stage company. The Company can give no assurance that it will be successful in such efforts or that its limited operating funds will be adequate to support the Company's operations, nor can there be any assurance of any additional funding being available to the Company.

Liquidity and Capital Resources

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

Net working capital reserves increased from the beginning of the 2014 fiscal year to the end by \$3,395,534 (to \$8,084,042 from \$4,688,508) primarily due to capital raised through the sale of common stock. At present, the Company has no bank line of credit or other fixed source of capital reserves. Should it need additional capital in the future, it will be primarily reliant upon private or public placement of its equities for which there can be no warranty or assurance that the Company may be successful in such efforts. The Company raised \$16.9 million in net proceeds from a registered direct offering in April 2014, and management believes the Company has sufficient capital to meet its planned operating needs through September 30, 2015.

Results of Operations

For the fiscal year ended September 30, 2014, the Company had zero revenues and operating expenses of approximately \$9,122,924. The loss from operations was comprised of \$3,990,875 in research and development costs, \$1,780,657 in professional fees, \$2,795,657 in salaries and wages, and \$555,735 in general and administrative expenses. During the same period, the Company recorded interest expense of \$5,576, a loss on investment of subsidiary of \$10,643 and other income items totaling \$8,479. The net loss for the year ended September 30, 2014 was \$9,130,664.

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For the fiscal year ended September 30, 2013, the Company had zero revenues and operating expenses of approximately \$4,620,916. The loss from operations was comprised of \$2,610,120 in research and development costs, \$608,408 in professional fees, \$1,089,847 in salaries and wages, and \$312,541 in general and administrative expenses. During the same period, the Company recorded interest expense of \$4,689, a loss on derivative liabilities of \$1,117,642 and other income items totaling \$90,759. The net loss for the year ended September 30, 2013 was \$5,652,488.

For the fiscal year ended September 30, 2012, the Company had zero revenues and operating expenses of approximately \$3,286,408. The loss from operations was comprised of \$1,625,695 in research and development costs, \$875,868 in professional fees, \$649,293 in salaries and wages, and \$135,552 in general and administrative expenses. During the same period, the Company recorded interest expense of \$1,817, a gain on the settlement of debt of \$21,005, a gain on derivative liabilities of \$1,812,224, and other income items totaling \$112. The net loss for the year ended September 30, 2012 was \$1,454,884.

As noted above, the Company had no revenues for fiscal year 2014, and does not anticipate that it will have meaningful revenues in fiscal year 2015. The operating expenses of the Company increased from fiscal year 2013 to 2014 by approximately \$4,502,008. The Company had increases in nearly all expense categories as ongoing development costs and testing efforts for its pharmaceutical products continue. The Company anticipates it will have higher expenditures in fiscal year 2014, including clinical development costs, again with no meaningful offsetting revenues.

Results of operations for the years ended September 30, 2014 reflect the following changes from the prior period:

	2014	2013	Change
Operating Expenses			
General and administrative	\$555,735	\$312,541	\$243,194
Professional fees	1,780,657	608,408	1,172,249
Research and development	3,990,875	2,610,120	1,380,755
Salaries and wages	2,795,657	1,089,847	1,705,810
Total Operating Expenses	9,122,924	4,620,916	4,502,008
Operating Income (Loss)	(9,122,924)	(4,620,916)	(4,502,008)
Share in losses on investment in joint venture	(10,643)	—	(10,643)
Change in derivative liability	—	(1,117,642)	1,117,642
Other income and expenses	2,903	86,070	(83,167)
Net Loss	\$(9,130,664)	\$(5,652,488)	\$(3,478,176)

Results of continuing operations for the years ended September 30, 2013 reflect the following changes from the prior period:

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	2013	2012	Change
Operating Expenses			
General and administrative	\$ 312,541	\$ 135,552	\$ 176,989
Professional fees	608,408	875,868	(267,460)
Research and development	2,610,120	1,625,695	984,425
Salaries and wages	1,089,847	649,293	440,554
Total Operating Expenses	4,620,916	3,286,408	1,334,508
Operating Income (Loss)	(4,620,916)	(3,286,408)	(1,334,508)
Share in losses on investment in joint venture	—	—	—
Change in derivative liability	(1,117,642)	1,812,224	(2,929,866)
Gain on settlement of debt	—	21,005	(21,005)
Other income and expenses	86,070	(1,705)	87,775
Net Loss	\$(5,652,488)	\$(1,454,884)	\$(4,197,604)

Until the Company experiences an increase in revenues as it continues to implement its business plan, significant losses are expected to continue as the trend is reflected in the chart above.

Critical Accounting Estimates

Fair Value of Financial Instruments

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

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

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

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

Derivative Financial Instruments

The Company generally does not use derivative financial instruments to hedge exposures to cash-flow risks or market-risks that may affect the fair values of its financial instruments. The Company utilizes various types of financing to fund our business needs, including warrants and other instruments not indexed to our stock. The Company is required to record its derivative instruments at their fair value. Changes in the fair value of derivatives are recognized in earnings in accordance with ASC 815.

Research and Development

The Company follows the policy of expensing its research and development costs in the period in which they are incurred in accordance with ASC 730. The Company incurred net research and development expenses of \$3,990,875, \$2,610,120, and \$1,625,695 during the years ended September 30, 2014, 2013, and 2012, respectively.

Share-based Compensation

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

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

Goodwill and Intangibles

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

The Company performs its annual impairment review of goodwill in September, and when a triggering event occurs between annual impairment tests. The Company recorded no impairment loss for the years ended September 30, 2014 and 2013.

The Company’s other finite-lived intangible assets consist of license rights and patents. The Company amortizes its patents over the life of each patent and license rights over the remaining life of the patents that it has rights for. The current license rights have a remaining life of 16 years. During the years ended September 30, 2014, 2013, and 2012 the Company recognized \$448,456, \$77,789, and \$78,273 in amortization expense on the patents and license rights, respectively. The amortization expense has been included in general and administrative expense.

Off-Balance Sheet Arrangements

The Company has not entered into any off-balance sheet arrangements.

Tabular Description of Principal Contracts

The Company is not engaged in any contract for sale or distribution of its product to date; and, therefore, does not have any specific disclosure under this heading.

ITEM 7A QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Following are the financial statements prepared by Ohr and audited by its independent auditors. These financial statements constitute the formal presentation of financial information by the Company, such that all other financial information contained in this 10-K report should be read and reviewed in light of the following financial statements and notes thereto. Should there exist any conflict between information appearing elsewhere in this Report and the following financial statements, the financial statements should be given primary definition and control. The notes attached to the financial statements constitute an integral part of the financial disclosure and should be read and reviewed in connection with the financial statements.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

To the Stockholders of OHR Pharmaceutical, Inc.:

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of the unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Accordingly, even an effective system of internal control over financial reporting will provide only reasonable assurance with respect to the reliability of financial reporting and financial statement preparation.

Management assessed our internal control over financial reporting as of September 30, 2014, the end of our fiscal year. Management based its assessment on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework). Management's assessment included the evaluation of such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies and our overall control environment.

Based on its assessment, management concluded that there was a material weakness in internal controls over financial reporting related to the control and evaluation regarding the assessment of fair value accounting principles related to non-recurring and complex transactions. A material weakness is a deficiency or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Based on its assessment, management concluded that our internal control over financial reporting was not effective as of the end of the period covered by this Annual Report on Form 10-K.

We reviewed the results of management's assessment with the Audit Committee of our Board of Directors. Additionally, our independent registered public accounting firm, Malone Bailey, LLP, independently assessed our internal control over financial reporting. Malone Bailey has issued a report on our internal control over financial reporting, which is included in this annual report.

/s/ IRACH TARAPOREWALA /s/ SAM BACKENROTH

Irach Taraporewala
Chief Executive Officer

Sam Backenroth
Chief Financial Officer and Principal Accounting Officer

December 22, 2014

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

OHR Pharmaceutical, Inc.

New York, NY

We have audited the accompanying consolidated balance sheets of OHR Pharmaceutical, Inc. and its subsidiaries (collectively, the “Company”) as of September 30, 2014 and 2013 and the related consolidated statements of operations, stockholders’ equity and cash flows for each of the three years in the period ended September 30, 2014. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of OHR Pharmaceutical, Inc. and its subsidiaries as of September 30, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2014, in conformity with accounting principles generally accepted in the United States of America.

We, also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), OHR Pharmaceutical Inc.’s internal control over financial reporting as of September 30, 2014, based on the criteria established in Internal Control — Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated December 22, 2014 expressed an adverse opinion.

/s/ MaloneBailey, LLP

www.malone-bailey.com

Houston, Texas

December 22, 2014

F-1

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

OHR Pharmaceutical, Inc.

New York, NY

We have audited OHR Pharmaceutical, Inc. and its subsidiaries' (collectively, the "Company") internal control over financial reporting as of September 30, 2014, based on criteria established in Internal Control – Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying "Management's Report on Internal Control over Financial Reporting." Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may

deteriorate.

A material weakness is a control deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. Management has identified a material weakness in controls over fair value accounting treatment of certain non-recurring and complex transactions. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2014 financial statements, and this report does not affect our report dated December 19, 2014 on those financial statements.

In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of September 30, 2014, based on criteria established in Internal Control—Integrated Framework (1992) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets and the related statements of operations, stockholders' equity, and cash flows of the Company, and our report dated December 22, 2014 expressed an unqualified opinion.

/s/ MaloneBailey, LLP

www.malone-bailey.com

Houston, Texas

December 22, 2014

F-2

OHR PHARMACEUTICAL, INC.

Consolidated Balance Sheets

	September 30, 2014	September 30, 2013
<u>ASSETS</u>		
CURRENT ASSETS		
Cash	\$ 13,220,494	\$ 5,122,895
Prepaid expenses and other current assets	133,527	45,350
Total Current Assets	13,354,021	5,168,245
EQUIPMENT, net	104,425	29,755
OTHER ASSETS		
Security deposit	12,243	—
Investment in joint venture	3,143	—
Intangible assets, net	17,810,400	545,865
Goodwill	740,912	—
TOTAL ASSETS	\$ 32,025,144	\$ 5,743,865
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 351,864	\$ 465,686
Notes payable	43,899	14,051
Contingent consideration	4,877,359	—
Total Current Liabilities	5,273,122	479,737
TOTAL LIABILITIES	5,273,122	479,737
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred stock, Series B; 6,000,000 shares authorized, \$0.0001 par value, 0 and 500,000 shares issued and outstanding, respectively	—	50
Common stock; 180,000,000 shares authorized, \$0.0001 par value, 25,254,190 and 19,741,541 shares issued and outstanding, respectively	2,525	1,974
Additional paid-in capital	70,063,045	39,444,988
Accumulated deficit	(43,313,548)	(34,182,884)
Total Stockholders' Equity	26,752,022	5,264,128
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 32,025,144	\$ 5,743,865

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

F-3

OHR PHARMACEUTICAL, INC.

Consolidated Statements of Operations

	For the Year Ended September 30,		
	2014	2013	2012
OPERATING EXPENSES			
General and administrative	\$555,735	\$312,541	\$135,552
Professional fees	1,780,657	608,408	875,868
Research and development	3,990,875	2,610,120	1,625,695
Salaries and wages	2,795,657	1,089,847	649,293
Total Operating Expenses	9,122,924	4,620,916	3,286,408
OPERATING LOSS	(9,122,924)	(4,620,916)	(3,286,408)
OTHER INCOME (EXPENSE)			
Interest expense	(5,576)	(4,689)	(1,817)
Change in derivative liability	—	(1,117,642)	1,812,224
Share in losses on investment in joint venture	(10,643)	—	—
Gain on settlement of debt	—	—	21,005
Other income and expense	8,479	90,759	112
Total Other Income (Expense)	(7,740)	(1,031,572)	1,831,524
LOSS FROM OPERATIONS BEFORE INCOME TAXES	(9,130,664)	(5,652,488)	(1,454,884)
PROVISION FOR INCOME TAXES	—	—	—
NET LOSS	\$(9,130,664)	\$(5,652,488)	\$(1,454,884)
BASIC AND DILUTED LOSS PER SHARE	\$(0.41)	\$(0.30)	\$(0.10)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:			
BASIC AND DILUTED	22,141,538	18,707,759	14,242,792

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

OHR PHARMACEUTICAL, INC.

Consolidated Statements of Stockholders' Equity

	Series B Preferred Stock Shares	Amount	Common Stock Shares	Amount	Additional Paid-in Capital	Stock Subscription Receivable	Accumulated Deficit	Total Stockholders' Equity
Balance, September 30, 2011	5,583,336	\$ 558	13,234,194	\$ 1,324	\$22,291,877	\$ —	\$(27,075,512)	\$(4,781,753)
Common stock and warrants issued for cash	—	—	611,114	61	958,469	—	—	958,530
Common stock and warrants issued in advance of services	—	—	132,589	13	941,398	—	—	941,411
Common stock issued in conversion of warrants	—	—	1,774,999	177	2,914,274	(11,891)	—	2,902,560
Fair value of employee stock options	—	—	—	—	406,267	—	—	406,267
Adjustment for derivative liability	—	—	—	—	3,454,094	—	—	3,454,094
Net loss for the year ended	—	—	—	—	—	—	(1,454,884)	(1,454,884)
September 30, 2012								
Balance, September 30, 2012	5,583,336	558	15,752,896	1,575	30,966,379	(11,891)	(28,530,396)	2,426,225
Common stock issued in exercise of warrants	—	—	2,131,784	214	5,239,650	—	—	5,239,864
Termination of derivative liability	—	—	—	—	1,886,338	—	—	1,886,338

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Conversion of preferred series B to common stock	(5,083,336)	(508)	1,694,446	169	339	—	—	—
Exercise of director options	—	—	109,982	11	(11)	—	—	—
Common stock issued for services	—	—	52,433	5	270,162	—	—	270,167
Warrants issued for services	—	—	—	—	335,869	—	—	335,869
Fair value of employee stock options	—	—	—	—	746,262	—	—	746,262
Proceeds received for subscription receivable	—	—	—	—	—	11,891	—	11,891
Net loss for the year ended September 30, 2013	—	—	—	—	—	—	(5,652,488)	(5,652,488)
Balance, September 30, 2013	500,000	50	19,741,541	1,974	39,444,988	—	(34,182,884)	5,264,128
Conversion of preferred series B to common stock	(500,000)	(50)	166,667	17	33	—	—	—
Exercise of warrants for cash	—	—	106,056	11	260,741	—	—	260,752
Cashless exercise of warrants	—	—	2,238,782	223	(223)	—	—	—
Common stock issued for settlement of accounts payable	—	—	6,282	1	49,999	—	—	50,000
Common stock issued for cash	—	—	1,800,000	180	16,875,820	—	—	16,876,000
Common stock issued for	—	—	1,194,862	119	10,180,105	—	—	10,180,224

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acquisition of assets								
Warrants issued for services	—	—	—	—	1,177,095	—	—	1,177,095
Fair value of employee stock options	—	—	—	—	2,074,487	—	—	2,074,487
Net loss for the year ended	—	—	—	—	—	—	(9,130,664)	(9,130,664)
September 30, 2014								
Balance, September 30, 2014	—	\$ —	25,254,190	\$ 2,525	\$ 70,063,045	\$ —	\$(43,313,548)	\$ 26,752,022

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

OHR PHARMACEUTICAL, INC.

Consolidated Statements of Cash Flows

	For the Year Ended September 30,		
	2014	2013	2012
OPERATING ACTIVITIES			
Net loss	\$(9,130,664)	\$(5,652,488)	\$(1,454,884)
Adjustments to reconcile net loss to net cash used by operating activities:			
Common stock issued for services	—	270,167	309,322
Fair value of warrants issued for services	1,177,095	335,869	632,089
Fair value of employee stock options	2,074,487	746,262	406,267
Gain on settlement of debt	—	—	(21,005)
Loss on derivative liability	—	1,117,642	(1,812,224)
Share in losses on investment in joint venture	10,643	—	—
Depreciation	17,850	13,356	9,456
Amortization of patent costs	448,456	77,789	78,273
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	105,823	236,492	78,465
Accounts payable and accrued expenses	(63,822)	165,224	20,412
Net Cash Used in Operating Activities	(5,360,132)	(2,689,687)	(1,753,829)
INVESTING ACTIVITIES			
Purchase of equipment	(1,083)	—	(33,403)
Investment in joint venture	(13,786)	—	—
Purchase of patents and other intellectual property	(3,500,000)	—	—
Net Cash Provided by (Used in) Investing Activities	(3,514,869)	—	(33,403)
FINANCING ACTIVITIES			
Proceeds from the sale of common stock and warrants	16,876,000	—	1,100,000
Proceeds from warrants exercised for cash	260,752	5,251,755	2,902,560
Repayments of short-term notes payable	(164,152)	(71,586)	(52,701)
Net Cash Provided by Financing Activities	16,972,600	5,180,169	3,949,859
NET CHANGE IN CASH AND CASH EQUIVALENTS	8,097,599	2,490,482	2,162,627
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	5,122,895	2,632,413	469,786
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$13,220,494	\$5,122,895	\$2,632,413
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
CASH PAID FOR:			
Interest	\$5,576	\$4,192	\$1,817
Income Taxes	—	—	—

NON CASH FINANCING ACTIVITIES:

Reclassification of derivative liability to permanent equity	\$—	\$1,886,338	\$3,454,094
Common stock issued to acquire intangible assets	10,180,224	—	—
Financing of insurance premiums through issuance of short term notes	194,000	63,600	74,738
Conversion of preferred for common stock	50	508	—
Noncash exercise of options and warrants	223	11	—
Common stock issued to settle accounts payable	50,000	—	—

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

OHR PHARMACEUTICAL, INC.

Notes to the Consolidated Financial Statements

September 30, 2014

NOTE 1 – DESCRIPTION OF BUSINESS

OHR Pharmaceutical, Inc. (“we”, or the “Company”) is a pharmaceutical company focused on the development of the Company’s previously acquired compounds and technologies with a focus on the clinical and preclinical development of ophthalmology products. Our lead clinical program, Squalamine eye drops (OHR-102), is being evaluated in multiple clinical trials for the treatment of back-of-the-eye disorders including the wet form of age-related macular degeneration (“wet-AMD”). We are also developing a recently acquired sustained release ocular drug delivery platform technology.

On June 3, 2013, the Company effected a 3:1 reverse stock split on its shares of common stock. Unless otherwise noted, impacted amounts and share information included in the financial statements and notes thereto 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 in the notes to the financial statements may be slightly different than previously reported due to rounding of fractional shares as a result of the reverse stock split.

On February 26, 2014, the Company entered into a Joint Venture Agreement and related agreements with Cold Spring Harbor Laboratory (“CSHL”) pursuant to which a joint venture, DepYmed Inc. (“DepYmed”), was formed to further preclinical and clinical development of Ohr’s Trodusquemine and analogues as PTP1B inhibitors for oncology indications. DepYmed is jointly owned and managed by CSHL and the Company, and licenses research from CSHL and intellectual property from the Company. This joint venture is being accounted for under the equity method, since it does not meet the criteria of a variable interest entity and the Company does not have control of the entity.

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.

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.

Accounting Basis and Principles of Consolidation

The Company prepared the accompanying consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, or GAAP, and they include the accounts of Ohr Pharmaceutical, Inc. and its subsidiaries. The Company has elected a September 30 fiscal year end. All intercompany balances and transactions have been eliminated in consolidation. The Company also uses the equity method to account for its joint venture. This method is used because the joint venture does not meet the variable interest entity requirements for consolidation and the Company does not have control of the entity.

Cash and Cash Equivalents

The Company considers all highly-liquid investments purchased with an original maturity date of three months or less to be cash equivalents.

Concentration of Credit Risk

Financial instruments, which potentially subject us to concentrations of credit risk, consist principally of cash. Our cash balances are maintained in accounts held by major banks and financial institutions located in the United States. The Company occasionally maintains amounts on deposit with a financial institution that are in excess of the federally insured limit of \$250,000. The risk is managed by maintaining all deposits in high quality financial institutions. The Company had approximately \$12,970,494 and \$4,872,895 of cash balances in excess of federally insured limits at September 30, 2014 and 2013, respectively.

Property and Equipment

Property and equipment is recorded at cost less accumulated depreciation. Depreciation and amortization is calculated using the straight-line method over the expected useful life of the asset, after the asset is placed in service. The Company generally uses the following depreciable lives for its major classifications of property and equipment:

Description	Useful Lives
Equipment	5 years
Lab Equipment	5 years
Leasehold Improvements	7 years
Office Furniture and Fixtures	3 years

Expenditures associated with upgrades and enhancements that improve, add functionality, or otherwise extend the life of property and equipment that exceed \$1,000 are capitalized, while expenditures that do not, such as repairs and maintenance, are expensed as incurred.

Valuation of Long-Lived Assets

Long-lived tangible assets and definite-lived intangible assets are reviewed for possible impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The Company uses an estimate of undiscounted future net cash flows of the assets over the remaining useful lives in determining whether the carrying value of the assets is recoverable. If the carrying values of the assets exceed the expected future cash flows of the assets, the Company recognizes an impairment loss equal to the difference between the carrying values of the assets and their estimated fair values. Impairment of long-lived assets is assessed at the lowest levels for which there are identifiable cash flows that are independent from other groups of assets. The evaluation of long-lived assets requires the Company to use estimates of future cash flows. However, actual cash flows may differ from the estimated future cash flows used in these impairment tests. As of September 30, 2014 and 2013, management does not believe any of the Company's long-lived assets were impaired.

Fair Value of Financial Instruments

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

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

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

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

The following table presents assets and liabilities that are measured and recognized at fair value as of September 30, 2014 and 2013, on a recurring basis:

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

Assets and liabilities measured at fair value on a recurring basis at September 30, 2013	Level 1	Level 2	Level 3	Total Carrying Value
Stock warrant derivative liabilities	\$ —	\$ —	\$ —	\$ —

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The following is a description of the valuation methodology used to measure fair value, as well as the general classification of such instruments pursuant to the valuation hierarchy.

Nonrecurring Fair Value Measurements

The Company also measures certain other financial assets at fair value on a nonrecurring basis in accordance with GAAP. As of September 30, 2014, the Company had intangible assets that were measured at fair value on a nonrecurring basis valued at \$17,810,000. The Company classified these fair value measurements as Level 3 of the fair value hierarchy as the valuations included Level 3 inputs that were significant to the estimate of fair value.

Stock Warrant Derivative Liability

Market prices are not available for the Company's warrants nor are market prices of similar warrants available. The Company assessed that the fair value of this liability approximates its carrying value since carrying value has been adjusted to fair value.

The method described above may produce a current fair value calculation that may not be indicative of net realizable value or reflective of future fair values. If a readily determined market value became available or if actual performance were to vary appreciably from assumptions used, assumptions may need to be adjusted, which could result in material differences from the recorded carrying amounts. The Company believes its method of determining fair value is appropriate and consistent with other market participants. However, the use of different methodologies or different assumptions to value certain financial instruments could result in a different estimate of fair value.

The following tables present the fair value of financial instruments as of September 30, 2014, by caption on the balance sheet and by ASC 820 valuation hierarchy described above.

Level 3 Reconciliation:	Stock Warrant Derivative	Contingent Stock Consideration
Level 3 assets and liabilities at September 30, 2011	\$(5,893,544)	\$ —

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Purchases, sales, issuances and settlements (net)	3,312,624	—
Mark to market adjustments	1,812,224	—
Level 3 assets and liabilities at September 30, 2012	(768,696)	—
Purchases, sales, issuances and settlements (net)	1,886,338	—
Mark to market adjustments	(1,117,642)	—
Total level 3 assets and liabilities at September 30, 2013	—	—
Purchases, sales, issuances and settlements (net)	—	4,877,359
Mark to market adjustments	—	—
Total level 3 assets and liabilities at September 30, 2014	\$—	\$ 4,877,359

In March 2013, the stock warrants were fully exercised; 24,000 warrants for cash and the remaining 816,000 warrants through a cashless exercise. Consequently, these instruments were no longer accounted for as derivatives. The stock warrants were marked to market as of the exercise date and the applicable fair value related to the 816,000 warrants of \$1,886,338 was credited to additional paid in capital while the applicable fair value for the 24,000 warrants of \$55,481 was credited to gain on derivative liability.

Derivative Financial Instruments

The Company generally does not use derivative financial instruments to hedge exposures to cash-flow risks or market-risks that may affect the fair values of its financial instruments. The Company utilizes various types of financing to fund its business needs, including warrants and other instruments not indexed to our stock. The Company is required to record its derivative instruments at their fair value. Changes in the fair value of derivatives are recognized in earnings in accordance with ASC 815.

Goodwill and Intangibles

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

The Company performs its annual impairment review of goodwill in September, and when a triggering event occurs between annual impairment tests. The Company recorded no impairment loss for the years ended September 30, 2014 and 2013.

The Company’s other finite-lived intangible assets consist of license rights and patents. The Company amortizes its patents over the life of each patent and license rights over the remaining life of the patents that it has rights for. The current license rights have a remaining life of 16 years. During the years ended September 30, 2014, 2013, and 2012 the Company recognized \$448,456, \$77,789, and \$78,273 in amortization expense on the patents and license rights, respectively. The amortization expense has been included in general and administrative expense.

Research and Development

Research and development expenses are expensed in the consolidated statements of operations as incurred in accordance with FASB ASC 730, *Research and Development*. Research and development expenses include salaries, related employee expenses, clinical trial expenses, research expenses, consulting fees, and laboratory costs. The Company incurred net research and development expenses of \$3,990,875, \$2,610,120, and \$1,625,695 during the years ended September 30, 2014, 2013, and 2012 respectively.

Share-based Compensation

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

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

Income Taxes

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The charge for taxation is based on the results for the year as adjusted for items which are non-assessable or disallowed. It is calculated using tax rates that have been enacted or substantively enacted by the balance sheet date.

In July, 2006, the FASB issued ASC 740, *Accounting for Uncertainty in Income Taxes*, which clarifies the accounting for uncertainty in tax positions taken or expected to be taken in a return. ASC 740 provides guidance on the measurement, recognition, classification and disclosure of tax positions, along with accounting for the related interest and penalties. Under this pronouncement, the Company recognizes the financial statement benefit of a tax position only after determining that a position would more likely than not be sustained based upon its technical merit if challenged by the relevant taxing authority and taken by management to the court of the last resort. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon settlement with the relevant tax authority. ASC 740 became effective for the Company as of July 1, 2008, and had no material impact on the Company's financial statements.

The Company's policy is to recognize both interest and penalties related to unrecognized tax benefits in income tax expense. Interest and penalties on unrecognized tax benefits expected to result in payment of cash within one year are classified as accrued liabilities, while those expected beyond one year are classified as other liabilities. The Company has not recorded any interest and penalties since its inception.

The Company files income tax returns in the U.S. federal tax jurisdiction and various state tax jurisdictions. The tax years for 2011 to 2013 remain open for examination by federal and/or state tax jurisdictions. The Company is currently not under examination by any other tax jurisdictions for any tax years.

Loss Per Share

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

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

For the years ended September 30, 2014 and 2013, all of the Company's potentially dilutive securities (warrants and options) were excluded from the computation of diluted loss per share as they were anti-dilutive. The total numbers of potentially dilutive shares that were excluded were 3,995,343 and 6,994,269 at September 30, 2014 and 2013, respectively.

Reclassification of Financial Statement Accounts

Certain amounts in the September 30, 2013 and 2012 financial statements have been reclassified to conform to the presentation in the September 30, 2014 financial statements.

Recent Accounting Pronouncements

Management has considered all recent accounting pronouncements issued since the last audit of the Company's financial statements. The Company's management believes that these recent pronouncements will not have a material effect on the Company's financial statements.

NOTE 3 – ASSET ACQUISITION

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.

Purchase Price	
Cash at closing	\$3,500,000
Stock Issued	10,180,224
Contingent Consideration Stock	4,877,359
Total Purchase Price	\$18,557,583

The acquisition of the assets of SKS has been accounted for as an acquisition of a business whereby the purchase price was allocated to tangible and intangible assets acquired based on their fair values as of the acquisition date.

The Company evaluated the contingent stock consideration in accordance with ASC 480 and 815, regarding contingent consideration arrangements. Based on this evaluation, the Company has determined that the contingent consideration met the liability criteria and should be recorded as a liability of the Company.

A summary of the pro forma purchase price allocation as of May 30, 2014 is as follows:

Purchase Price Allocation	
Lab equipment	\$86,733
Computer and software	2,523
Leasehold improvements	2,181
Security deposit	12,243
License rights	17,712,991
Goodwill	740,912
Total Purchase Price Allocation	\$18,557,583

The following pro forma statement of operations presents the results of operations as if the SKS Acquisition had taken place on October 1, 2013 and represents the combined revenues and expenses of the Company had the SKS Acquisition existed for the entire year ended September 30, 2014:

Pro Forma Consolidated Statement of Operations For the Year Ended September 30, 2014 (Unaudited)	
REVENUES	\$1,839,000
OPERATING EXPENSES	
General and administrative	827,345
Professional fees	2,335,422
Research and development	5,948,332
Salaries and wages	2,616,783
Total Operating Expenses	11,727,882
OPERATING LOSS	(9,888,882)
OTHER INCOME (EXPENSE)	
Interest expense	(62,944)
Other income	8,478
Total Other Income (Expense)	(54,466)
NET LOSS	\$(9,943,348)

NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment at September 30, 2014 and 2013 consist of:

	2014	2013
Equipment	\$59,503	\$58,241
Lab Equipment	86,733	—
Leasehold Improvements	2,181	—
Office Furniture and Fixture	2,523	—
	150,940	58,241
Accumulated Depreciation	(46,515)	(28,486)
Total Property and Equipment	\$104,425	\$29,755

Depreciation expense for the years ended September 30, 2014, 2013 and 2012 was \$17,850, \$13,356 and \$9,456, respectively.

NOTE 5 – INTANGIBLE ASSETS

Intangible assets at September 30, 2014 and 2013 consist of:

	2014	2013
License Rights	\$17,712,991	\$—
Patent Costs	800,000	800,000
	18,512,991	800,000
Accumulated Amortization	(702,591)	(254,135)
Total Intangible Assets	\$17,810,400	\$545,865

During the years ended September 30, 2014, 2013 and 2012, the Company recognized \$448,456, \$77,789 and \$78,273, respectively, in amortization expense on the patents. The amortization expense has been included in research and development expense.

NOTE 6 – NOTES PAYABLE

On February 28, 2013, the Company entered into a financing arrangement for its directors and officers insurance policy in the amount of \$63,600. The financing arrangement bears interest at 7.25% and was fully paid 9 months from the date of issuance. As of September 30, 2014, the Company had repaid \$63,600 of principal and had paid interest of \$2,301 in cash.

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 bears interest at 6.75% and will be fully paid in 12 months from the date of issuance. As of September 30, 2014, the Company had repaid \$150,101 of principal and had paid interest of \$5,064 in cash.

F-13

NOTE 7 – DERIVATIVE LIABILITY AND FAIR VALUE MEASUREMENTS

Effective July 31, 2009, the Company adopted ASC Topic No. 815-40 which defines determining whether an instrument (or embedded feature) is solely indexed to an entity's own stock. As of September 30, 2013, the Company no securities which contain certain provisions which result in these securities not being solely indexed to the Company's own stock and are not afforded equity treatment.

On January 15, 2010 the Company issued 1,861,112 warrants (the "Class H Warrants") with an exercise price of \$1.65 to warrant holders that had exercised warrants during the period at \$0.54. On December 30, 2010, the Company issued 840,000 warrants (the "Class I Warrants") with an exercise price of \$1.65 that were attached to shares sold to a group of institutional and accredited investors for gross proceeds of \$1,005,000. The exercise prices of both sets of warrants were subject to certain "reset" provisions in the event the Company subsequently issues common stock, stock warrants, stock options or convertible debt with a stock price, exercise price or conversion price lower than \$0.54 for the Class H Warrants and \$0.75 for the Class I Warrants. If these provisions were triggered, the exercise price of all the warrants would have been reduced. Due to the "reset" provisions of the warrants, the warrants were not considered to be solely indexed to the Company's own stock and were not afforded equity treatment.

The fair value of the derivative liability was calculated using a Lattice Model that values the embedded derivatives based on future projections of the various potential outcomes. The assumptions that are analyzed and incorporated into the model include the conversion feature with the full ratchet and weighted average anti-dilution reset, expectations of future stock price performance and expectations of future issuances based on the Company's prior stock history, prior issuances of stock, and expected capital requirements. Probabilities were assigned to various scenarios in which the reset provisions would go into effect and weighted accordingly.

The total fair value of the Class H Warrants at issuance date, amounting to \$2,868,242, has been recognized as a derivative liability with all future changes in the fair value of these warrants being recognized in earnings in the Company's statement of operations under the caption "Other income (expense) – Gain (loss) on derivative liabilities" until such time as the warrants are exercised or expire.

On January 15, 2012, the reset provisions included in the Class H Warrants expired. As a result, the warrants are deemed to be indexed solely to the Company's own stock as of that date and therefore are eligible to be included within permanent equity. On January 15, 2012, the Company assessed the fair market value of the derivative prior to expiration and recorded a corresponding gain of \$51,769 based on the decrease in fair market value since December 31, 2011. The Company then reclassified the \$3,454,094 fair market value of the derivative liability for the reset provision on the date of expiration to shareholders' equity in accordance with ASC 815-15-35.

The total fair value of the Class I Warrants at issuance date, amounting to \$528,847, has been recognized as a derivative liability with all future changes in the fair value of these warrants being recognized in earnings in the Company's Statement of Operations under the caption "Other income (expense) – Gain (loss) on warrant derivative liabilities" until such time as the warrants are exercised or expire. The total cash proceeds of \$1,050,000 were first applied to the warrants with the remaining \$521,153 allocated to the common shares and recorded in additional paid-in capital.

On December 16, 2011 the Company sold 611,114 shares of common stock and 305,559 Class J warrants to a group of institutional and accredited investors for gross proceeds of \$1,100,000. As part of the sale, the Company agreed to protect investors against any potential decrease in the price of a later offering made by the Company (the "Ratchet Provision"); that is, if the Company issues shares at a price per share (the "Lower Price") below \$1.80 per share (the "Benchmark Price") then the Company has agreed to issue each investor a predetermined number of additional shares ("Ratchet Shares") without additional payment from the investor. The Ratchet Shares provided for lowering each investor's effective purchase price to be equal to either the Lower Price or \$1.50 per share (the "Floor Price"), whichever is higher. This provision expired in October 2012.

As a result, the Company recorded the fair value of the Class J Warrants as a derivative liability. The fair value of the derivative liability was calculated using a Lattice Model that values the embedded derivatives based on future projections of the various potential outcomes. The assumptions that are analyzed and incorporated into the model include expectations of additional potential shares to be issued under the provision, the expectations of future stock price performance, expectations of future issuances based on the Company's prior stock history, prior issuances of stock, and expected capital requirements. Probabilities were assigned to various scenarios in which the reset provisions would go into effect and weighted accordingly.

Out of the total \$1,100,000 raised in the offering, the Company has allocated \$141,470 of the proceeds to the Ratchet Provision derivative liability based on the total fair value on the date of issuance. The \$141,470 has been recognized as a derivative liability on the date of issuance with all subsequent changes in the fair value of this derivative being recognized in earnings in the Company's Statement of Operations under the caption "Other income (expense) – Gain (loss) on derivative liabilities" until such time as the Ratchet Provision expires. The remaining proceeds of \$958,530 have been allocated to the common stock and warrants based on their relative fair market values.

ASC 815 requires Company management to assess the fair market value of certain derivatives at each reporting period and recognize any change in the fair market value as other income or expense item. In March 2013, the Company's derivative liability decreased from \$768,696 to \$0 due to exercise of the warrants (See Note 1 for additional information).

NOTE 8 – CAPITAL STOCK

On December 16, 2011 the Company sold 611,114 common shares with warrants to a group of institutional and accredited investors for gross proceeds of \$1,100,000.

As part of the sale, a price protection Ratchet Provision (since expired), was included in the warrants, which has been recorded as a derivative liability (see Note 5). In addition, the investors received 305,559 five year Class J Warrants to purchase shares of the Company's common stock at an exercise price of \$1.95 per share which have been recorded within permanent equity. The Company allocated the \$1,100,000 in proceeds first to the derivative liability based on its fair value at issuance of \$141,470. The remaining \$958,530 was allocated between the shares of common stock and warrants based on their relative fair values on the date of issuance. The fair value of the warrants was \$314,453 leaving a net of \$644,077 for the value of the shares issued.

On February 15, 2012, the Company issued 55,556 common shares as a deposit on a service contract. The shares were valued at \$1.80 per share based on the fair market value of the services to be provided. The Company recorded the corresponding \$100,000 fair market value as research and development expense.

On March 18, 2012, the Company issued 43,333 common shares as a deposit on a service contract. The shares were valued at \$2.52 per share based on the fair market value of the stock on the date of issuance. The Company recorded the corresponding \$109,200 fair market value as professional fees.

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On April 10, 2012 the Company converted 14,464 warrants into shares of common stock through a cashless exercise. The cashless calculation resulted to 4,221 common shares which were issued April 11, 2012.

On June 28, 2012, the Company issued 1,766,334 common shares for total proceeds of \$2,914,452 to investors who elected to convert their series H warrants at an exercise price of \$1.65. As an incentive to exercise the options, the Company agreed to issue 0.6 replacement warrants for each full warrant exercised. The Company issued 1,059,803 replacement warrants under the incentive provision with an exercise price of \$3.60. The warrants were valued at \$2,663,204. As the original warrants were issued as part of cash financing, the value of these warrants has been included as an offsetting entry within additional paid-in capital. As of September 30, 2012, the Company has received \$2,902,560 in cash and has recorded a stock subscription receivable of \$11,891 which was fully collected during the year ended September 30, 2013.

On July 9, 2012, the Company converted 10,000 warrants into shares of common stock through a cashless exercise. The cashless calculation resulted to 4,444 common shares which were issued on July 17, 2012.

On September 12, 2012, the Company issued 33,333 common shares as a deposit on a service contract. The shares were valued at \$2.97 per share based on the fair market value of the stock on the date of issuance. The Company recorded the corresponding \$99,000 fair market value as professional fees.

On September 19, 2012, the Company issued 367 common shares to a consultant for services. The shares were valued at \$3.06 per share based on the market price of the shares on the date of issuance. The Company recorded the corresponding \$1,122 expense to general and administrative expense.

On October 5, 2012, two holders of its Series B preferred shares converted an aggregate of 138,889 preferred shares into common shares. Accordingly, the Company issued 46,296 common shares.

On October 24, 2012, the Company issued 66,667 shares of common stock for total proceeds of \$100,000 upon exercise of warrants at an exercise price per share of \$1.50.

On November 30, 2012, the Company received notice from a former director to exercise 53,624 options to purchase common stock using the cashless exercise feature in the option. Accordingly, the Company issued 30,842 common shares.

In March 2013, the Company issued 36,379 shares of common stock for total proceeds of \$76,682 upon exercise of warrants at an exercise price per share ranging from \$1.65 to \$3.57.

On March 13, 2013, the Company received notice from a director to exercise 128,698 options using the cashless exercise feature in the option. Accordingly, the Company issued 79,140 common shares.

F-15

On March 27, 2013, the Company received notices of cashless exercise for 816,000 Class I warrants. Accordingly, the Company issued 560,822 common shares.

On April 1, 2013, the Company issued 43,333 common shares in exchange for consulting services. These shares were valued at \$214,500 using the stock price at the grant date.

On April 16, 2013, a holder of its Series B preferred shares converted 138,889 preferred shares into common shares. Accordingly, the Company issued 46,296 common shares.

On April 18, 2013, the Company issued 1,406,320 shares of common stock for total proceeds of \$5,025,345 upon exercise of warrants at an exercise price per share of \$3.57.

On May 15, 2013, several holders of its Series B preferred shares converted an aggregate of 3,911,108 preferred shares into common shares. Accordingly, the Company issued 1,303,704 common shares.

On June 7, 2013, the Company issued 6,519 shares of common stock for total proceeds of \$10,756 upon exercise of warrants at an exercise price per share of \$1.65.

On June 14, 2013, two holders of its Series B preferred shares converted an aggregate of 894,450 preferred shares into common shares. Accordingly, the Company issued 298,150 common shares.

On June 14, 2013, 1,000 Class I warrants at an exercise price per share of \$1.50 were exercised by cashless exercise. Accordingly, the Company issued 730 common shares.

On July 1, 2013, 50,000 warrants at an exercise price per share of \$1.50 were exercised by cashless exercise. Accordingly, the Company issued 40,458 common shares.

On July 24, 2013, the Company issued 9,100 common shares to a consultant for services. The shares were valued at \$55,667 using the stock price at the grant date.

On September 20, 2013, the Company issued 13,889 shares of common stock for total proceeds of \$27,084 upon exercise of warrants at an exercise price per share of \$1.95.

During the year ended September 30, 2013, the Company collected the subscription receivable from the prior year's exercise of warrants of \$11,891.

On October 2, 2013, the Company issued 6,282 shares of common stock to a legal firm to settle \$50,000 in accounts payable. These shares were valued at \$7.96 which was the price of the stock at the close of business on the previous trading day.

On October 31, 2013, 55,556 Series A Warrants with an exercise price of \$3.60 were exercised. Accordingly, the Company issued 55,556 common shares for proceeds of \$200,002.

On November 13, 2013, two holders of its Series B preferred shares converted an aggregate of 500,000 preferred shares into 166,667 common shares. As of the date of this filing, there are no Series B preferred shares outstanding.

On February 26, 2014, 30,741 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 10,634 common shares.

On February 28, 2014, 23,867 warrants were exercised at an exercise price per share of \$3.60 using cashless exercise. Accordingly, the Company issued 18,408 common shares.

On March 18, 2014, 28,000 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 14,959 common shares.

On March 19, 2014, 1,616,667 warrants were exercised at an exercise price per share of \$1.50 using cashless exercise. Accordingly, the Company issued 1,468,765 common shares.

On March 20, 2014, 19,723 warrants were exercised at an exercise price per share of \$1.95 using cashless exercise. Accordingly, the Company issued 17,672 common shares.

On March 24, 2014, 13,889 warrants were exercised at an exercise price per share of \$1.95 using cashless exercise. Accordingly, the Company issued 12,448 common shares.

On March 24, 2014, 33,267 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 19,123 common shares.

On March 26, 2014, 27,778 warrants were exercised at an exercise price per share of \$1.95 using cashless exercise. Accordingly, the Company issued 24,660 common shares.

On March 26, 2014, 500 warrants with an exercise price of \$1.50 were exercised. Accordingly, the Company issued 500 common shares for proceeds of \$750.

On March 28, 2014, 34,723 warrants were exercised at an exercise price per share of \$1.95 using cashless exercise. Accordingly, the Company issued 30,826 common shares.

On March 28, 2014, 339,841 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 198,165 common shares.

On March 31, 2014, 16,204 warrants were exercised at an exercise price per share of \$1.95 using cashless exercise. Accordingly, the Company issued 14,332 common shares.

On April 28, 2014, the Company received subscription notices to purchase 1,800,000 shares of common stock with a price of \$10.00 less issuance costs. Accordingly, the Company issued 1,800,000 common shares and received net proceeds of approximately \$16.9 million.

On April 10, 2014, 14,815 warrants were exercised at an exercise price per share of \$3.60 using cashless exercise. Accordingly, the Company issued 11,068 common shares.

On April 16, 2014, 3,334 warrants were exercised at an exercise price per share of \$3.60 using cashless exercise. Accordingly, the Company issued 2,978 common shares.

On April 16, 2014, 5,652 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 3,199 common shares.

On May 30, 2014, the Company issued 1,194,862 common shares to acquire certain assets of SKS pursuant to a contribution agreement (see Note 3). The shares were valued at \$8.52 per share for a fair value of \$10,180,224.

On June 25, 2014, 50,000 warrants were exercised at an exercise price per share of \$1.20. Accordingly, the Company issued 50,000 common shares and received gross proceeds of \$60,000.

On September 3, 2014, 14,418 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 3,147 common shares.

On September 11, 2014, 1,434,166 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 304,707 common shares.

On September 12, 2014, 330,122 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 67,802 common shares.

On September 16, 2014, 13,889 warrants were exercised at an exercise price per share of \$1.95 using cashless exercise. Accordingly, the Company issued 10,362 common shares.

On September 25, 2014, 28,837 warrants were exercised at an exercise price per share of \$6.75 using cashless exercise. Accordingly, the Company issued 5,527 common shares.

NOTE 9 – COMMON STOCK WARRANTS

For all warrants included within permanent equity, the Company has determined the estimated value of the warrants granted to non-employees in exchange for services and financing expenses using the Black-Scholes pricing model and the following assumptions: stock price at valuation, \$0.63-\$7.96; expected term of 2-5 years, exercise price of \$1.50-\$7.96, a risk free interest rate of 0.21-2.90 percent, a dividend yield of 0 percent and volatility of 98-276 percent. All warrants accounted for as a derivative liability have been valued using a Lattice Model as described in Note 7.

In connection with the December 16, 2011 financing, the investors received 305,559 Class J five year warrants to purchase common stock at an exercise price of \$1.95 per share. On the date of issuance, the Company calculated the relative fair value of these warrants to be \$314,453.

On December 21, 2011, the Company issued a total of 1,042 warrants for services rendered to the Company. In connection with this issuance, the Company recognized \$1,967 in consulting expense. The warrants are exercisable for five years at an exercise price of \$1.95 per share.

On March 3, 2012, the Company issued a total of 116,667 fully-vested warrants with a fair market value of \$220,422 as a retainer for services to be rendered to the Company. In accordance with ASC 505-50-25, the Company recorded the fair market value of the warrants as professional fees.

On April 12, 2012, the Company issued a total of 5,000 fully-vested warrants with a fair market value of \$12,775 as a retainer for services to be rendered to the Company. In accordance with ASC 505-50-25, the Company recorded the fair market value of the warrants as professional fees.

Between May 18, 2012 and July 11, 2012, the Company issued a total of 133,333 warrants with a fair market value of \$357,394 for services yet to be rendered to the Company. The 116,667 warrants vest in two equal amounts three and six months from the date of issuance while the remaining 16,666 warrants vest over four quarters effective October 11, 2012. For the years ended September 30, 2013 and 2012, the Company has recorded \$200,159 and \$157,235, respectively, in professional fees related to the warrants that have vested to date.

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On June 28, 2012, the Company issued 1,059,803 replacement warrants under an incentive provision offered to investors who converted their Series H warrants. The warrants were valued at \$2,663,204. As the original warrants were issued as part of cash financing, the value of these warrants has been included as an offsetting entry within additional paid-in capital.

On September 7, 2012, the Company issued 25,000 fully-vested warrants with a fair value of \$65,978 to a related party as compensation for the use of the office facilities and receptionist. Such warrants have an exercise price of \$3.00 and will be exercisable for a period of five years. In accordance with ASC 505-50-25, the Company recorded the fair market value of the warrants as Professional Fees.

On October 30, 2012, the Company agreed to extend the term of the 3,995,122 common stock warrants issued to investors which were scheduled to expire on October 31, 2012 to April 30, 2013. The warrants were also amended to remove the cashless exercise provision and provided for the early termination of the extension period, at the sole discretion of the Company, in the event that the Company's common stock trades at or above \$4.50 for 5 consecutive days. The warrants are exercisable at \$3.57 per share.

On March 21, 2013, the Company issued a total of 56,667 warrants with a fair market value of \$232,374 for services rendered to the Company. 40,000 warrants vest equally over the next four quarters from the date of issuance. 16,667 warrants vest equally over the next two quarters from the date of issuance. For the year ended September 30, 2013, the Company recorded \$135,710 in consulting expense related to the portion of warrants that has vested to date. The warrants are exercisable at \$4.32 and are scheduled to expire in 3 to 5 years.

On April 18, 2013, the Company converted 2,253,531 Series B warrants to amended Series B warrants in connection with the exercising of 1,414,995 warrants into common stock. 326,597 Series B warrants expired. The amended Series B warrants issued have the exercise price raised to \$6.75 per share, and the expiration date has been extended to September 30, 2014.

On October 1, 2013, the Company issued a total of 100,000 warrants with a fair market value of \$481,724 for services rendered to the Company. The warrants vested immediately, have an exercise price of \$7.96 per share and a term of 3 years.

On December 30, 2013, the Company issued a total of 26,667 warrants with a fair market value of \$65,748 for services rendered to the Company. The warrants vested immediately, have an exercise price of \$7.94 per share and a term of 2 years.

On January 2, 2014, the Company issued 20,550 warrants with a fair market value of \$150,665 to a consultant for services rendered to the Company. The warrants vested immediately, have an exercise price of \$7.88 per common share and a term of 5 years.

On January 7, 2014, the Company issued 100,000 warrants with a fair market value of \$390,852 to a consultant for services to be rendered to the Company. 25,000 warrants vested immediately, with the remainder vesting over the next three quarterly periods, have an exercise price of \$7.94 per common share and a term of 3 years.

During the year ended September 30, 2014, an aggregate of 4,029,933 warrants at an exercise price per share of \$1.50 through \$6.75 were exercised by cashless exercise. In addition, 106,056 warrants were exercised at prices ranging from \$1.20 to \$3.60 for which \$260,752 in cash was received by the Company.

Below is a table summarizing the warrants issued and outstanding as of September 30, 2014:

	Number Outstanding	Weighted-Average Exercise Price
Outstanding at September 30, 2011	8,878,874	\$ 2.50
Granted	1,646,405	3.10
Exercised	(1,790,798)	1.65
Forfeited	(206,843)	2.37
Outstanding at September 30, 2012	8,527,638	\$ 2.80

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Granted	56,667		4.32
Exercised	(2,396,774)		2.78
Forfeited	(326,597)		3.57
Outstanding at September 30, 2013	5,860,934	\$	2.78
Granted	247,217		7.94
Exercised	(4,135,989)		4.41
Forfeited	(25,154)		1.20
Outstanding at September 30, 2014	1,947,008	\$	3.64

F-18

The outstanding warrants as of September 30, 2014 have an intrinsic value of approximately \$4.9 million. For the years ended September 30, 2014, 2013 and 2012, the Company has expensed \$1,177,095, \$335,869, and \$632,809, respectively, related to the fair value of warrants issued for services.

NOTE 10 – COMMON STOCK OPTIONS

The Company has determined the estimated value of the options granted to employees and non-employees in exchange for services and financing expenses using the Black-Scholes pricing model and the following assumptions: stock price at valuation, \$1.20-10.11; expected term of five years, exercise price of \$1.50-10.11, a risk free interest rate of 0.68-2.60 percent, a dividend yield of 0 percent and volatility of 81-277 percent.

On March 9, 2012, the Company granted 566,667 options to board members and executives. The Company calculated a fair value of \$1.89 per option. Of the 566,667 options issued, 141,667 vested upon issuance and the remaining 425,000 vest in 25 percent tranches on each anniversary. For the years ended September 30, 2014, 2013 and 2012, 425,000, 283,333 and 141,667 options have vested, respectively, resulting in compensation expense of \$268,078, \$328,354 and \$358,367, respectively.

On April 30, 2013, the Company granted 116,667 options to a board member. The Company calculated a fair value of \$4.59 per option. Of the 116,667 options issued, 29,167 vested upon issuance and the remaining 87,500 vest in 33 percent tranches on the next three anniversary dates. For the years ended September 30, 2014, 2013, and 2012 58,333, 29,167 and 0 options have vested, respectively, resulting in compensation expense of \$133,690, \$189,852, and \$0, respectively.

On May 17, 2013, the Company granted 116,667 options to a board member. The Company calculated a fair value of \$4.50 per option. Of the 116,667 options issued, 29,167 vested upon issuance and the remaining 87,500 vest in 33 percent tranches on the next three anniversary dates. For the years ended September 30, 2014, 2013, and 2012, 58,333, 29,167 and 0 options have vested, respectively, resulting in compensation expense of \$131,165, \$180,156, and \$0, respectively.

On February 3, 2014, the Company granted 500,000 options, with an exercise price of \$10.11 per share, to employees as part of its 2014 stock option plan. The Company calculated a fair value of \$1,954,384 for the options. Of the 500,000 options issued, 125,000 vested upon issuance and the remaining 375,000 vest in 25 percent tranches on each anniversary of grant. For the years ended September 30, 2014, 2013 and 2012, 125,000, 0 and 0 options have vested, respectively, resulting in compensation expense of \$814,327, \$0 and \$0, respectively.

On July 24, 2014, the Company granted 355,000 options, with an exercise price of \$8.39 per share, to employees as part of its 2014 stock option plan. The Company calculated a fair value of \$1,661,682 for the options. Of the 355,000 options issued, 88,750 vested upon issuance and the remaining 266,250 vest in 25 percent tranches on each anniversary of grant. For the years ended September 30, 2014, 2013 and 2012, 88,750, 0 and 0 options have vested, respectively, resulting in compensation expense of \$610,436, \$0 and \$0, respectively.

On September 5, 2014, the Company granted 60,000 options, with an exercise price of \$7.77 per share, to an employee as part of its 2014 stock option plan. The Company calculated a fair value of \$250,683 for the options. Of the 60,000 options issued, 15,000 vested upon issuance and the remaining 45,000 vest in 25 percent tranches on each anniversary of grant. For the years ended September 30, 2014, 2013 and 2012, 15,000, 0 and 0 options have vested, respectively, resulting in compensation expenses of \$86,957, \$0 and \$0, respectively.

During the year ended September 30, 2014, the Company recognized \$2,074,487 of expense related to vested options that were granted both in the current year and in prior years. Unamortized option expense as of September 30, 2014, 2013 and 2012 for all options outstanding amounted to approximately \$3,161,447, \$1,112,000 and \$737,496, respectively.

Below is a table summarizing the options issued and outstanding as of September 30, 2014:

	Number Outstanding	Weighted-Average Exercise Price
Outstanding at September 30, 2011	515,656	\$ 1.66
Granted	566,667	1.71
Exercised	—	—
Forfeited	—	—
Outstanding at September 30, 2012	1,082,323	\$ 1.69
Granted	233,334	4.71
Exercised	(182,322)	1.69
Forfeited	—	—
Outstanding at September 30, 2013	1,133,335	\$ 2.31
Granted	915,000	9.29
Exercised	—	—
Forfeited	—	—
Outstanding at September 30, 2014	2,048,355	\$ 5.43

As of September 30, 2013, the outstanding options have an intrinsic value of approximately \$5.6 million.

NOTE 11 – 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 September 30, 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.

Lease Obligation

The Company is currently obligated under an operating lease for office space and associated building expenses. The lease expires in August 2016 with an optional renewal period for an additional two years. As of September 30, 2014, future minimum payments for all lease obligations are as follows:

Year	Amount
2015	\$250,835
2016	255,386
	\$506,221

Rental expense related to the operating lease has been recorded in the consolidated statements of operations in the amounts of \$83,556, \$0 and \$0 for each of the years ended September 30, 2014, 2013 and 2012, respectively.

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 liability is adjusted according to management's assessment.

NOTE 12 – QUARTERLY FINANCIAL DATA (Unaudited)

	First	Second	Third	Fourth	Total
2014					
Total revenue	\$—	\$—	\$—	\$—	\$—
Operating loss	(2,021,493)	(1,968,383)	(2,056,416)	(3,076,632)	(9,122,924)
Net loss	(2,021,925)	(1,968,251)	(2,052,089)	(3,088,399)	(9,130,664)
Net loss per basic and diluted share	\$(0.10)	\$(0.10)	\$(0.09)	\$(0.12)	\$(0.41)

	First	Second	Third	Fourth	Total
2013					
Total revenue	\$—	\$—	\$—	\$—	\$—
Operating loss	(814,751)	(668,143)	1,335,575	(1,802,447)	4,620,916
Net loss	(2,218,352)	(292,258)	(1,338,431)	(1,803,447)	(5,652,488)
Net loss per basic and diluted share	\$(0.14)	\$(0.02)	\$(0.07)	\$(0.07)	\$(0.30)

NOTE 13 – SUBSEQUENT EVENTS

On October 14, 2014, 2,000 warrants with an exercise price of \$1.50 were exercised. Accordingly, the Company issued 2,000 common shares for proceeds of \$3,000.

On October 29, 2014, the Company issued 4,000 shares of restricted common stock as payment for ongoing scientific and consulting services to the Company.

Part III

ITEM 9 CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

On October 24, 2012 Ohr Pharmaceutical, Inc. (the “Company”) dismissed Anderson Bradshaw PLLC (“Anderson Bradshaw”) as its independent registered public accounting firm, and on October 25, 2012, the Company selected MaloneBailey, LLP (“MaloneBailey”) as its new independent registered public accounting firm responsible for auditing its financial statements. The dismissal of the Company’s former accounting firm and engagement of the new accounting firm were unanimously approved by the Company’s Board of Directors.

None of the reports of Anderson Bradshaw on the Company’s financial statements for either of the past two years or subsequent interim period contained an adverse opinion or disclaimer of opinion, or was qualified or modified as to uncertainty, audit scope or accounting principles.

There were no disagreements between the Company and Anderson Bradshaw concerning the two most recent fiscal years and any subsequent interim period through October 24, 2012 (date of dismissal) on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which, if not resolved to the satisfaction of Anderson Bradshaw, would have caused them to make reference to the subject matter of the disagreement in connection with its report. Further, Anderson Bradshaw has not advised the Registrant that:

- 1) internal controls necessary to develop reliable financial statements did not exist; or
- 2) information has come to the attention of Anderson Bradshaw which made it unwilling to rely upon management’s representations, or made it unwilling to be associated with the financial statements prepared by management; or
- 3) the scope of the audit should be expanded significantly, or information has come to the attention of Anderson Bradshaw that they have concluded will, or if further investigated, might materially impact the fairness or reliability of a previously issued audit report or the underlying financial statements, of the financial statements issued or to be issued covering the fiscal year ended September 30, 2012.

The Company did not consult with MaloneBailey prior to the date of dismissal on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure.

ITEM 9A CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedure

The Company maintains disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the U.S. Securities and Exchange Commission, and to ensure that the information required to be disclosed by us in reports that we file under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As required by Rule 15d-15(b) under the Exchange Act, management annually reviews our accounting policies and practices, and as a result of such review, identified it had an inefficiency in the financial reporting process regarding the assessment of fair value accounting principles related to non-recurring and complex transactions. As a result of these material weaknesses (as further discussed below), our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures as of September 30, 2014 were not effective at a reasonable level of assurance, based on the evaluation of these controls and procedures required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act. Notwithstanding the material weaknesses further discussed below, our Chief Executive Officer and Chief Financial Officer believe that the financial statements included in this report fairly present in all material respects (and in accordance with U.S. generally accepted accounting principles) our financial condition, results of operations and cash flows for the periods presented.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as that term is defined by Exchange Act Rules 13a-15(f) and 15d-15(f)). Our internal control over financial reporting is designed under the supervision of our Chief Executive Officer and Chief Financial Officer in order to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Our control environment is the foundation for our system of internal control over financial reporting and is an integral part of the changes within the organization and internal reporting.

We carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our internal controls over financial reporting pursuant to Rule 13a-15(c) under the Securities Exchange Act as of the end of the period covered by this Form 10-K. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Management evaluated the effectiveness of our internal control over financial reporting as of September 30, 2014. In making this evaluation, management used the criteria established in *1992 Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In connection with such evaluation, our management identified a material weakness in our internal control over financial reporting based on the criteria established in the *1992 Internal Control-Integrated Framework* issued by the COSO. A material weakness is a control deficiency, or a combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of our annual or interim financial statements will not be prevented or detected.

The material weakness identified was related to our lack of a sufficient control over our financial accounting and reporting processes regarding fair-value accounting treatment for certain non-routine and complex transactions. Because of this material weakness, management has concluded that the Company did not maintain effective internal control over financial reporting as of September 30, 2014. Notwithstanding this material weakness, management has concluded that our consolidated financial statements included in this annual report are fairly stated in all material respects in accordance with U.S. generally accepted accounting principles for each period presented herein.

Remediation of a Material Weakness

The material weakness identified was related to our lack of a sufficient control over our financial accounting and reporting processes regarding the assessment of fair-value accounting for non-routine and complex transactions. As of September 30, 2014, management has concluded that our control over the selection and application of our accounting policies related to non-routine valuation calculations were ineffective to ensure that such transactions were recorded in accordance with U.S. generally accepted accounting principles. We expect to remediate the material weakness as set forth below.

Changes in Internal Controls over Financial Reporting

As a result of the material weakness identified during the period covered by this Form 10-K, management will continue to implement 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 are in the process of making 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 internal or external 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.

MaloneBailey, LLP, the registered public accounting firm that audited the financial statements included in the Form 10-K has also issued an attestation report on the Company's internal control over financial reporting." See the report of MaloneBailey, LLP set forth above in Item 8.

ITEM 9B OTHER INFORMATION

NONE

ITEM 10 DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Following this table is a brief biographical description for each of Ohr's executive officers and directors, with a brief description of their business experience and present relationship to Ohr as of September 30, 2014, together with all required relevant disclosures for the past five years.

Following the biographical information for the directors and officers is a remuneration table showing current compensation, and following this table is a security ownership table showing security ownership of the principal officers and directors, as well as those holding 5% or more of the issued and outstanding stock.

Name	Position	Current Term of Office
Ira Greenstein	Chairman	Director since 2007
Irach Taraporewala	CEO, President, and Director	Officer since 2010, Director since 2012
Sam Backenroth	CFO and Vice President of Business Development	Officer since 2010
Orin Hirschman	Director	Director since 2009
Thomas Riedhammer	Director	Director since 2013
June Almenoff	Director	Director since 2013

Dr. Irach B. Taraporewala- Chief Executive Officer, President, and Director 58

Dr. Taraporewala has served as CEO of the Company since April 2010. Dr. Taraporewala has over 30 years in drug development and regulatory affairs experience. He was formerly the Vice President of Regulatory Affairs and Clinical Research at Austin, TX-based Mystic Pharmaceuticals Inc. where he led the regulatory strategy for the company's ophthalmic and intranasal drug products and drug delivery systems. Prior to that, Dr. Taraporewala served as Senior Consultant in the Drug Development Consulting division of Boston-based PAREXEL International Corp., a leading global pharmaceutical services provider, where he provided technical expertise and regulatory advice to small and large biotechnology and pharmaceutical company clients worldwide, and also conducted due diligence for companies and venture capital firms on technology and portfolio evaluation and product acquisitions. From 1998 to 2004, Dr. Taraporewala was Director of Chemistry and Quality Control at Yonkers, NY-based Advanced Viral Research Corporation where he helped take OHR/AVR118, an immunomodulator drug, into clinical trials for AIDS, cancer cachexia and rheumatoid arthritis. At Advanced Viral Research he worked closely with Shalom Hirschman, M.D.,

Ohr's Chief Science Advisor. Prior to that, Dr. Taraporewala worked in research and development at Ciba-Geigy, which later merged with Sandoz to become Novartis. He has also served as principal investigator on four National Institute of Health and U.S. Department of Defense funded biomedical research grants on antiviral drugs, DNA-based cancer diagnostics and on antimalarial compound development. Dr. Taraporewala earned bachelors' and masters' degrees in chemistry and microbiology from the University of Bombay, India and a Ph.D. in medicinal chemistry from the Philadelphia College of Pharmacy. He conducted postdoctoral research at the University of Texas at Austin, the University of Minnesota and the Southwest Foundation for Biomedical Research. Dr. Taraporewala has multiple scientific publications and patents to his credit, and has lectured extensively.

Sam Backenroth- Chief Financial Officer and Vice President of Business Development 30

Mr. Backenroth has served as CFO and Vice President of Business Development since April 2010. Mr. Backenroth has previously worked as an investment banker with The Benchmark Company LLC, an investment banking firm specializing in micro-cap biotech transactions. While at Benchmark, he helped fund numerous small biotech companies raise in excess of \$75 million of growth equity capital through a variety of structures. Mr. Backenroth also acted as an advisor to multiple public and private biotech companies in assisting with business development activities, joint ventures, licensing, strategic partnerships, and mergers & acquisitions. He graduated with honors from Touro College with a Bachelors degree in finance.

Ira Greenstein –Chairman of the Board, Director 54

Mr. Greenstein has served as a Director of Ohr Pharmaceutical since March 30, 2007. Mr. Greenstein has served as President of Genie Energy Ltd. (NYSE:GNE) since December 2011. Mr. Greenstein currently also serves as Counsel to the Chairman of IDT Corporation (NYSE: IDT) and had served as the President of IDT from 2001 through 2011 and Counsel to the Chairman of IDT in 2000 and 2001. He has served as a Director of IDT and General Counsel and Secretary of IDT's subsidiary, Net2Phone, Inc. (NASDAQ: NTOP). Prior to joining IDT, Mr. Greenstein was a partner in Morrison & Foerster LLP, where he served as the Chairman of that firm's New York Office's Business Department. Mr. Greenstein was an associate in the New York and Toronto offices of Skadden, Arps, Slate, Meagher & Flom LLP and served on the Securities Advisory Committee and as secondment counsel to the Ontario Securities Commission. Mr. Greenstein serves on the Boards of Directors of Document Security Systems, Inc., Arista Power Inc., NanoVibronix, Inc. and Regal Bank of New Jersey. Mr. Greenstein received a B.S. from Cornell University and a J.D. from Columbia University Law School where he serves as a member of the Dean's Council.

June S. Almenoff, M.D., Ph.D. - Director 58

June S. Almenoff, M.D., Ph.D. has been a Director of Ohr Pharmaceutical since May 2013. Dr. Almenoff most recently served as president, principal executive officer and chief medical officer of Furiex Pharmaceuticals, Inc. from its inception in 2010 to its acquisition by Forest/Actavis for up to \$1.46 B in 2014. She served as Furiex's most senior executive officer, responsible for attaining all strategic and financial goals and was a member of the Board of Directors. Dr. Almenoff joined Furiex after a successful 12-year career at GlaxoSmithKline ("GSK"). She was vice president in the clinical safety organization, where she served on the company's senior governing medical boards and managed a diverse therapeutic portfolio supporting numerous regulatory approvals. Also during her tenure at GSK, she worked in the area of scientific licensing, leading the scientific diligence for the acquisition of Stiefel Laboratories and establishing a licensing program for a drug development unit. Dr. Almenoff led several GSK teams that developed pioneering systems for minimizing risk in early- and late-stage drug development; these have been widely implemented by pharmaceutical companies and regulatory agencies. Their impact on the industry has been recognized by the Wall Street Journal Technology Innovation Award and several other prestigious awards. Dr. Almenoff also chaired a Pharma-FDA working group and was the lead author on its influential position paper. Prior to joining GSK, Dr. Almenoff was on the faculty of Duke University Medical Center, where she is currently a Consulting Professor of Medicine. Dr. Almenoff earned a bachelor's degree, cum laude, from Smith College. She graduated from the M.D.-Ph.D. program at Mt. Sinai School of Medicine and completed a residency in Internal Medicine and a fellowship in Infectious Diseases at Stanford University Medical Center. She is a Fellow of the American College of Physicians with 10 years of clinical practice experience and is an author on more than 50 publications.

Orin Hirschman –Director 46

Mr. Hirschman has served as a Director at Ohr since March 2009. Mr. Hirschman has over 20 years of experience in money management, leveraged buyouts, restructuring and venture capital. From 1994 until 2001 Orin served as a co-manager of two private investment funds, Adam Smith Investment Partnerships and Adam Smith Investment Partners, Ltd (the "Adam Smith Funds"). In addition to Orin's private placement investments over the last eight years, and the Adam Smith Funds, Orin's experience in the securities industry includes tenures with Wesray Capital, the investment firm founded by former U.S. Secretary of the Treasury William E. Simon, and Randall Rose & Company, a \$100 million money management firm based in New York. Orin has been actively involved in the financing and structuring of over 70 companies, including many high technology companies. Mr. Hirschman's educational background includes an M.B.A. in Finance from New York University Graduate School of Business and a degree in Biology and Finance from Touro College where he graduated Summa Cum Laude.

Thomas M. Riedhammer, Ph.D. – Director 66

Dr. Riedhammer has been a Director of Ohr Pharmaceutical since April 2013. He most recently served as Chairman of Sirion Therapeutics Inc, a position he held from 2007 to 2013. Prior to that, Dr. Riedhammer served as Chief

Operating Officer of Presby Corp., a medical device company engaged in the research and development of treatments for eye disorders. Prior to Presby Corp., Dr. Riedhammer served as President and Senior Vice President of Worldwide Pharmaceuticals at Bausch and Lomb from 1994 to 2000. He also held various other positions at Bausch and Lomb including: Senior Vice President, and Chief Technical Officer from 1998 to 2000, Senior Vice President and President for Worldwide Pharmaceutical, Surgical, and Hearing Care Products from 1994 to 1998, and Vice President from 1993 to 1994. He was a corporate Vice President of Paco Pharmaceuticals and President of Paco Research Corp from 1984 to 1991. Dr. Riedhammer began his career at Bausch & Lomb as a Research Chemist and was its Director, Lens Care Products R&D. He has served as Chairman and Director of Prevent Blindness Florida, Director of Prevent Blindness America, Sjogren's Syndrome Foundation as secretary and Junior Achievement International. Dr. Riedhammer holds a B.A. in Chemistry and a Ph.D. in Electrochemistry from State University of New York at Buffalo.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics (“Code of Ethics”) that applies to all of our directors and employees, including our chief executive officer, chief financial officer and other officers. Our Code of Ethics includes provisions covering conflicts of interest, the reporting of illegal or unethical behavior, business gifts and entertainment, compliance with laws and regulations, insider trading practices, antitrust laws, bribes or kickbacks, corporate record keeping, and corporate accounting and disclosure. The Code of Ethics is available at the Investor Relations section of our website at www.ohrpharmaceutical.com. Our Code of Ethics may also be obtained without charge upon written request to Ohr Pharmaceutical, Inc. 800 3rd Avenue, 11th Floor, New York, NY 110022, Attention: Investor Relations.

Nomination of Directors

Due to its current limited staffing levels, the Company does not have a Nominating Committee for nomination of Directors. The Company’s current Board of Directors participates in the consideration of director nominees.

In May 2013, the Company adopted new By-Laws that provide that stockholders may nominate one or more persons for election as director or directors at the Company’s Annual Meeting of Stockholders only if written notice of intent to make such nomination or nominations has been given either by personal delivery or by mail to the Secretary of the Company not less than 90 days before the meeting of stockholders at which such election is held. Each such notice shall state (i) the name and address of the stockholder who intends to make the nomination and of the person or persons to be nominated; (ii) a representation that the stockholder is a holder of record of stock of the Corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice; (iii) a description of all arrangements or understandings between the stockholder and each nominee and any other person or persons (naming such person or persons) pursuant to which the nomination or nominations are to be made by the nominee proposed by such stockholder as would be required to be included in a proxy statement filed pursuant to the proxy rules of the Securities and Exchange Commission, had the nominee been nominated, or intended to be nominated, by the Board of Directors; and (iv) the consent of each nominee to serve as a director of the corporation if so elected.

The Board of Directors will consider director candidates recommended by stockholders. The Board does not intend to alter the manner in which it evaluates candidates based on whether the candidate was recommended by a stockholder or not. Stockholders who wish to recommend individuals for consideration by the Board to become nominees for election to the Board may do so by delivering a written recommendation to Ohr at the following address: Ohr Pharmaceutical, Inc., 800 3rd Avenue, 11th Floor, New York, NY 110022. To date, the Board of Directors has not received any director nominations from stockholders of the Company.

Audit Committee

Audit Committee. The members of the Audit Committee are Ira Greenstein, Dr. Thomas Riedhammer and Dr. June Almenoff. Dr. Riedhammer currently serves as chairman of this committee. Each member was appointed to the Audit Committee in May 2013. Each of the individuals that currently serve on the Audit Committee, and that served on the Audit Committee during our fiscal year ended September 30, 2014, was an independent member of our Board of Directors. In addition, the Board of Directors has determined that the members of the Audit Committee that served during fiscal 2014 and at present meet the additional independence criteria required for audit committee membership set forth in Rule 10 A-3 promulgated by the SEC.

The Audit Committee acts to: (i) acquire a complete understanding of our audit functions; (ii) review with management our finances, financial condition and interim financial statements; (iii) review with our independent auditors the year-end financial statements; and (iv) review implementation with the independent auditors and management any action recommended by the independent auditors. Our Board of Directors adopted a Charter governing the activities of the Audit Committee, which is available on our corporate website at www.ohrpharmaceutical.com under the following tabs: “home—corporate governance—Corporate Governance - Audit”. During the fiscal year ended September 30, 2014, the Audit Committee met on four occasions.

Audit Committee Financial Expert. Our Board of Directors has determined that Audit Committee member Thomas Riedhammer is our audit committee financial expert, as defined under applicable SEC regulations, and is an independent member of our board.

Corporate Governance

We have included as exhibits to this Annual Report on Form 10-K certificates of our Chief Executive Officer and Principal Financial Officer certifying the quality of our public disclosure.

We make available free of charge through the investor relations page of our web site (<http://ir.ohrpharmaceutical.com/>) our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, and all beneficial ownership reports on Forms 3, 4 and 5 filed by directors, officers and beneficial owners of more than 10% of our equity, as soon as reasonably practicable after such reports are electronically filed with the Securities and Exchange Commission. We have adopted a code of ethics for all of our employees, including our principal executive officer, principal financial officer and principal accounting officer. Copies of the codes of business conduct and ethics are available on our web site.

Our web site and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K or our other filings with the Securities and Exchange Commission.

Additional information required by this Item concerning our directors is incorporated by reference from the section captioned “Proposal No. 1—Election of Directors” contained in our proxy statement related to the 2015 Annual Meeting of Stockholders which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

The information required by this Item concerning compliance with Section 16(a) of the United States Securities Exchange Act of 1934, as amended, is incorporated by reference from the section of the proxy statement captioned “—Section 16(a) Beneficial Ownership Reporting Compliance.”

Related-Party Transactions

NASDAQ rules require any related-party transaction to be reviewed and approved by the Board or the Audit Committee based on the nature of the transaction. A related-party transaction is any transaction or series of similar transactions, to which the Company or any of its subsidiaries was or is to be a participant, in which the amount involved exceeds \$120,000 and in which any related person had or will have a direct or indirect material interest.

Each director and executive officer of the Company must provide annually to the Company’s Secretary a list of any existing or potential related-party transactions and the material facts about such transactions. The Secretary will provide the information, as well as his assessment of any transaction, to the Audit Committee, as appropriate based on the subject matter, for its review. The Audit Committee will consider the transaction at its next meeting unless the

chair calls a special meeting to consider the transaction. Any related-party transaction must be approved in advance by a majority of the disinterested Audit Committee members.

ITEM 11 – EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the information under the sections captioned “Executive Compensation:,” “—Compensation for Non-Employee Directors,” “—Compensation Discussion and Analysis,” “—Summary Compensation Table,” “—Grants of Plan Based Awards in Fiscal 2014,” “—Outstanding Equity Awards at Fiscal Year End 2014,” “—Compensation Committee Report,” and “—Compensation Committee Interlocks and Insider Participation” contained in the proxy statement.

ITEM 12 SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is incorporated by reference to the information under the section captioned “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” contained in the proxy statement.

ITEM 13 CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The Company is not aware of any transactions which would require disclosure under this section by the Company and any affiliated party.

ITEM 14 PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to the information under the section captioned “—Report of the Audit Committee” and “—Fees Paid to the Independent Registered Public Accounting Firm” contained in the proxy statement.

Part IV

ITEM 15 EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Documents listed below are filed as exhibits to this Annual Report on Form 10-K.

(a) Exhibit Index:

Exhibit
No.

- (2.1) Contribution Agreement, dated May 14, 2014. ¹
- (2.2) Agreement and Plan of Merger, dated May 30, 2014. ²
- (3.1) Articles of Incorporation, dated May 8, 2014. ²
- (3.1(a)) Certificate of Amendment to Articles of Incorporation Filed on May 30, 2014 ²
- (3.2) ByLaws, dated May 8, 2014 ²
- (10.14) Asset Purchase Agreement with Genaera Liquidating Trust, dated August 21, 2009 ³
- (10.15) Form of Class H Common Stock Purchase Warrant issued pursuant to the warrant exercise agreement, dated as of January 15, 2010 ⁴
- (10.18) The 2014 Stock Incentive Plan ⁵
- (10.21) Form of consulting warrants ⁶
- (10.25) Form of Class J Common Stock Purchase Warrant issued pursuant to the Subscription Agreement, dated as of December 16, 2011 ⁷
- (10.26) Form of Non-Qualified Option, dated March 9, 2012 ⁸
- (10.27) Form of Employment Agreement, dated March 9, 2012 ⁸
- (10.28) Form of Class A Common Stock Purchase Warrant issued pursuant to the Offer letter dated June 26, 2012 ⁹
- (10.33) Form of Audit Committee Charter. ¹⁰
- (10.34) Compensation Committee Charter Adopted on June 13, 2013. ¹¹
- (10.35) Employment Agreement with Irach Taraporewala, dated August 9, 2013. ¹²
- (10.36) Employment Agreement with Sam Backenroth, dated August 9, 2013. ¹²
- (10.45) Assignment and Assumption Agreement, dated May 30, 2014. ²
- (10.46) Form of Amendment No. 1 to Class J Common Stock Purchase Warrant Agreement, Dated March 11, 2014. ¹³
- (10.47) Subscription Agreement, dated April 8, 2014. ¹⁴
- (10.48) Placement Agency Agreement, dated April 8, 2014. ¹⁴
- (10.49) Second Research Agreement, dated July 31, 2013 ¹⁵
- (21.1) List of Subsidiaries. ¹⁶
- (31) Certification made pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
- (32) Certification made pursuant to Section 906 of the Sarbanes Oxley Act of 2002.

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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

1. Filed and incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on May 16, 2014.

2. Filed and incorporated by reference to the Registrant's Current Report on Form 8-K, filed on June 2, 2014.

3. Filed and incorporated by reference to the Registrant's Current Report on Form 8-K, filed on August 26, 2009.

4. Filed and incorporated by reference to the Registrant's Annual Report on Form 10-K, filed on January 13, 2010.

5. Filed and incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on April 14, 2014.

6. Filed and incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed on July 13, 2011.

7. Filed and incorporated by reference to the Registrant's Current Report on Form 8-K filed on December 20, 2011.

8. Filed and incorporated by reference to the Registrant's Current Report on Form 8-K filed on March 15, 2012.

9. Filed and incorporated by reference to the Registrant's Current Report on Form 8-K filed on July 3, 2012.

10. Filed and incorporated by reference to Exhibit 3.2(a) and 10.33 to the Registrant's Current Report on Form 8-K, filed on May 24, 2013.

11. Filed and incorporated by reference to Exhibit 99.2 and Exhibit 10.34 to the Registrant's Current Report on Form 8-K, filed on June 16, 2013.

12. Filed and incorporated by reference to Exhibits 10.35 and 10.36 to the Registrant's Quarterly Report on Form 10-Q, filed on August 13, 2013.
13. Filed and incorporated by reference to Exhibit 10.39 to the Registrant's Current Report on Form 8-K, filed on March 3, 2014.
14. Filed and incorporated by reference to Exhibits 10.40 and 10.41 to the Registrant's Current Report on Form 8-K, filed on April 8, 2014.
15. Filed and incorporated by reference to Exhibit 10.45 to the Registrant's Amended Quarterly Report on Form 10-Q, filed on December 10, 2014.
16. Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REGISTRANT:
OHR PHARMACEUTICAL, INC.

Dated: December 22, 2014 By: /s/ IRACH TARAPOREWALA
Irach Taraporewala, CEO

Dated: December 22, 2014 By: /s/ SAM BACKENROTH
Sam Backenroth, CFO,
Principal Accounting and Financial Officer

POWER OF ATTORNEY

KNOW BY ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints jointly and severally, Irach Taraporewala and Sam Backenroth, and each one of them, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Dated: December 22, 2014 By: /s/ IRACH TARAPOREWALA
Irach Taraporewala, CEO and Director

Dated: December 22, 2014 By: /s/ IRA GREENSTEIN
Ira Greenstein, Director

Dated: December 22, 2014 By: /s/ ORIN HIRSCHMAN
Orin Hirschman, Director

Dated: December 22, 2014 By: /s/ JUNE ALMENOFF

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June Almenoff, Director

Dated: December 22, 2014 By: /s/ THOMAS RIEDHAMMER
Thomas Riedhammer, Director