Ohr Pharmaceutical Inc
Form 10-K
December 14, 2015

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, 2015

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.

*(*Exac*t* Name of Regis*t*ran*t* as Specified in its Char*t*er)

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

800 Third Ave, 11th Floor
New York, NY 10022

(Address of Principal Executive Offices)

212-682-8452

Reg*i*strant'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

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, 2015, the last business day of the registrant’s most recently completed second fiscal quarter, was $65,938,100 (based on the closing price of the registrant’s common stock on the NASDAQ Capital Market on such date). 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 14, 2015, the registrant had 30,331,309 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The Company’s definitive Proxy Statement for its 2016 Annual Meeting of Stockholders expected to be held on or about March 17, 2016, is incorporated by reference into Part III of this Form 10-K to the extent described herein.

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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 11 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, except as required by law. Actual future results, events and trends may differ materially from those expressed in or implied by such statements depending on a variety of factors, including, but not limited to those set forth in our filings with the Securities and Exchange Commission (“SEC”). Specifically, and not in limitation of these factors, we may alter our plans, strategies, objectives or business.

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,” “us,” “our,” “Ohr,” the “Company” or the “Registrant”) is a pharmaceutical company focused the development of novel therapeutics and delivery technologies for the treatment of ocular disease. Our development pipeline consists of multiple 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, for the treatment of retinal diseases including wet-AMD, retinal vein occlusion and proliferative diabetic retinopathy. Data from a Phase II clinical trial in wet-AMD demonstrated a positive and clinically meaningful treatment effect of OHR-102 combination therapy in classic containing choroidal neovascularization (classic CNV) and smaller occult only neovascularization (occult CNV) less than $10mm^2$.

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 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 increasing compliance rates and reducing treatment burden.

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 SEC.

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.

On June 13, 2013, the Company’s shares of common stock began trading on The NASDAQ Capital Market under the symbol “OHRP.”

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 acquisition agreement, in exchange for substantially all the assets of SKS, Ohr made an upfront payment of $3.5 million in cash and issued 1,194,862 shares of Ohr common stock to SKS. In addition, SKS is eligible to receive up to an aggregate of 1,493,577 additional shares of Ohr common stock in three contingent milestone payments, each milestone resulting in the issuance of 497,859 shares of Ohr common stock. Milestone 1 required Ohr to demonstrate a consistent long-term release of a therapeutic agent above threshold therapeutic levels in the targeted ocular tissues of an animal model. Ohr met this milestone in December 2015. Milestone 2 requires the completion of a pharmacodynamic study in an animal model showing clinically relevant efficacy from a drug substance released from SKS Microparticles within 24 months of the date of the closing of the SKS Acquisition. Milestone 3 requires, among other things, the approval of an Investigational New Drug Application ("IND") within three years of the date of the closing of the SKS Acquisition. An IND is required to be submitted by us (or one of our subsidiaries) to the U.S. Food and Drug Administration (the "FDA") within four months of the date of the successful completion of an IND enabling toxicity study and other IND enabling processes (the "IND Ready Date"); however if an IND is not submitted to the FDA within four months of the IND Ready Date, then Milestone 3 shall mean the approval of an IND at any time (regardless of whether the date of such approval is earlier or later than the date that is three years of the date of the closing of the SKS Acquisition; provided that if we (or one of our subsidiaries) fail to submit such IND to the FDA within nine months of the IND Ready Date, then milestone 3 will be considered to have been achieved.

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, Ohr completed a holding company reorganization in which Ohr merged with a wholly-owned subsidiary and a new parent corporation succeeded Ohr as a public holding company under the same name. The business operations of Ohr did not change as a result of the reorganization. The new holding company retains the name "Ohr Pharmaceutical, Inc." Outstanding shares of the capital stock of the former Ohr Pharmaceutical, Inc. were automatically converted, on a share for share basis, into identical shares of common stock of the new holding company.

Recent Developments

On November 12, 2015, the Company announced that it submitted a Special Protocol Assessment (SPA) request to the FDA, as part of the Company's ongoing interactions with the FDA on the detailed design of the Phase III clinical development program of OHR-102 (Squalamine Lactate Ophthalmic Solution, 0.2%) for the treatment of neovascular Age-Related Macular Degeneration (Wet AMD).

On December 3, 2015, the Company announced the achievement of Milestone 1 from the SKS Acquisition, demonstrating consistent long-term release of a therapeutic agent above threshold therapeutic levels in the targeted ocular tissues of an animal model. The achievement of Milestone 1 required that the Company issue 497,859 shares of its common stock to SKS.

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 ("bFGF"). Recent clinical evidence has shown PDGF to be an additional target for the treatment of Wet-AMD and bFGF levels have been shown to be elevated in retinal vein occlusion and wet-AMD patients 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 to potentially provide increased comfort in an elderly patient population. The Company is advancing its clinical wet-AMD program with this topical formulation. Unlike other combination therapy approaches being evaluated in clinical studies, OHR-102 does not require direct injection into the eye.

We believe that OHR-102 used in combination with an anti-VEGF agent may provide several potential advantages over other combination therapy approaches currently being investigated in clinical studies including:

Daily eye drop therapy compared to an additional monthly intravitreal injection.

Potential for use in combination with an as-needed anti-VEGF injection (PRN) or treat-and-extend regimen instead of a monthly anti-VEGF injection regimen.

Inhibition of multiple growth factor pathways.

Cost advantage of manufacturing a small molecule when compared to large molecule proteins and antibodies.

The Company has conducted a preclinical program which consisted of pharmacology, pharmacokinetic, and toxicology studies which support the ongoing clinical development of OHR-102.

Completed 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 was a multi-center, randomized, double masked, placebo controlled Phase II study to evaluate the efficacy and safety of OHR-102 combination therapy for the treatment of wet-AMD. The study enrolled treatment naïve wet-AMD patients at more than 20 clinical sites in the U.S. who were randomly assigned to treatment with OHR-102 eye drops or placebo eye drops for a nine month period, along with Lucentis® injections, as necessary. Full enrollment was completed in April 2014. In March 2015, we completed the IMPACT Study and announced topline results. We presented the final data from the study at the 2015 Association for Research in Vision and Ophthalmology (ARVO), American Society of Retina Specialists (ASRS), and American Academy of Ophthalmology (AAO) Conferences. The final data from the IMPACT Study was presented at other scientific conferences or forums throughout 2015 with additional data presentations expected at scientific conferences in calendar 2016.

In a prespecified analysis, data from the IMPACT study demonstrated that, in the intent-to-treat (ITT-LOCF) population with lesions containing classic choroidal neovascularization ("classic CNV") (OHR-102 n=38, Lucentis® monotherapy n=32), 42% of the patients receiving OHR-102 achieved a ≥3 line gain at nine months, as compared to 28% in the Lucentis monotherapy group. In patients with classic CNV (ITT-LOCF), mean gains in visual acuity were +10.5 letters for the OHR-102 combination arm and +5.4 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.1 letters. The positive effect on visual acuity in classic CNV was seen early in the course of treatment and continued to increase through the end of the study. Less of a visual acuity benefit was seen in the overall population (classic CNV and occult only CNV lesions).The mean number of injections between the treatment arms, the primary endpoint of the study, was not meaningfully different.

Further analyses were conducted to determine the patient population most likely to benefit from combination treatment. Patients with classic CNV are a heterogeneous population and, within the enrollment criteria of our study, could have encompassed small classic lesions with no occult component up to a lesion 12 disc areas (~30mm^2) in size made up almost entirely of occult CNV, yet both lesions fall under the same category of "classic containing lesion" even though they would be expected to respond differently to treatment. Correlation analyses determined that the occult CNV size at baseline, regardless of whether there was a classic CNV component present, directly correlated with improved visual acuity outcomes in the OHR-102 combination group (p=<0.0001), which was not seen in the monotherapy group. This suggests that the occult CNV size was a more important predictor of success for combination therapy than the presence of classic CNV, and a cutoff less than 10mm^2 of occult size at baseline was determined to be the optimal size to include in future clinical studies. In those patients with occult CNV less than 10mm^2 in area (n=94 of 128 completing the study), 40% of those treated with OHR-102 combination therapy achieved a gain of 3 or more lines of vision, compared with 26% of patients in the Lucentis monotherapy arm, a 54% additional benefit. In addition, mean gains in visual acuity compared to baseline were +11.0 letters for the OHR-102 combination arm and +5.7 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.3 letters. Importantly, this group of patients represents a larger proportion of the subjects enrolled in the IMPACT study than the classic containing group. We intend to enroll this optimized patient population in our upcoming Phase III clinical program.

Regulatory Guidance from the FDA on OHR-102 Program in Wet-AMD

At the end of Phase II meetings with the FDA in September 2014 and July 2015, the FDA agreed with the Company that a nine month primary efficacy endpoint for the Phase III trials will be acceptable based on the proportion of patients achieving a ≥ 3 line improvement in visual acuity and provided further guidance on the design of the Phase III trials. The Phase III trials for OHR-102 are being designed to measure the efficacy of combination therapy with squalamine eye drops plus Lucentis injections compared with Lucentis monotherapy in treatment naive patients with wet-AMD. All patients will be followed for safety and efficacy for two years. Two pivotal confirmatory efficacy and safety studies will be required.

In May 2012, the FDA awarded Fast Track Designation to the Squalamine eye drop program for the potential treatment of wet-AMD. As a result of our end of Phase II meetings with the FDA in September 2014 and July 2015, and the submission of the Special Protocol Agreement (SPA) in November 2015, we intend to initiate the Phase III program upon completion of the SPA procedure, and begin enrolling patients in the first calendar quarter of 2016.

Phase III Trials in Wet-AMD

The Phase III program will evaluate the efficacy and safety of OHR-102 given in combination with Lucentis for newly diagnosed, treatment naive patients with wet-AMD. The comprehensive clinical program will be comprised of double-masked, placebo-controlled, multicenter, international studies of OHR-102 administered twice a day in patients with newly diagnosed wet AMD, in combination with Lucentis injections. The primary endpoint will be a measurement of visual acuity gains at nine months, with patients followed to two years for safety. We intend to enroll a patient population that we believe is the most likely to benefit from OHR-102 combination therapy based on our full analysis of the IMPACT study. 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 eye drops. During the second year they will receive Lucentis PRN (as needed) plus OHR-102 or placebo eye drops twice a day.

OHR–1501 Study

OHR-1501 is an exploratory, double-masked, randomized, placebo-controlled study designed to assess safety and efficacy of treatment with Squalamine Lactate Ophthalmic Solution in combination with monthly Lucentis injections in patients with neovascular AMD. Approximately 20 subjects will participate for a six month duration. Efficacy parameters will include functional visual acuity (BCVA), and retinal imaging modalities. The primary endpoints of the study are the outcome measures at Week 12. We expect data from this study in calendar 2016.

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

Study 003 was 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 in February 2014. In this case report, the oral presentation discussed the case of a treatment naïve patient diagnosed with PDR. The data demonstrated that topical application of OHR-102 in a monotherapy regimen, twice daily and then four times daily, was associated with regression of retinal neovascularization within two months. The retinal neovascularization remained regressed throughout the six months of four times daily OHR-102 eye drop therapy. One month after cessation of treatment, the abnormal blood vessels returned in this patient's retina in the absence of OHR-102 treatment, and continued to grow through the second month, the latest time point measured. We expect the final data will be disseminated by the investigator in a scientific publication.

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

Study 004 was 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 10 weeks, with injections of Lucentis at week two and six, and a data readout at week 10. At week 10, the patients entered into the extension phase and were randomized 1:1 to either continue or discontinue taking OHR-102 eye drops through week 38 ("extension phase"). During the extension phase, the patients received Lucentis injections on a PRN basis as determined by fluid based OCT criteria. The principal investigator presented the 10 week data from the study in August 2014. The data demonstrated that, at week 10 (1) the mean gain in visual acuity was 20.3 letters for all 20 patients using the combination therapy, (2) the mean visual acuity for all 20 patients at was 20/32, (3) the average central foveal thickness for all 20 patients was reduced to 270u, and (4) only one of 20 patients qualified for an injection of Lucentis, indicating dryness of the retina and a 95% macular deturgescence rate.

In July 2015, final data was presented by demonstrating that at week 38, (1) the mean gain in visual acuity from baseline for patients randomized (at week 10) to treatment with OHR-102 + Lucentis PRN was +27.8 letters compared with +23.3 for patients randomized to treatment with Lucentis plus PRN alone (control group), a clinically meaningful difference of +4.5 letters, (2) 80% of patients in the OHR-102 + Lucentis treated group had a gain in visual acuity, compared with 50% of patients treated with Lucentis alone, and (3) none of the patients in the OHR-102 + Lucentis treated group lost any vision. After the initial combination therapy phase, the mean gain in visual acuity from week 10 to week 38 was +7.4 letters for patients who continued treatment with OHR-102 + Lucentis PRN compared with +3.1 letters in those receiving Lucentis PRN alone. Patients treated with OHR-102 + Lucentis PRN required a mean of 2.0 Lucentis injections between weeks 10 and 38, compared with a mean of 3.3 Lucentis injections for the monotherapy group over the same time period.

(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. This technology platform is adaptable to multiple routes of ocular delivery and amenable to multiple different polymers.

The SKS sustained release technology was designed to develop best-in-class drug formulations for ocular disease. The technology employs micro fabrication techniques to create nano and microparticle drug formulations that can provide sustained and predictable release of a therapeutic drug over a 3 – 6 month period. The versatility of this delivery technology makes it well suited to deliver hydrophilic or hydrophobic small molecules, as well as proteins with complex structures. 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 glaucoma, steroid induced glaucoma, allergies, and retinal disease. Ohr has several molecules under development for these indications and anticipates expanding the pipeline during calendar year 2016 to include additional molecules and indications in ocular disease. We also anticipate presenting in-vivo proof of concept data on our internal programs and potentially filing an investigational new drug application with the FDA on one sustained release program in calendar 2016.

(c) Animal Model for Dry-AMD

As part of the SKS Acquisition, we acquired the exclusive rights to an animal model for dry-AMD whereby mice are immunized with a carboxyethylpyrrole ("CEP") which is bound to mouse serum albumin ("MSA"). CEP is produced following the oxidation of docosahexaenoic acid, which is abundant in the photoreceptor outer segments that are phagocytosed by the retinal pigment epithelium ("RPE"). A number of CEP-adducted proteins have been identified in proteomic studies examining the composition of drusen and other subretinal deposits found in the eyes of patients with dry-AMD. Studies have shown that immunization of CEP-MSA can lead to an ophthalmic phenotype very similar to dry-AMD, including deposition of complement in the RPE, thickening of the Bruch's membrane, upregulation of inflammatory cytokines, and immune cell influx into the eye. Ohr licenses the intellectual property rights to this model, and EyeCRO, a development partner of the Company, has obtained exclusive rights to provide contracted screening services in the CEP model. EyeCRO is a contract research organization specializing in preclinical services to the ophthalmology industry. As part of the EyeCRO arrangement, 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 2016.

(d) Non-Ophthalmology Assets

Ohr also owns various other compounds in earlier stages of development, including the PTP1b inhibitor Trodusquemine and related analogs. See “Corporate Strategy” concerning the Trodusquemine joint venture. During fiscal 2015, the Company ceased all development of OHR/AVR 118 and recognized an impairment on the patent portfolio in the amount of $338,906.

COMPETITIVE FACTORS

Competition in General

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

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

Competition in Wet AMD

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 percentage 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 "Competitive Landscape in Wet-AMD" 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 2014, 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 2014 revenues of approximately$2 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 the last of 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 are currently in Phase II or Phase III trials include MP0112, a VEGF targeting DARPin molecule being developed by Allergan, RTH258, an anti-VEGF agent being developed by Alcon/Novartis, X-82, an oral tyrosine kinase inhibitor being developed by Tyrogenex, ALG-1001, an integrin targeting peptide being developed by Allegro Ophthalmics, and REG-2176, a combination injection with anti-VEGF and PDGF agents being developed by Regeneron. 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.

Competitive Landscape in Sustained Release Drug Delivery

There are a number of companies developing various forms of sustained release drug delivery platforms for ophthalmic applications. These include GreyBug with a biodegradable polymer microsphere/nanoparticle matrix system, Enivsia Therapeutics with the PRINT® technology system for microparticle and nanoparticle formulations, Kala Pharmaceuticals with a mucus-penetrating particle (MPP) technology, and Ocular Therapeutix with a proprietary hydrogel technology ophthalmic sustained drug delivery. All of these programs are in the preclinical or early clinical development stage. Each of these may prove to be effective means to deliver drugs in a sustained manner and we cannot assure you that none of them will get to market before us or that the SKS technology will be a better drug delivery approach.

CORPORATE STRATEGY

The Company is currently actively developing its pipeline products for applications in ophthalmology. Beginning in the 2014 fiscal year, we transitioned Ohr to a core focus on ophthalmology indications and building an ophthalmology-focused pipeline, and we expect to continue to see growth in our pipeline and ophthalmology initiatives.

After the presentations of the final 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 several third parties regarding the licensure, sale or acquisition of our products and technologies or a merger, or the 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 enter into or complete such a transaction.

As part of its core strategy, 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 licenses research from CSHL and intellectual property from the Company. In December 2014, DepYmed hired a full time CEO to run the operations of DepYmed and intends to seek private investment to fund the ongoing operations of DepYmed, leaving Ohr as a passive joint venturer.

Patents and Other Proprietary Rights

Patents and other proprietary rights are important to our business. It is our policy to seek patent protection for our assets, and also to rely upon trade secrets, know-how and licensing opportunities to develop and maintain our competitive position.

We generally seek worldwide patent protection for our products and have foreign patent rights corresponding to most of our U.S. patents. We currently own or have exclusively licensed several issued U.S. patents and non-US patents and have additional U.S. and non-U.S. pending patent applications. These patent and patent applications include US 7981876, 8716270, 6262283, 7728157, 6962909, and 20130281420 to cover the Squalamine (OHR-102) formulations, composition of matter, methods of manufacture and synthesis and uses. Additional patent applications covering combination therapy with Squalamine have been filed.

Under an agreement with Akina, Inc ("Akina"), we license patents, with an estimated expiration date of May 28, 2029, relating to nano/micro particle fabrication technology for sustained release of proteins and other biologics. The worldwide, exclusive, sub-licensable license was granted to SKS (now Ohr) for use in developing ocular products. Under the agreement with Akina, the parties will collaborate on at least three nano/micro particle products and SKS (now Ohr) agreed to use commercially reasonable efforts to either develop the licensed technology by means of a partnership with a third party or an investigational new drug application. Additional patent applications have been filed that expand on the platform technology and are specific to our active development programs using the sustained release technology.

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Pursuant to the terms of the Uruguay Round Agreements Act, the term of a U.S. patent is 20 years and is measured from the date that the patent application was filed rather than the prior calculation of term which was 17 years from the date that the patent issued. Patent term may be extended beyond the 20-year period when the U.S. Patent Office fails to examine the patent application in a timely manner before issuance of the patent. Our issued U.S. patents expire between 2015 and 2029, excluding any potential patent grants or extensions which would extend the term of patent protection. We take advantage of patent term adjustment whenever available and expect to seek patent term extensions following marketing approval. Under the Drug Price Competition and Patent Term Restoration Act of 1984 and the Generic Animal Drug and Patent Term Restoration Act of 1988, a patent that claims a product, use or method of manufacture covering a drug may be extended for up to five years to compensate the patent holder for a portion of the time required for FDA review.

While we file and prosecute patent applications to protect our inventions, our pending patent applications might not result in the issuance of patents or our issued patents might not provide competitive advantages. Also, our patent protection might not prevent others from developing competitive products using related or other technology.

In addition to seeking the protection of patents and licenses, we also rely upon trade secrets, know-how and continuing technological innovation, which we seek to protect, in part, by confidentiality agreements with employees, consultants, suppliers and licensees.

The scope, enforceability and effective term of issued patents can be highly uncertain and often involve complex legal and factual questions. No consistent policy has emerged regarding the breadth of claims in pharmaceutical patents, so that even issued patents might later be modified or revoked by the relevant patent authorities or courts. Moreover, the issuance of a patent in one country does not assure the issuance of a patent with similar claim scope in another country, and claim interpretation and infringement laws vary among countries, so we are unable to predict the extent of patent protection in any country. The patents we obtain and the unpatented proprietary technology we hold might not afford us significant commercial protection. Additional information regarding risks associated with our patents and other proprietary rights that affect our business is contained under the headings “Intellectual property litigation is increasingly common and increasingly expensive and may result in restrictions on our business and substantial costs, even if we prevail” under the heading “Risk Factors”.

There are no contested proceedings and/or third-party claims over any of our patents or patent applications.

NUMBER OF PERSONS EMPLOYED

At present, the Company has 16 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.

GOVERNMENT COMPLIANCE

The Drug Development Process

Regulation by government authorities in the United States and foreign countries is a significant factor in the research, development, manufacture, and marketing of our product candidates. All of our product candidates will require regulatory approval before they can be commercialized. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other pre-market approval requirements by the FDA and foreign authorities. Many aspects of the structure and substance of the FDA and foreign pharmaceutical regulatory practices have been reformed during recent years, and continued reform is under consideration in a number of jurisdictions. The ultimate outcome and impact of such reforms and potential reforms cannot be predicted.

The activities required before a product candidate may be marketed in the United States begin with preclinical tests. Preclinical tests include laboratory evaluations and animal studies to assess the potential safety and efficacy of the product candidate and its formulations. The results of these studies must be submitted to the FDA as part of an IND, which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. In Phase I, trials are conducted with a small number of subjects to determine the early safety profile of the product candidate. In Phase II, clinical trials are conducted with subjects afflicted with a specific disease or disorder to provide enough data to evaluate the preliminary safety, tolerability, and efficacy of different potential doses of the product candidate. In Phase III, large-scale clinical trials are conducted with patients afflicted with the specific disease or disorder in order to provide enough data to understand the efficacy and safety profile of the product candidate, as required by the FDA. The results of the preclinical and clinical testing of a therapeutic product candidate are then submitted to the FDA in the form of an NDA for evaluation to determine whether the product candidate may be approved for commercial sale. In responding to an NDA, the FDA may grant marketing approval, request additional information, or deny the application.

Any approval required by the FDA for any of our product candidates may not be obtained on a timely basis, or at all. The designation of a clinical trial as being of a particular phase is not necessarily indicative that such a trial will be sufficient to satisfy the parameters of a particular phase, and a clinical trial may contain elements of more than one

phase notwithstanding the designation of the trial as being of a particular phase. The results of preclinical studies or early stage clinical trials may not predict long-term safety or efficacy of our compounds when they are tested or used more broadly in humans.

Approval of a product candidate by comparable regulatory authorities in foreign countries is generally required prior to commencement of marketing of the product in those countries. The approval procedure varies among countries and may involve additional testing, and the time required to obtain such approval may differ from that required for FDA approval.

Other Regulations

Various federal, state and local laws, regulations, and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, the environment and the purchase, storage, movement, import, export, use, and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research are applicable to our activities. They include, among others, the U.S. Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Occupational Safety and Health Act, the National Environmental Policy Act, the Toxic Substances Control Act, and Resources Conservation and Recovery Act, national restrictions on technology transfer, import, export, and customs regulations, and other present and possible future local, state, or federal regulation. The compliance with these and other laws, regulations and recommendations can be time-consuming and involve substantial costs. In addition, the extent of governmental regulation which might result from future legislation or administrative action cannot be accurately predicted and may have a material adverse effect on our business, financial condition, results of operations and prospects.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Business and Industry

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

We are a development stage pharmaceutical company and currently do not have, and may never have, any products that generate revenues. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. To date, we have not generated any product revenues from our product candidates currently in development. We cannot guarantee that any of our product candidates currently in development will ever become marketable products.

We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA, and other regulatory authorities in the United States, the European Union and elsewhere. Significant additional research, preclinical testing and clinical testing is required before we can file applications with the FDA or other regulatory authorities for premarket approval of our drug candidates. In addition, to compete effectively, our drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. We recently completed a Phase II clinical trial for OHR-102, our most advanced drug candidate. The results of the Phase II clinical trial continue to support conducting Phase III clinical trials for OHR-102 for a targeted population, with enrollment criteria based on the complete analysis of the Phase II clinical trial. We cannot be certain that the clinical development of this or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

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

We have experienced significant net losses since our inception. As of September 30, 2015, we had an accumulated deficit of approximately $58.5 million. We expect to incur net losses over the next several years as we advance our programs and incur significant clinical development costs. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We do not expect to receive, for at least the next several years, any revenues from the commercialization of our product candidates.

There is no guarantee that our future Phase III clinical trials for OHR-102 in wet-AMD will commence or be completed in the anticipated timeframe or that they will be successful.

We commenced a clinical study, Study OHR-002 (or IMPACT Study), which began enrolling patients in late 2012. The IMPACT Study was a randomized, double masked, placebo controlled Phase II study to evaluate the efficacy and safety of OHR-102 for the treatment of wet-AMD. The study enrolled treatment naïve wet-AMD patients at 23 clinical sites in the U.S., who were treated with OHR-102 eye drops or placebo eye drops for a nine month period. Full enrollment was completed in April 2014, and final results were released in March 2015. The results of the Phase II clinical trial continue to support conducting Phase III clinical trials for OHR-102 with enrollment criteria for a targeted population, based on the complete analysis of the Phase II clinical trial. While we expect to initiate the Phase III clinical program upon completion of the SPA procedure and begin enrolling patients in the first calendar quarter of 2016, there can be no assurance that the Phase III clinical trials will commence or be completed in the anticipated timeframe or that they will be successful.

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

At an end of Phase II meeting with the FDA in September 2014, the FDA agreed with the Company on a nine month primary efficacy endpoint for the Phase III trials. 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 two years. We met with the FDA in July 2015 and discussed the results of the Phase II trial and the upcoming Phase III trials. Following this meeting, we submitted a special protocol assessment request to the FDA which includes a detailed protocol to address and adequately provide the FDA with a Phase III program that produces data that would allow assessment of efficacy and safety of OHR-102 for the treatment of patients with wet AMD.

The Company currently intends to initiate the Phase III clinical trials, upon completion of the SPA procedure, to evaluate the efficacy and safety of OHR-102 given in combination with Lucentis for newly diagnosed, treatment naïve patients with enrollment criteria based on the complete analysis of the Phase II clinical trial. 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 an improvement in visual acuity parameters, as measured by a

standard ETDRS visual acuity chart.

There can be no assurance that we will meet the goals of the Phase III clinical trials or that we will have the same level of success in these the Phase III clinical trials as we have in our prior clinical trials, or be successful at all. We believe that OHR-102 may also have clinical utility in indications other than wet-AMD. We have completed 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, and proliferative diabetic retinopathy.

If we do not successfully complete clinical development of OHR-102, we will be unable to market and sell products derived from it and to generate product revenues. Even if we do successfully complete clinical trials for OHR-102 in patients with wet-AMD, those results are not necessarily predictive of results of future pivotal trials that may be needed before we may submit a New Drug Application, or NDA, to the FDA for the initial or other future indications. Of the vast number of drugs in development, only a small percentage result in the submission of an NDA to the FDA, and even fewer result in the NDA ultimately being approved by the FDA for commercialization.

We will need to raise substantial additional capital to further our drug and delivery platform development programs as well as future trials, including our planned Phase III clinical trials for OHR-102 in wet-AMD, and may not be able to raise additional capital on favorable terms, if at all. If additional capital is not available, we may have to delay, reduce or cease operations.

We will need substantial additional capital to further our drug and delivery platform development programs as well as future trials. Specifically, we will require significant additional funds to complete our planned Phase III clinical trials for OHR-102 in wet-AMD. 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 have to delay, reduce or cease operations.

Our long-term strategy with respect to OHR-102 in wet-AMD is to seek a strategic commercial partner, or partners, such as large pharmaceutical companies, with extensive experience in the development, commercialization, and marketing of our products. However, we currently do not have any agreement to enter into such a transaction, and there is no assurance that the Company will enter into or complete such a transaction.

Results from early clinical trials for OHR 102 in wet-AMD are not necessarily predictive of the results of later clinical trials for OHR 102 in wet-AMD. If we cannot replicate the results from our earlier clinical trials for OHR 102 in wet-AMD in our later clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize OHR 102 in wet-AMD.

Results from our Phase II clinical trial for OHR 102 in wet-AMD may not necessarily be predictive of the results from required later clinical trials. We may not be able to commence or complete our planned Phase III clinical trials for OHR 102 in wet-AMD. Similarly, even if we are able to complete our planned Phase III clinical trials for OHR 102 in wet-AMD according to our current development timeline, the results from our Phase II clinical trial for OHR 102 in wet-AMD may not be replicated in our Phase III clinical trial results. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been

caused by, among other things, pre-clinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials nonetheless failed to obtain FDA approval. If we fail to produce positive results in our planned Phase III clinical trials for OHR 102 in wet-AMD, the development timeline and regulatory approval and commercialization prospects for our leading product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected.

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

The commencement of clinical trials can be delayed for a variety of reasons, including: delays in demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial; reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites; manufacturing sufficient quantities of a product candidate; obtaining clearance from the FDA to commence clinical trials pursuant to an Investigational New Drug application, or IND; financial or strategic considerations; obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site; and patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including: ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results; failure to conduct clinical trials in accordance with regulatory requirements; lower than anticipated screening or retention rates of patients in clinical trials; serious adverse events or side effects experienced by participants; financial or strategic considerations; and insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

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

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

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

fail to receive the regulatory approvals required to market them as drugs;

be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;

be difficult or expensive to manufacture on a commercial scale;

have adverse side effects that make their use less desirable; or

fail to compete with product candidates or other treatments commercialized by our competitors.

In addition, our clinical trials may involve a specific patient population. Because of the small sample size, the results of these early clinical trials may not be indicative of future results. Adverse or inconclusive results may cause us to abandon a drug candidate and may delay development of other drug candidates. Any delay in, or termination of, our clinical and preclinical studies will delay the filing of our NDAs with the FDA and, ultimately, significantly impair our ability to commercialize our drug candidates and generate product revenues which would have a material adverse effect on our business and results of operations. If we are unable to receive the required regulatory approvals, secure our intellectual property rights, minimize the incidence of any adverse side effects or fail to compete with our competitors' products, our business, financial condition, and results of operations could be materially and adversely affected.

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

For the diseases or disorders that our product candidates are intended to treat, we expect only a subset of the patients with these diseases to be eligible for our clinical trials. Given that each of our product candidates is in 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.

We rely, and expect that will continue to rely, on third parties to conduct any future clinical trials for us, including our planned Phase III clinical trial for OHR 102 in wet-AMD. If such third parties do not successfully carry out their duties or if we lose our relationships with such third parties, our drug development efforts could be delayed.

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

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

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

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

Although we do design our clinical trials for OHR 102 in wet-AMD and other drug candidates, contract research organizations conduct all of the clinical trials. As a result, many important aspects of our drug development programs are outside of our direct control. In addition, the contract research organizations may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements, but we remain responsible and are subject to enforcement action that may include civil penalties up to and including criminal prosecution for any violations of FDA laws and regulations during the conduct of our clinical trials. If the contract research organizations do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of OHR 102 in wet-AMD and other drug candidates may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these contract research organizations devote to our program. If we are unable to rely on clinical data

collected by our contract research organizations, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures.

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 and clinical trials related to our drug discovery and development efforts, and we will likely continue to depend on them to assist in our future discovery and development efforts. These parties are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If they fail to devote sufficient time and resources to our drug development programs or if their performance is substandard, it will delay the development and commercialization of our product candidates. The parties with which we contract for execution of our clinical trials and ISTs play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to achieve their research goals or otherwise meet their obligations on a timely basis could adversely affect clinical development of our product candidates.

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

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

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

the ability to provide acceptable evidence of safety and efficacy;

pricing and cost effectiveness, which may be subject to regulatory control;

our ability to obtain sufficient third-party insurance coverage or reimbursement;

effectiveness of our or our collaborators' sales and marketing strategy;

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects; and

availability of alternative treatments.

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

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

We work with scientific and clinical advisors at academic and other institutions who are experts in the field of ocular disorders. They advise us with respect to our clinical trials. These advisors are not our employees and may have other commitments that would limit their future availability to us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services, which may impair our reputation in the industry and delay the development or commercialization of our product candidates.

We rely completely on third-party manufacturers may result in delays in our clinical trials, regulatory approvals and product introductions.

We have no manufacturing facilities and do not have extensive experience in the manufacturing of drugs or in designing drug-manufacturing processes. We have contracted with third-party manufacturers to produce, in collaboration with us, our product candidates, including OHR-102, for clinical trials. If any of our product candidates are approved by the FDA or other regulatory agencies for commercial sale, we may need to amend our contract with our current manufacturer or contract with another third party to manufacture them in larger quantities. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on these third parties for development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study and trial protocols. If these third parties do

not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study and trial plans and protocols, or if there are disagreements between us and these third parties, we will not be able to complete, or may be delayed in completing, the clinical trials required to support future approval of our product candidates. In some such cases we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay with respect to the approval of our product candidates and would thereby have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

The manufacturers of our product candidates are obliged to operate in accordance with FDA-mandated cGMPs. In addition, the facilities used by our contract manufacturers or other third party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we request regulatory approval from the FDA. A failure of any of our current or future contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates or the ultimate launch of products based on our product candidates into the market. Furthermore, all of our contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our contract manufacturers' facilities generally. Failure by our current or future third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating

restrictions, and criminal prosecutions. Many aspects of the clinical trial and manufacturing process are outside of our control. In addition, the third-party manufacturers may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If a third-party manufacturer breaches their obligations to us or fails to comply with regulatory requirements, the commercialization of OHR 102 in wet-AMD and other drug candidates may be delayed or irreversibly harmed.

The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

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

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

Our long-term strategy is to ultimately seek a strategic commercial partner, or partners, such as large pharmaceutical companies, with extensive experience in the development, commercialization, and marketing of our products. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) and sales and marketing of our products. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States.

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

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If we are ever in a position to commercialize our product candidates, of which there can be no assurance, we have no experience selling, marketing or distributing products and no internal capability to do so.

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

our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;

the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

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

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

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

developing drugs;

undertaking preclinical testing and human clinical trials;

obtaining FDA and other regulatory approvals of drugs;

formulating and manufacturing drugs; and

launching, marketing and selling drugs.

These organizations also compete with us to attract qualified personnel, acquisitions and joint ventures candidates and for other collaborations. Activities of our competitors may impose unanticipated costs on our business which would have a material adverse effect on our business and results of operations.

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

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

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

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 several 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.

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

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

Risks Related to FDA Regulation

We face heavy government regulation, and FDA regulatory approval of our products is uncertain.

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

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

a drug candidate may not be shown to be safe or effective;

the FDA may not approve our manufacturing process;

the FDA may interpret data from preclinical and clinical trials in different ways than we do; and

the FDA may not meet, or may extend, the Prescription Drug User Fee Act date with respect to a particular New Drug Application (“NDA”).

For example, if certain of our methods for analyzing our trial data are not accepted by the FDA, we may fail to obtain regulatory approval for our product candidates. Moreover, if and when our products do obtain marketing approval, the marketing, distribution and manufacture of such products would remain subject to extensive ongoing regulatory requirements. Failure to comply with applicable regulatory requirements could result in:

warning letters;

fines;

civil penalties;

injunctions;

recall or seizure of products;

total or partial suspension of production;

refusal of the government to grant future approvals;

withdrawal of approvals; and

criminal prosecution.

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

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

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

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

Healthcare policy changes, including pending legislation recently adopted and further proposals still pending to reform the U.S. healthcare system, may harm our future business.

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

In March 2010, the U.S. Congress enacted and President Obama signed into law healthcare reform legislation that may significantly impact the pharmaceutical industry. In addition to requiring most individuals to have health insurance and establishing new regulations on health plans, this legislation will require discounts under the Medicare

drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the legislation imposes an annual fee, which will increase annually, on sales by branded pharmaceutical manufacturers starting in 2011. The financial impact of these discounts, increased rebates and fees and the other provisions of the legislation on our business is unclear and there can be no assurance that our business will not be materially adversely affected. In addition, these and other ongoing initiatives in the United States have increased and will continue to increase pressure on drug pricing. The announcement or adoption of any such initiative could have an adverse effect on potential revenues from any product that we may successfully develop.

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

Risks Related to Our Intellectual Property

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

Our commercial success depends on obtaining and maintaining proprietary rights to our product candidates and technologies and their uses, as well as successfully defending these rights against third-party challenges. We will be able to most effectively protect our product candidates, technologies, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. For example, we have rights under patents and patent applications US 7981876, 8716270, 6262283, 7728157, 6962909, and 20130281420 to cover the Squalamine formulations, composition of matter, methods of manufacture and synthesis and uses. Nonetheless, the issued patents and patent applications covering our primary technology programs remain subject to uncertainty due to a number of factors, including:

we may not have been the first to make one or more of the inventions covered by our pending patent applications or issued patents;

we may not have been the first to file patent applications for one or more of our product candidates or the technologies we rely upon;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

our disclosures in a particular patent application may be determined to be insufficient to meet the statutory requirements for patentability;

one or more of our pending patent applications may not result in issued patents;

we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;

one or more patents issued to us or to our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;

we may fail to file for patent protection in all of the countries where patent protection will ultimately be necessary or fail to comply with other procedural, documentary, fee payment or other provisions during the patent process in any such country, and we may be precluded from filing at a later date or may lose some or all patent rights in the relevant jurisdiction;

one or more of our technologies may not be patentable;

others may design around one or more of our patent claims to produce competitive products which fall outside of the scope of our patents;

others may identify prior art which could invalidate our patents; or

changes to patent laws may limit the exclusivity rights of patent holders.

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

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

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

Some of our research collaborators and scientific advisors have rights to publish data and information to which we have rights. Additionally, employees whose positions may be eliminated in connection with restructurings may seek future employment with our competitors. Although each of our employees is required to sign a confidentiality agreement with us at the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of such future employment. In addition, technology that we may license in may become important to some aspects of our business. We generally will not control all of the patent prosecution, maintenance or enforcement of in-licensed technology.

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

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

these agreements may be breached;

these agreements may not provide adequate remedies for the applicable type of breach; or

our trade secrets or proprietary know-how will otherwise become known.

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

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

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

obtain licenses, which may not be available on commercially reasonable terms, if at all;

redesign our products or processes to avoid infringement;

stop using the subject matter claimed in the patents held by others, which could cause us to lose the use of one or more of our drug candidates;

defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of management resources; or

pay damages.

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

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

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

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

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

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

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

Changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. In particular, there have been proposals to shorten the exclusivity periods available under U.S. patent law that, if adopted, could substantially harm our business. The product candidates that we are developing are protected by intellectual property rights, including patents and patent applications. If any of our product candidates becomes a marketable product, we will rely on our exclusivity under patents to sell the compound and recoup our investments in the research and development of the compound. If the exclusivity period for patents is shortened, then our ability to generate revenues without competition will be reduced and our business could be materially adversely impacted. The laws of some countries do not protect

intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our product candidates. In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect our products or technologies or limit the exclusivity periods that are available to patent holders. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was recently signed into law and includes a number of significant changes to U.S. patent law. These include changes to transition from a “first-to-invent” system to a “first-to-file” system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The U.S. Patent and Trademark Office has been in the process of implementing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

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

Risks Related to our Common Stock

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

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

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

adverse results or delays in our clinical trials;

fluctuations in our results of operations, timing and announcements of our bio-technological innovations or new products or those of our competitors;

developments concerning any strategic alliances or acquisitions we may enter into;

announcements of FDA non-approval of our drug products, or delays in the FDA or other foreign regulatory review process or actions;

adverse actions taken by regulatory agencies with respect to our drug products, clinical trials, manufacturing processes or sales and marketing activities;

any lawsuit involving us or our drug products;

developments with respect to our patents and proprietary rights;

announcements of technological innovations or new products by our competitors;

public concern as to the safety of products developed by us or others;

regulatory developments in the United States and in foreign countries;

changes in stock market analyst recommendations regarding our common stock or lack of analyst coverage;

the pharmaceutical industry conditions generally and general market conditions;

failure of our results of operations to meet the expectations of stock market analysts and investors;

sales of our common stock by our executive officers, directors and five percent stockholders or sales of substantial amounts of our common stock;

changes in accounting principles; and

loss of any of our key scientific or management personnel.

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

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

lower trading volume; and

market conditions.

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

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 OHR 102 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 OHR 102 and our sustained release ophthalmological platform or our other products in the United States unless we submit, and the FDA approves, an NDA for each such product. We must conduct clinical trials of each of our products in humans before we submit an NDA. We currently do not have sufficient capital to complete the necessary trials to complete the development of OHR-102 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 OHR-102 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. 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 OHR 102 and our sustained release ophthalmological platform or any other products. Our products may never be approved for commercial distribution by any country. Because our research and development expenses and clinical and preclinical study expenses will be charged against earnings for financial reporting purposes, we expect that losses from operations will continue to be incurred for the near future. We currently do not have sufficient funds to complete all phases of clinical and preclinical testing of any of our products which are required to permit the commercial sale of such products.

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

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

Our internal controls over financial reporting may not be effective, and our independent auditors may not be able to certify as to their effectiveness, which could have a significant and adverse effect on our business and reputation.

We are subject to the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and the rules and regulations of the SEC thereunder ("Section 404"). Section 404 requires us to report on the design and effectiveness of our internal controls over financial reporting. In our Form 10-Q for the quarterly period ended March 31, 2015 , our management identified "material weaknesses" in our internal controls over financial reporting relating to an inefficiency in the financial reporting process regarding the assessment of fair value accounting principles related to non-recurring and complex transactions. We retained a third party to assist us in remediating these material weaknesses, which we believe has been remediated. However, any failure to maintain or implement new or improved controls, or any difficulties we encounter in their implementation, could result in significant deficiencies or material weaknesses, and cause us to fail to meet our periodic reporting obligations, or result in material misstatements in our financial statements. We may also be required to incur costs to improve our internal control system and hire additional personnel. This could negatively impact our results of operations.

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

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

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

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

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

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

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

ITEM 2 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 being rented to us on a monthly basis.

ITEM 3 LEGAL PROCEEDINGS

The Company is not a party to any material pending legal proceedings.

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 2015	**High**	**Low**	**FY 2014**	**High**	**Low**
October 1 - December 31, 2014	$ 9.24	$ 6.69	October 1 - December 31, 2013	$ 8.26	$ 6.61
January 1 - March 31, 2015	$ 12.31	$ 2.51	January 1 - March 31, 2014	$ 19.65	$ 7.85
April 1 - June 30, 2015	$ 3.04	$ 2.35	April 1 - June 30, 2014	$ 14.03	$ 6.82
July 1 -September 30, 2015	$ 4.34	$ 2.02	July 1 - September 30, 2014	$ 9.98	$ 7.23

Performance Graph

The following graph compares our cumulative total stockholder return from October 1, 2010, 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, 2010 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.

	9/30/2010	9/30/2011	9/30/2012	9/30/2013	9/30/2014	9/30/2015
OHRP	$ 100	$ 300	$ 404	$ 1,081	$ 967	$ 368
Nasdaq Capital Market Composite Index	$ 100	$ 85	$ 109	$ 135	$ 129	$ 110
Nasdaq Biotech Index	$ 100	$ 108	$ 166	$ 244	$ 319	$ 354

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Holders

As of December 14, 2015 there were 185 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers.

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.

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, 2011, 2012, 2013, 2014 and 2015, and for the five years in the period ended September 30, 2015. 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,

	2011	**2012**	**2013**	**2014**	**2015**
Operating expenses					
General and administrative	$574,915	$989,571	$1,775,857	$4,287,205	$7,509,601
Research and development	585,002	2,209,108	2,753,914	4,369,413	8,777,519
Depreciation and amortization	83,484	87,729	91,145	466,306	1,179,254
Impairment of intangibles	—	—	—	—	338,906
Total Operating Expenses	1,243,401	3,286,408	4,620,916	9,122,924	17,805,280
Operating loss	(1,243,401)	(3,286,408)	(4,620,916)	(9,122,924)	(17,805,280)
Interest expense	(2,433)	(1,817)	(4,689)	(5,576)	(5,977)
Change in derivative liability	(3,977,041)	1,812,224	(1,117,642)	—	—
Change in fair value of contingent consideration	—	—	—	—	2,637,756
Share in losses on investment in joint venture	—	—	—	(10,643)	(103,143)
Gain on sale of assets	70,500	—	—	—	—
Gain on settlement of debt	49,179	21,005	—	—	—
Other income and expense	1,677	112	90,759	8,479	78,779
Total other income (expense)	(3,858,118)	1,831,524	(1,031,572)	(7,740)	2,607,415
Loss from operations	(5,101,519)	(1,454,884)	(5,652,488)	(9,130,664)	(15,197,865)
Provision for income taxes	—	—	—	—	—
Net loss	$(5,101,519)	$(1,454,884)	$(5,652,488)	$(9,130,664)	$(15,197,865)
Net loss per basic and diluted share	$(0.40)	$(0.10)	$(0.30)	$(0.41)	$(0.54)
Weighted-average shares used to compute net loss per basic and diluted share:	12,888,915	14,242,792	18,707,759	22,141,538	28,404,405

Combined and Consolidated Balance Sheet Data:

	As of September 30,				
	2011	2012	2013	2014	2015
Total assets	$1,412,846	$3,517,420	$5,743,865	$32,025,144	$46,370,807
Total liabilities	6,194,599	1,091,195	479,737	5,273,122	3,880,014
Total stockholders' equity	(4,781,753)	2,426,225	5,264,128	26,752,022	42,490,793

ITEM 7 MANAGEMENT'S 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, except as required by law. 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 11 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.

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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 2015 fiscal year to the end by $17,075,123 (to $25,156,022 from $8,080,899) and increased from the beginning of the 2014 fiscal year to the end by $3,392,391 (to $8,080,899 from $4,688,508) primarily due to capital raised through the sale of common stock. During Fiscal 2015, our quarterly cash burn was approximately $2-3mm per quarter, which was higher than in fiscal 2014. We expect our cash burn to significantly increase in fiscal 2016 with the full phase III clinical program underway and the ongoing development of our sustained release platform technology. 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, or a transaction with a pharmaceutical partner, for which there can be no warranty or assurance that the Company may be successful in such efforts. On February 11, 2015, the Company sold 4,259,259 shares of common stock in an underwritten public offering resulting in net proceeds of $26.6 million. With this additional capital, management believes the Company has sufficient capital to meet its planned operating needs through September 2016.

Results of Operations

For the fiscal year ended September 30, 2015, the Company had zero revenues and operating expenses of approximately $17,805,280. The loss from operations was comprised of $8,777,519 in research and development costs, $7,509,601 in general and administrative expenses, $1,179,254 in depreciation and amortization and $338,906 in impairment of intangibles. During the same period, the Company recorded interest expense of $5,977, a loss on

investment of subsidiary of $103,143, change in fair value of contingent consideration of $2,637,756 and other income items totaling $78,779. The net loss for the year ended September 30, 2015 was $15,197,865.

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 $4,369,413 in research and development costs, $4,287,205 in general and administrative expenses and $466,306 in depreciation and amortization. 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.

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 $2,753,914 in research and development costs, $1,775,857 in general and administrative expenses, and $91,145 in depreciation and amortization. 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.

As noted above, the Company had zero revenues for fiscal year 2015, and does not anticipate that it will have any revenues in fiscal year 2016. The operating expenses of the Company increased from fiscal year 2014 to fiscal year 2015 by $8,682,356. The Company had increases in 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 2016, including clinical development costs, again with no offsetting revenues.

Results of operations for the year ended September 30, 2015 reflect the following changes from the prior period:

	2015	**2014**	**Change**
General and administrative	$7,509,601	$4,287,205	$3,222,396
Research and development	8,777,519	4,369,413	4,408,106
Depreciation and amortization	1,179,254	466,306	712,948
Impairment of intangibles	338,906	—	338,906
Total Operating Expenses	17,805,280	9,122,924	8,682,356
Operating Loss	(17,805,280)	(9,122,924)	(8,682,356)
Change in fair value of contingent consideration	2,637,756	—	2,637,756
Share in losses on investment in joint venture	(103,143)	(10,643)	(92,500)
Other income and expenses	72,802	2,903	69,899
Net Loss	$(15,197,865)	$(9,130,664)	$(6,067,201)

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

	2014	2013	Change
General and administrative	$4,287,205	$1,775,857	$2,511,348
Research and development	4,369,413	2,753,914	1,615,499
Depreciation and amortization	466,306	91,145	375,161
Total Operating Expenses	9,122,924	4,620,916	4,502,008
Operating 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)

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 $8,777,519, $4,369,413, and $2,753,914 during the years ended September 30, 2015, 2014, and 2013, 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 for both goodwill and other finite-lived intangible assets. The Company recorded no impairment loss for the years ended September 30, 2015, 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 15 years. During the years ended September 30, 2015, 2014, and 2013 the Company recognized $1,138,631, $448,456, and $77,789 in amortization expense on the patents and license rights, respectively. The amortization expense has been included in general and administrative expense.

In January 2015, the Company discontinued development of the OHR/AVR118 program. In connection with this decision, the patent portfolio is no longer being maintained and the remaining $338,906 in unamortized patent costs have been impaired (Patent cost of $600,000 less $261,094 previously amortized).

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, 2015, the end of our fiscal year. Management based its assessment on the framework in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. 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 our internal control over financial reporting was 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, MaloneBailey, LLP, independently assessed our internal control over financial reporting. MaloneBailey, LLP has issued a report on our internal control over financial reporting, which is included in this annual report.

/s/ JASON S. SLAKTER	/s/ SAM BACKENROTH
Jason S. Slakter	Sam Backenroth
Chief Executive Officer	Chief Financial Officer and Principal Accounting Officer

December 14, 2015

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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, 2015 and 2014 and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended September 30, 2015. 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, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2015, 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, 2015, based on the criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated December 14, 2015 expressed an unqualified opinion.

/s/ MaloneBailey, LLP

www.malone-bailey.com

Houston, Texas

December 14, 2015

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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, 2015, based on criteria established in Internal Control - Integrated Framework (2013) 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.

In our opinion, , the Company maintained effective internal control over financial reporting as of September 30, 2015, based on criteria established in Internal Control—Integrated Framework (2013) 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 14, 2015 expressed an unqualified opinion.

/s/ MaloneBailey, LLP

www.malone-bailey.com

Houston, Texas

December 14, 2015

OHR PHARMACEUTICAL, INC.

Consolidated Balance Sheets

	September 30, 2015	**September 30, 2014**
ASSETS		
CURRENT ASSETS		
Cash	$28,697,323	$13,220,494
Prepaid expenses and other current assets	338,713	133,527
Total Current Assets	29,036,036	13,354,021
EQUIPMENT, net	248,753	104,425
OTHER ASSETS		
Security deposit	12,243	12,243
Investment in joint venture	—	3,143
Intangible assets, net	16,332,863	17,810,400
Goodwill	740,912	740,912
TOTAL ASSETS	$46,370,807	$32,025,144
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$1,592,348	$351,864
Notes payable	48,063	43,899
Contingent consideration	2,239,603	4,877,359
Total Current Liabilities	3,880,014	5,273,122
TOTAL LIABILITIES	3,880,014	5,273,122
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred stock, Series B; 6,000,000 shares authorized, $0.0001 par value, 0 shares issued and outstanding, respectively	—	—
Common stock; 180,000,000 shares authorized, $0.0001 par value, 30,331,309 and 25,254,190 shares issued and outstanding, respectively	3,033	2,525
Additional paid-in capital	100,999,173	70,063,045
Accumulated deficit	(58,511,413)	(43,313,548)
Total Stockholders' Equity	42,490,793	26,752,022
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$46,370,807	$32,025,144

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

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OHR PHARMACEUTICAL, INC.

Consolidated Statements of Operations

	For the Year Ended September 30,		
	2015	2014	2013
OPERATING EXPENSES			
General and administrative	$7,509,601	$4,287,205	$1,775,857
Research and development	8,777,519	4,369,413	2,753,914
Depreciation and amortization	1,179,254	466,306	91,145
Impairment of intangibles	338,906	—	—
OPERATING LOSS	17,805,280	9,122,924	4,620,916
OTHER INCOME (EXPENSE)			
Interest expense	(5,977)	(5,576)	(4,689)
Change in derivative liability	—	—	(1,117,642)
Change in fair value of contingent consideration	2,637,756	—	—
Share in losses on investment in joint venture	(103,143)	(10,643)	—
Royalty income	35,813	—	—
Other income and expense	42,966	8,479	90,759
Total Other Income (Expense)	2,607,415	(7,740)	(1,031,572)
LOSS FROM OPERATIONS BEFORE INCOME TAXES	(15,197,865)	(9,130,664)	(5,652,488)
PROVISION FOR INCOME TAXES	—	—	—
NET LOSS	$(15,197,865)	$(9,130,664)	$(5,652,488)
BASIC AND DILUTED LOSS PER SHARE	$(0.54)	$(0.41)	$(0.30)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING: BASIC AND DILUTED	28,404,405	22,141,538	18,707,759

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

OHR PHARMACEUTICAL, INC.

Consolidated Statements of Stockholders' Equity

	Series B Preferred Stock		Common Stock		Additional Paid-in Capital	Stock Subscription Receivable	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
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
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 acquisition of assets			1,194,862	119	10,180,105	—	—	10,180,224
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 September 30, 2014	—	—	—	—	—	—	(9,130,664)	(9,130,664)
Balance, September 30, 2014	—	$—	25,254,190	$2,525	$70,063,045	$—	$(43,313,548)	$26,752,022
Exercise of warrants for cash	—	—	36,548	4	79,999	—	—	80,003
Cashless exercise of warrants	—	—	663,608	66	(66)	—	—	—
Common stock issued for	—	—	5,952	1	49,999	—	—	50,000

settlement of accounts payable								
Common stock issued for cash, net of stock issuance costs	—	—	4,259,259	426	26,582,572	—	—	26,582,998
Common stock issued for services	—	—	111,752	11	635,277	—	—	635,288
Fair value of employee stock options and warrants issued for services	—	—	—	—	3,588,347	—	—	3,588,347
Net loss for the year ended September 30, 2015	—	—	—	—	—	—	(15,197,865)	(15,197,865)
Balance, September 30, 2015	—	$—	30,331,309	$3,033	$100,999,173	$—	$(58,511,413)	$42,490,793

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,		
	2015	2014	2013
OPERATING ACTIVITIES			
Net loss	$(15,197,865)	$(9,130,664)	$(5,652,488)
Adjustments to reconcile net loss to net cash used in operating activities:			
Common stock issued for services	635,288	—	270,167
Warrants issued for services	8,559	1,177,095	335,869
Stock option expense	3,579,788	2,074,487	746,262
Change in fair value of contingent consideration	(2,637,756)	—	—
Loss on derivative liability	—	—	1,117,642
Share in losses on investment in joint venture	103,143	10,643	—
Depreciation	40,623	17,850	13,356
Amortization of intangible assets	1,138,631	448,456	77,789
Impairment of intangibles	338,906	—	—
Gain on settlement of accounts payable	(40,636)	—	—
Changes in operating assets and liabilities			
Prepaid expenses and deposits	7,214	105,823	236,492
Other receivables and other current assets	—	—	—
Accounts payable and accrued expenses	1,331,120	(63,822)	165,224
Net Cash Used in Operating Activities	(10,692,985)	(5,360,132)	(2,689,687)
INVESTING ACTIVITIES			
Acquisition of SKS Ocular's assets	—	(3,500,000)	—
Investment in joint venture	(100,000)	(13,786)	—
Purchase of property and equipment	(184,951)	(1,083)	—
Net Cash Used in Investing Activities	(284,951)	(3,514,869)	—
FINANCING ACTIVITIES			
Proceeds for issuance of common stock for cash	26,582,998	16,876,000	—
Proceeds from warrants exercised for cash	80,003	260,752	5,251,755
Repayments of short-term notes payable	(208,236)	(164,152)	(71,586)
Net Cash Provided by Financing Activities	26,454,765	16,972,600	5,180,169
NET CHANGE IN CASH	15,476,829	8,097,599	2,490,482
CASH AT BEGINNING OF PERIOD	13,220,494	5,122,895	2,632,413
CASH AT END OF PERIOD	$28,697,323	$13,220,494	$5,122,895

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION			
CASH PAID FOR:			
Interest	$5,977	$5,576	$4,192
Income taxes	—	—	—
NON CASH FINANCING ACTIVITIES:			
Reclassification of derivative liability to permanent equity	$—	$—	$1,886,338
Financing of insurance premiums through issuance of short term notes	212,400	194,000	63,600
Conversion of preferred for common stock	—	50	508
Noncash exercise of options and warrants	—	223	11
Common stock issued to acquire intangible assets	—	10,180,224	—
Common stock issued to settle accounts payable	50,000	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, 2015

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, OHR-102 (Squalamine Lactate Ophthalmic Solution, 0.2%), 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 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 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 $27,947,323 and $12,970,494 of cash balances in excess of federally insured limits at September 30, 2015 and 2014, 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	3 to 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 $500 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, 2015, management discontinued development of the OHR/AVR118 program. In connection with this decision, the patent portfolio is no longer being maintained and the remaining $338,906 in unamortized patent costs have been impaired. As of September 2015, 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, 2015 and 2014, on a recurring basis:

Assets and liabilities measured at fair value on a recurring basis at September 30, 2015	Level 1	Level 2	Level 3	Total Carrying Value
Contingent stock consideration	$ —	$ —	$2,239,603	$2,239,603
	$ —	$ —	$2,239,603	$2,239,603

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

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 fair value of the contingent stock consideration was based on the decision tree analysis method that considers the impact on project value of different scenarios at nominated decision points along the development path.

Stock Warrant Derivative Liability

As of September 30, 2012, certain outstanding stock warrants of the Company are classified as derivatives instruments due to reset provisions in the exercise prices. 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 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.

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.

The following table provides a summary of the changes in fair value, including net transfers in and/or out, of the financial instruments, measured at fair value on a recurring basis using significant unobservable inputs:

Level 3 Reconciliation:	Stock Warrant Derivative	Contingent Stock Consideration
Level 3 assets and liabilities at September 30, 2012	$(768,696)	$—
Purchases, sales, issuances and settlements (net)	1,886,338	—
Mark to market adjustments, net of gain on derivative liability of $55,481	(1,117,642)	—
Level 3 assets and liabilities at September 30, 2013	—	—
Purchases, sales, issuances and settlements (net)	—	4,877,359
Mark to market adjustments	—	—
Level 3 assets and liabilities at September 30, 2014	—	4,877,359
Purchases, sales, issuances and settlements (net)	—	—
Mark to market adjustments	—	(2,637,756)
Total Level 3 assets and liabilities at September 30, 2015	$—	$2,239,603

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 for both goodwill and other finite-lived intangible assets. The Company recorded no impairment loss for the years ended September 30, 2015 and 2014.

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 15 years. During the years ended September 30, 2015, 2014, and 2013 the Company recognized $1,138,631, $448,456, and $77,789 in amortization expense on the patents and license rights, respectively.

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 $8,777,519, $4,369,413, and $2,753,914 during the years ended September 30, 2015, 2014, and 2013 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 nonassessable 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 2012 to 2014 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, 2015,2014 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 1,313,536, 3,995,343 and 6,994,269 at September 30, 2015, 2014 and 2013, respectively.

Reclassification of Financial Statement Accounts

Certain amounts in the September 30, 2014 and 2013 financial statements have been reclassified to conform to the presentation in the September 30, 2015 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, 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, 2015 and 2014 consist of:

	2015	2014
Equipment	$91,715	$59,503
Lab Equipment	239,472	86,733
Leasehold Improvements	2,181	2,181
Office Furniture and Fixture	2,523	2,523
	335,891	150,940
Accumulated Depreciation	(87,138)	(46,515)
Total Property and Equipment	$248,753	$104,425

Depreciation expense for the years ended September 30, 2015, 2014, and 2013 was $40,623, $17,850, and $13,356, respectively.

NOTE 5 - INTANGIBLE ASSETS

Intangible assets at September 30, 2015 and 2014 consist of:

	2015	2014
License Rights	$17,712,991	$17,712,991
Patent Costs	200,000	800,000
	17,912,991	18,512,991
Accumulated Amortization	(1,580,128)	(702,591)
Total Intangible Assets	$16,332,863	$17,810,400

During the years ended September 30, 2015, 2014, and 2013, the Company recognized $1,138,631, $448,456, and $77,789, respectively, in amortization expense on the patents. The amortization expense has been included in research and development expense.

In January 2015, the Company discontinued development of the OHR/AVR118 program. In connection with this decision, the patent portfolio is no longer being maintained and the remaining $338,906 in unamortized patent costs have been impaired (Patent cost of $600,000 less $261,094 previously amortized).

The estimated future amortization of intangibles for the next five years is as follows:

Years ending September 30,	Estimated Amortization Expense
2016	$1,124,645
2017	1,120,616
2018	1,117,731
2019	1,116,449
2020	1,119,508
Total	$5,598,949

NOTE 6 - NOTES PAYABLE

On February 28, 2014, the Company entered into a premium financing arrangement for its directors and officers insurance in the amount of $194,000. The financing arrangement bears interest at 6.75% per annum and will be fully paid in 12 months from the date of issuance. As of September 30, 2015, the Company had repaid $194,000 of principal and had paid interest of $5,435.

On February 28, 2015, the Company entered into a premium financing arrangement for its directors and officers insurance in the amount of $212,400. The financing arrangement bears interest at 6.75% and will be fully paid in nine months from the date of issuance. As of September 30, 2015, the Company had repaid $164,337 of principal and had paid interest of $5,544.

NOTE 7 - CAPITAL STOCK

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.

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.

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

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

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

On January 6, 2015, the Company received a notice of exercise for 16,667 warrants with an exercise price of $2.85 per share. Accordingly, the Company issued 16,667 common shares for proceeds of $47,500.

On January 6, 2015, the Company issued 37,038 shares of common stock at a price of $8.19 per share as compensation for services performed in the amount of $303,350.

On January 12, 2015, the Company received a notice of exercise for 10,137 warrants with an exercise price of $1.65 per share. Accordingly, the Company issued 10,137 common shares for proceeds of $16,726.

On January 12, 2015, the Company received a notice of exercise for 2,818 warrants with an exercise price of $1.65 per share. Accordingly, the Company issued 2,818 common shares for proceeds of $4,649.

On January 13, 2015, the Company received a notice of exercise for 4,926 warrants with an exercise price of $1.65 per share. Accordingly, the Company issued 4,926 common shares for proceeds of $8,128.

On January 15, 2015, 66,667 warrants were exercised at an exercise price per share of $1.65 using cashless exercise. Accordingly, the Company issued 54,659 common shares.

On February 6, 2015, the Company issued 10,714 restricted shares of common stock at a price of $7.00 per share as compensation for services performed in the amount of $74,998 at the time of the grant. These shares will vest 25% at the end of each quarter of 2015 at the current market price per share. During the twelve months ended September 30, 2015 $20,918 were expensed as compensation of services performed.

On February 11, 2015, the Company issued 4,259,259 shares of common stock at a price of $6.75 per share. Accordingly, the Company received net proceeds of approximately $26,582,998 which were net of stock issuance costs amounting to $2,167,000.

On February 24, 2015, the Company issued 60,000 shares of common stock at a price of $9.78 per share as compensation for services to be performed in the amount of $586,800. Fifty percent of these shares will vest on the first anniversary of the date issuance and twenty five percent of these shares will vest on the second and third anniversaries of the date of issuance. During the twelve months ended September 30, 2015 $282,260 were expensed as compensation of services performed.

On March 27, 2015, 164,631 warrants were exercised at an exercise price per share of $1.95 using cashless exercise. Accordingly, the Company issued 131,331 common shares.

On March 27, 2015, 168,520 warrants were exercised at an exercise price per share of $3.60 using cashless exercise. Accordingly, the Company issued 104,901 common shares.

On April 2, 2015 73,337 warrants were exercised at an exercise price per share of $1.95 using cashless exercise. Accordingly, the Company issued 57,780 common shares.

On April 2, 2015, 505,935 warrants were exercised at an exercise price per share of $3.60 using cashless exercise. Accordingly, the Company issued 314,937 common shares.

NOTE 8 - 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 1.

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. 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, 2015, an aggregate of 979,090 warrants at an exercise price per share of $1.65 through $3.60 were exercised by cashless exercise. In addition, 36,548 warrants were exercised at prices ranging from $1.50 to $2.85 for which $80,002 in cash was received by the Company.

Below is a table summarizing the warrants issued and outstanding as of September 30, 2015:

	Number Outstanding	Weighted-Average Exercise Price
Outstanding at September 30, 2012	8,527,638	$ 2.80
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
Granted	—	—
Exercised	(1,015,638)	3.03
Forfeited	(184,501)	2.39
Outstanding at September 30, 2015	746,869	$ 4.75
Exercisable at	746,869	$ 4.75

	September 30, 2015

The outstanding warrants as of September 30, 2015 have an intrinsic value of approximately $130,718. For the years ended September 30, 2015, 2014, and 2013, the Company has expensed $8,559, $1,177,095, and $335,869, respectively, related to the fair value of warrants issued for services.

NOTE 9 - 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 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, 2015, 2014, and 2013, 29,167, 58,333, and 29,167 options have vested, respectively, resulting in compensation expense of $133,813, $133,690, and $189,852, 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, 2015, 2014, and 2013, 29,167, 58,333, and 29,167 options have vested, respectively, resulting in compensation expense of $131,285, $131,165, and $180,156, 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, 2015, 2014, and 2013, 125,000, 125,000, and 0 options have vested, respectively, resulting in compensation expense of $488,596, $814,327, 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. During the 2015 Fiscal Year 30,000 options were forfeited as a result of grantee’s resignations and 10,000 vested options expired. The Compensation recorded on the vested options totaled $46,808. For the years ended September 30, 2015, 2014, and 2013, 78,750, 88,750, and 0 options have vested, respectively, resulting in compensation expense of $332,957, $610,436, 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, 2015, 2014, and 2013, 15,000, 15,000, and 0 options have vested, respectively, resulting in compensation expenses of $62,671, $86,957, and $0, respectively.

On January 6, 2015, the Company granted 140,000 options, with an exercise price of $8.19 per share, to employees as part of its 2014 stock option plan. The Company calculated a fair value of $529,252 for the options. Of the 140,000 options issued, 35,000 vested upon issuance and the remaining 105,000 vest in 25 percent tranches on each anniversary of grant. During the 2015 Fiscal Year 15,000 options were forfeited as a result of grantee's resignations and 5,000 vested options expired. The Compensation recorded on the vested options totaled $18,902. For the years ended September 30, 2015, 2014, and 2013, 35,000, 0, and 0 options have vested, respectively, resulting in compensation expense of $275,563, $0, and $0, respectively.

On February 13, 2015, the Company granted 120,000 options, with an exercise price of $7.68 per share, to an employee as part of its 2014 stock option plan. The Company calculated a fair value of $411,962 for the options. Of the 250,000 options issued, 50,000 vested upon issuance and the remaining 150,000 vest in 25 percent tranches on each anniversary of grant. For the years ended September 30, 2015, 2014, and 2013, 50,000, 0, and 0 options have vested, respectively, resulting in compensation expense of $167,360, $0, and $0, respectively.

On March 1, 2015, the Company granted 200,000 options, with an exercise price of $7.06 per share, to an employee as part of its 2014 stock option plan. The Company calculated a fair value of $1,128,604 for the options. Of the 120,000 options issued, 30,000 vested upon issuance and the remaining 90,000 vest in 25 percent tranches on each December 31 2015, 2016 and 2017 respectively. For the years ended September 30, 2015, 2014, and 2013, 50,000, 0, and 0 options have vested, respectively, resulting in compensation expense of $456,420, $0, and $0, respectively.

On March 3, 2015, the Company granted 100,000 options, with an exercise price of $9.78 per share, to an employee as part of its 2014 stock option plan. The Company calculated a fair value of $509,845 for the options. Of the 100,000 options issued, 25,000 vested upon issuance and the remaining 75,000 vest in 25 percent tranches on each anniversary of grant. For the years ended September 30, 2015, 2014, and 2013, 25,000, 0, and 0 options have vested, respectively, resulting in compensation expense of $350,519, $0, and $0, respectively.

On March 10, 2015, the Company granted 546,000 options, with an exercise price of $10.14 per share, to employees as part of its 2014 stock option plan. The Company calculated a fair value of $2,700,392 for the options. Of the 546,000 options issued, 136,500 vested upon issuance and the remaining 409,500 vest in 25 percent tranches on each anniversary of grant. For the years ended September 30, 2015, 2014, and 2013, 136,000, 0, and 0 options have vested, respectively, resulting in compensation expense of $1,068,905, $0, and $0, respectively.

During the years ended September 30, 2015, 2014, and 2013 the Company recognized $3,579,788, $2,074,487 and $746,262 respectively, 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, 2015, 2014, and 2013 for all options outstanding amounted to approximately $4,462,655, $3,161,447, and $1,112,000, respectively.

Below is a table summarizing the options issued and outstanding as of September 30, 2015:

	Number Outstanding	Weighted - Average Exercise Price
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	2,048,335	$ 5.43
Granted	1,106,000	9.04
Exercised	—	—
Forfeited	(45,000)	8.32
Expired	(348,334)	1.79
Outstanding at September 30, 2015	2,761,001	$ 7.27
Exercisable at September 30, 2015	1,450,667	$ 5.74

As of September 30, 2015, the outstanding options have an intrinsic value of approximately $595,000.

NOTE 10 - 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, 2015 and 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.

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, 2015, future minimum payments for all lease obligations are as follows:

Year	Amount
2016	$45,550
	$45,550

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Rental expense related to the operating lease has been recorded in the consolidated statements of operations in the amounts of $305,638, $83,556, and $0 for each of the years ended September 30, 2015, 2014, and 2013, 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 11 - QUARTERLY FINANCIAL DATA (Unaudited)

	First	Second	Third	Fourth	Total
2015					
Total revenue	$—	$—	$—	$—	$—
Operating loss	(4,205,513)	(6,806,088)	(3,334,840)	(3,458,839)	(17,805,280)
Net loss	(4,540,957)	(3,400,548)	(3,345,997)	(3,910,363)	(15,197,865)
Net loss per basic and diluted share	$(0.18)	$(0.12)	$(0.11)	$(0.13)	$(0.54)

	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)	$(0.13)	$(0.41)

NOTE 12 - SUBSEQUENT EVENTS

On December 3, 2015, the Company announced the achievement of Milestone 1 from the SKS Ocular acquisition, demonstrating consistent long term release of an therapeutic agent above threshold therapeutic levels in the targeted ocular tissues of an animal model. The achievement of Milestone 1 requires that the Company issue 497,859 shares of its common stock to SKS.

Effective December 11, 2015, Irach B. Taraporewala, President and Chief Technology Officer, resigned from all officer positions with the Company and as a member of the Board of Directors of the Company, subject to a mandatory seven-day revocation period. In connection with Dr. Taraporewala's resignation, on December 11, 2015, the Company and Dr. Taraporewala entered into a two year Consulting Agreement and Release (the "Consulting Agreement and Release") dated December 11, 2015 (the "Effective Date"), pursuant to which Dr. Taraporewala will be engaged as a consultant to the Company.

As compensation for the consulting services to be rendered by Dr. Taraporewala, Dr. Taraporewala will receive the following:

- A retainer in the amount of $15,000 within 30 days following the Effective Date.
- A retainer in the amount of $15,000 on the first anniversary of the Effective Date.
- A monthly fee of $5,000 during each month of the term of the Consulting Agreement in consideration for providing the Company up to five hours of consulting services per week. In any week in which Dr. Taraporewala provides the Company in excess of five hours of consulting services, the Company will pay Dr. Taraporewala $1,000 per day, up to a maximum of five days.
- 120,000 shares of the Company's restricted stock under the Company's 2014 Stock Incentive Plan and related restricted stock agreement, dated as of December 11, 2015 (the "Restricted Stock Agreement"), between the Company and Dr. Taraporewala. The restricted stock will vest in four equal, semiannual installments, beginning on July 16, 2016, subject to Dr. Taraporewala continuously providing consulting services to the Company from the Effective Date until each such vesting date.

Part III

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

NONE

ITEM 9A CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our principal executive officer and principal financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring 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 on a timely basis, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of September 30, 2015 using the framework in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management has concluded that our internal control over financial reporting was effective as of September 30, 2015. The effectiveness of our internal control over financial reporting as of September 30, 2015 has been audited by MaloneBailey, LLP, an independent registered public accounting firm, as stated in their report.

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.

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Remediation of a Material Weakness

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.

As disclosed in the Company's 2014 Annual Report on Form 10-K, management concluded that our internal control over financial reporting was previously not effective based on the material weakness due to lack of sufficient control over our financial accounting and reporting processes regarding the assessment of fair-value accounting for non-routine and complex transactions. Management has remediated this material weakness in fiscal 2015. Specifically during the year ended September 30, 2015, we identified technical accounting resources for assistance with complex transactions on an ad hoc basis; re-evaluated the key processes that support our financial reporting and technical accounting function and added new controls and enhanced existing controls to strengthen those processes; and hired additional external resources for assistance in these areas.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B OTHER INFORMATION

Effective December 11, 2015, Irach B. Taraporewala, President and Chief Technology Officer, resigned from all officer positions with the Company and as a member of the Board of Directors of the Company, subject to a mandatory seven-day revocation period. In connection with Dr. Taraporewala's resignation, on December 11, 2015, the Company and Dr. Taraporewala entered into a two year Consulting Agreement and Release (the "Consulting Agreement and Release") dated December 11, 2015 (the "Effective Date"), pursuant to which Dr. Taraporewala will be engaged as a consultant to the Company.

As compensation for the consulting services to be rendered by Dr. Taraporewala, Dr. Taraporewala will receive the following:

- A retainer in the amount of $15,000 within 30 days following the Effective Date.
- A retainer in the amount of $15,000 on the first anniversary of the Effective Date.
- A monthly fee of $5,000 during each month of the term of the Consulting Agreement in consideration for providing the Company up to five hours of consulting services per week. In any week in which Dr. Taraporewala provides the Company in excess of five hours of consulting services, the Company will pay Dr. Taraporewala $1,000 per day, up to a maximum of five days.
- 120,000 shares of the Company's restricted stock under the Company's 2014 Stock Incentive Plan and related restricted stock agreement, dated as of December 11, 2015 (the "Restricted Stock Agreement"), between the Company and Dr. Taraporewala. The restricted stock will vest in four equal, semiannual installments, beginning on July 16, 2016, subject to Dr. Taraporewala continuously providing consulting services to the Company from the Effective Date until each such vesting date.

Dr. Taraporewala agreed to a general release of claims in favor of the Company, as well to customary confidentiality, non-competition, non-solicitation, non-disparagement and other standard covenants set forth in the Consulting Agreement and Release.

On December 11, 2015, Dr. Taraporewala also entered into a lock-up agreement (the "Lock-Up Agreement"), pursuant to which Dr. Taraporewala agreed, subject to customary exceptions, not to sell or transfer any shares of the Company's common stock held by him for 180 days from the date of the Lock-Up Agreement.

The foregoing descriptions of the Consulting Agreement and Release, the Restricted Stock Agreement and the Lock-Up Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the

Consulting Agreement and Release, the Restricted Stock Agreement and the Lock-Up Agreement, which are included as Exhibits 10.2(c), 10.2(d), and 10.2(e), respectively, to this Annual Report on Form 10-K for the year ended September 30, 2015 and are incorporated by reference herein.

ITEM 10 DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated by reference to the information under the section captioned "Proposal 1: Election of Directors - Nominees for Class II Directors," "- Corporate Governance Matters," "Stockholder Communications with the Board of Directors," and "-Section 16(a) Beneficial Ownership Reporting Compliance" contained the 2016 Proxy Statement.

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. We intend to disclose future amendments to certain provisions of the Code, or waivers of such provisions granted to executive officers and directors, on the website within four business days following the date of such amendment or waiver.

ITEM 11 - EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the information under the sections captioned "Proposal 1: Election of Directors - Executive Compensation:, "—Compensation for Non-Employee Directors," "—Compensation Discussion and Analysis," "—Summary Compensation Table," "— Grants of Plan Based Awards in Fiscal 2016," "—Outstanding Equity Awards at Fiscal Year End 2016," "—Compensation Committee Report," and "—Compensation Committee Interlocks and Insider Participation" contained in the 2016 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 2016 Proxy Statement.

ITEM 13 CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated by reference to the information under the sections captioned "Proposal 1: Election of Directors - Certain Relationships and Related Transactions "contained in the 2016 Proxy Statement.

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 2016 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 Number	**Description of Exhibit**	**The filings referenced for incorporation by reference are Ohr Pharmaceutical, Inc. (File No. 001-35963)**
2.1	Contribution Agreement, dated May 14, 2014, among Ohr Pharmaceutical, Inc., certain affiliates of Ohr, SKS Ocular, LLC, SKS Ocular 1, LLC, and the controlling members of SKS	May 16, 2014, Form 8-K, Exhibit 2.1
2.2	Agreement and Plan of Merger, dated May 30, 2014, Ohr Pharmaceutical, Inc., Ohr Holdco, Inc., and Ohr Merger Sub, Inc.	June 2, 2014, Form 8-K, Exhibit 2.2
2.3	Asset Purchase Agreement, dated August 21, 2009, between Ohr Pharmaceutical, Inc. and Genaera Liquidating Trust	August 26, 2009, Exhibit 10.01
3.1	Certificate of Incorporation of Ohr Pharmaceutical, Inc.	June 2, 2014, Form 8-K, Exhibit 3.1(a)
3.2	Certificate of Amendment to Certificate of Incorporation of Ohr Pharmaceutical, Inc.	June 2, 2014, Form 8-K, Exhibit 3.1(b)
3.3	By-Laws of Ohr Pharmaceutical, Inc.	June 2, 2014, Form 8-K, Exhibit 3.2
4.1(a)	Form of Class J Common Stock Purchase Warrant issued on December 16, 2011	December 20, 2011, Form 8-K, Exhibit 10.25
4.1(b)	Amendment, dated March 11, 2014, to Class J Common Stock Purchase Warrants	March 14, 2014, Form 8-K, Exhibit 10.39
4.2	Form of Consulting Warrants	June 30, 2011, Form 10-Q, Exhibit 10.21
10.1*	Form of Non-Qualified Option Agreement	March 15, 2012, Form 8-K, Exhibit 10.26

10.2(a)*	Employment Agreement, dated January 8, 2014, between Ohr Pharmaceutical, Inc. and Irach B. Taraporewala	January 10, 2014, Form 8-K, Exhibit 10.37
10.2(b)*	Amendment 1, dated as of January 6, 2015, to the Employment Agreement, dated January 8, 2014, between Ohr Pharmaceutical, Inc. and Irach B. Taraporewala	January 8, 2015, Form 8-K, Exhibit 10.50
10.2(c)*	Consulting Agreement and Release, dated December 11, 2015, between Ohr Pharmaceutical, Inc. and Irach B. Taraporewala	Filed herewith
10.2(d)*	Restricted Stock Agreement, dated December 11, 2015, between Ohr Pharmaceutical, Inc. and Irach B. Taraporewala	Filed herewith
10.2(e)*	Lock-up Agreement, dated December 11, 2015, from Irach B. Taraporewala	Filed herewith
10.2(f)*	Proprietary Information and Invention Agreement, dated April 10, 2010, between Ohr Pharmaceutical, Inc. and Irach B. Taraporewala	Filed herewith
10.3(a)*	Employment Agreement, dated January 8, 2014, between Ohr Pharmaceutical, Inc. and Sam Backenroth	January 10, 2014, Form 8-K, Exhibit 10.38
10.3(b)*	Amendment 1, dated as of January 6, 2015, to the Employment Agreement, dated January 8, 2014, between Ohr Pharmaceutical, Inc. and Sam Backenroth	January 8, 2015, Form 8-K, Exhibit 10.51
10.3(c)*	Proprietary Information and Inventions Agreement, dated April 10, 2010, between Ohr Pharmaceutical, Inc. and Sam Backenroth	Filed herewith
10.4*	Employment Agreement, dated as of February 24, 2015, between Ohr Pharmaceutical, Inc. and Avner Ingerman	February 26, 2015, Form 8-K, Exhibit 10.52

Exhibit Number	Description of Exhibit	The filings referenced for incorporation by reference are Ohr Pharmaceutical, Inc. (File No. 001-35963)
10.5	Assignment and Assumption Agreement, dated as of May 30, 2014, between Ohr Pharmaceutical, Inc. and Ohr Holdco, Inc.	June 2, 2014, Form 8-K, Exhibit 10.44
10.6	Subscription Agreement, dated as of April 8, 2014, among Ohr Pharmaceutical, Inc. and the purchasers identified on the signature page thereto	April 8, 2014, Form 8-K, Exhibit 10.41
10.7	Placement Agency Agreement, dated as of April 8, 2014, among Ohr Pharmaceutical, Inc. and Chardan Capital Markets, LLC and Brean Capital, LLC	April 8, 2014, Form 8-K, Exhibit 10.40
10.8(a)*	The 2014 Stock Incentive Plan	April 14, 2014, Form 8-K, Exhibit 10.42
10.8(b)*	Amendment to The 2014 Stock Incentive Plan	Filed herewith
10.9*	Form of Stock Option Agreement	March 31, 2015, Form 10-Q, Exhibit 10.53
10.10*	The 2009 Stock Incentive Plan	March 31, 2010, Form 10-Q, Exhibit 10.1
14	Code of Ethics	Filed herewith
21	Subsidiaries of the Registrant	Filed herewith
23	Consent of Independent Registered Public Accounting Firm	Filed herewith
31.1	Section 302 Certification of Chief Executive Officer	Filed herewith
31.2	Section 302 Certification of Chief Financial Officer	Filed herewith
32.1	Section 906 Certification of Chief Executive Officer	Filed herewith
32.2	Section 906 Certification of Chief Financial Officer	Filed herewith
101.INS	XBRL Instance Document	Filed herewith
101.SCH	XBRL Taxonomy Extension Schema Document	Filed herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith

101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith

* Management contract or compensation plan or arrangement.

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 14, 2015 By: */s/* JASON SLAKTER
Jason Slakter, CEO

Dated: December 14, 2015 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, Jason Slakter 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 14, 2015 By: /s/ JASON SLAKTER
Jason Slakter, Director

Dated: December 14, 2015 By: /s/ IRA GREENSTEIN
Ira Greenstein, Director

Dated: December 14, 2015 By: /s/ ORIN HIRSCHMAN
Orin Hirschman, Director

Dated: December 14, 2015 By: /s/ JUNE ALMENOFF
June Almenoff, Director

Dated: December 14, 2015 By: /s/ THOMAS RIEDHAMMER
Thomas Riedhammer, Director