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, 2016

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

For the transition period from to

Commission File No: 333-88480

OHR PHARMACEUTICAL, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**46-5622433**
(State or Other Jurisdiction of 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
Registrant's telephone number, including area code

Securities registered under Section 12(b) of the Exchange Act: Common Stock, par value $0.0001 per share
Name of each exchange on which registered: NASDAQ Capital Market
Securities registered under to Section 12(g) of the Exchange Act: None

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this Chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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, 2016, the last business day of the registrant's most recently completed second fiscal quarter, was $87,714,938 (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 of the registrant 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 20, 2016, the registrant had 35,961,396 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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Part I

Our discussion and analysis of the business and subsequent discussion of financial conditions may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Statements that are not historical in nature, including statements about beliefs and expectations, are forward-looking statements. Words such as "may," "will," "should," "estimates," "predicts," "believes," "anticipates," "plans," "expects," "intends" and similar expressions are intended to identify these forward-looking statements, but are not the exclusive means of identifying such statements. Such statements are based on currently available operating, financial and competitive information and are subject to various risks and uncertainties as described in greater detail in our "Risk Factors" on page 15 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.

ITEM 1 BUSINESS

GENERAL AND HISTORICAL

Summary

Ohr Pharmaceutical, Inc. ("we," "us," "our," "Ohr," or the "Company") is a pharmaceutical company focused on the development of novel therapeutics and delivery technologies for the treatment of ocular disease. Our development pipeline consists of several programs and indications at various stages of development. Our lead clinical asset, topical Squalamine (also known as squalamine lactate ophthalmic solution, 0.2%, or OHR-102), is a novel therapeutic product which could provide a non-invasive therapy to improve vision outcomes beyond that achieved with current standard of care, without requiring multiple injections per office visit. We are conducting a Phase 3 registration program evaluating Squalamine in combination with Lucentis® injections for the treatment of wet-AMD. This clinical program is proceeding based on the data from a Phase 2 clinical trial in wet-AMD which demonstrated a positive and clinically meaningful treatment effect of Squalamine combination therapy in classic containing choroidal neovascularization (classic CNV) as well as those with occult 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.

Corporate and Historical Information

We are a Delaware corporation that was organized on August 4, 2009, as successor to BBM Holdings, Inc. (formerly Prime Resource, Inc., which was organized March 29, 2002 as a Utah corporation) pursuant to a reincorporation merger. On August 4, 2009, we reincorporated in Delaware as Ohr Pharmaceutical, Inc.

On May 30, 2014, we completed the ophthalmology assets acquisition (the "SKS Acquisition") of the privately held SKS Ocular LLC and its affiliate, SKS Ocular 1 LLC ("SKS"). Under the terms of the acquisition agreement, in exchange for substantially all the assets of SKS, Ohr made an upfront payment of $3.5 million in cash and issued 1,194,862 shares of Ohr common stock to SKS. In addition, SKS is eligible to receive up to an aggregate of 1,493,577 additional shares of Ohr common stock in three contingent milestone payments, each milestone resulting in the issuance of 497,859 shares of Ohr common stock. Milestone 1 required Ohr to demonstrate a consistent long-term release of a therapeutic agent above threshold therapeutic levels in the targeted ocular tissues of an animal model. Ohr met this milestone in December 2015. Milestone 2 required the completion of a pharmacodynamic study in an animal model showing clinically relevant efficacy from a drug substance released from SKS microparticles within 24 months of the date of the closing of the SKS Acquisition. Ohr achieved the study results in May 2016, and the Board reviewed and approved Milestone 2 in July 2016. Milestone 3 requires, among other things, the approval of an Investigational New Drug Application ("IND") within three years of the date of the closing of the SKS Acquisition. We do not expect such Milestone 3 to be achieved within the timeline provided for in the agreement.

The SKS 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 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 retained the name "Ohr Pharmaceutical, Inc." Outstanding shares of the capital stock of the former Ohr Pharmaceutical, Inc. were automatically converted, on a share for share basis, into identical shares of common stock of the new holding company.

PRODUCT PIPELINE

(a) SQUALAMINE LACTATE OPHTHALMIC SOLUTION 0.2%

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

Squalamine lactate is a small molecule anti-angiogenic drug with a novel intracellular mechanism of action. The drug acts against the development of aberrant neovascularization by inhibiting multiple protein growth factors of angiogenesis, including vascular endothelial growth factor ("VEGF"), platelet-derived growth factor ("PDGF") and basic fibroblast growth factor ("bFGF"). Scientific evidence has shown PDGF to be an additional target for the treatment of wet-AMD and bFGF levels have been shown to be elevated in retinal vein occlusion and wet-AMD patients.

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

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

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

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

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

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

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

Regulatory (FDA) Status of Squalamine Program in Wet-AMD

In March 2016, the Company reached an agreement on a Special Protocol Assessment (SPA) with the United States Food and Drug Administration (US FDA) on the design of the Phase 3 trial. The FDA awarded Fast Track Designation to the Squalamine eye drop program for the potential treatment of wet-AMD in 2012.

Phase 3 Trials in Wet-AMD

The Phase 3 program is being conducted to evaluate the efficacy and safety of Squalamine given in combination with Lucentis® for treatment naive patients with wet-AMD. The comprehensive clinical program is comprised of double-masked, placebo-controlled, multicenter, international studies of Squalamine 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 are enrolling a patient population that we believe is the most likely to benefit from Squalamine 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 Squalamine twice a day or Lucentis® plus placebo eye drops twice a day. During the second year they will continue to use Squalamine or placebo eye drops twice a day and receive Lucentis® PRN (as needed) as determined by monthly monitoring visits. The Company began enrolling patients in the first phase III study in April 2016.

OHR–1501 Study

OHR-1501 is an ongoing exploratory, double-masked, randomized, placebo-controlled study designed to assess safety and efficacy of treatment with squalamine lactate ophthalmic solution in combination with monthly anti-VEGF (both Lucentis® and Eylea®) injections in patients with neovascular AMD. Approximately 40 subjects will participate for a six-month duration. Safety, functional, and anatomical parameters will be evaluated including retinal imaging modalities and functional visual acuity (BCVA). The primary endpoints of the study are the outcome measures at Week 12.

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

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

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

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

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

(b) SKS SUSTAINED RELEASE OCULAR DRUG DELIVERY PLATFORM TECHNOLOGY

The SKS sustained release technology employs a hydrogel template approach to prepare nano, micro and macroparticles of predefined size and shape and with homogeneous size distribution. The size and shape of the particles can be adjusted, providing flexibility in controlling the drug load and release rate in drug delivery formulations. The drug loading capacity is much higher than that achieved by conventional methods, 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 and other 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, micro and macroparticle drug formulations that can provide sustained and predictable release of a therapeutic drug over a 3 – 6 month period. The versatility of this delivery technology makes it well suited to 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, ocular allergy, and retinal disease.

In December 2015, we announced the achievement of Milestone 1, demonstrating sustained release in vivo proof of concept in one of our internal programs, and data from this study was presented at the Association for Research in Vision and Ophthalmology (ARVO) in May 2016. In this study, we dosed rabbits with a single intravitreal dose of our SKS sustained release formulation of a novel small molecule anti-angiogenic compound (OHR3031), and then followed the rabbits over a six week period. The study showed that sustained supratherapeutic levels of active drug could be achieved in the retina and choroid, which are the target ocular tissues for back of the eye disease. These observations were made at all time points in the study which demonstrates a prolonged pharmacokinetic profile. Furthermore, vitreous concentrations remained at stable, high levels throughout the six week study indicating that the true duration of effect is potentially longer.

In May 2016, we completed an in vivo study demonstrating sustained pharmacological anti-angiogenic activity of OHR3031 in a rabbit model of laser-induced CNV (Milestone 2). A single intravitreal injection of OHR3031 produced clinically meaningful and statistically significant efficacy six weeks after dose administration in the CNV rabbit model. A dose response in the reduction of average CNV lesion areas with the OHR3031 containing microparticles compared to vehicle treatment was evident, with the highest dose exhibiting a statistically significant effect at Week 6. The magnitude of the difference in average CNV lesion size for the high dose of OHR3031 compared to the vehicle treatment at 6 weeks was comparable to that seen at 2 weeks with a currently approved anti-VEGF agent conducted in a previous study. These studies serve as an important validation of our SKS sustained release technology which we believe holds the promise of improving the standard of care in a number of ocular conditions by allowing for physician administration of drugs at convenient treatment intervals. We anticipate presenting additional in-vivo proof of concept data on our internal programs in calendar 2017.

(c) Animal Model for Dry-AMD

As part of the SKS Acquisition, we acquired the exclusive rights to an animal model for dry-AMD whereby mice are immunized with a carboxyethylpyrrole (“CEP”) which is bound to mouse serum albumin (“MSA”). CEP is produced following the oxidation of docosahexaenoic acid, which is abundant in the photoreceptor outer segments that are phagocytosed by the retinal pigment epithelium (“RPE”). A number of CEP-adducted proteins have been identified in proteomic studies examining the composition of drusen and other subretinal deposits found in the eyes of patients with dry-AMD. Studies have shown that immunization of CEP-MSA can lead to an ophthalmic phenotype very similar to dry-AMD, including deposition of complement in the RPE, thickening of the Bruch’s membrane, upregulation of inflammatory cytokines, and immune cell influx into the eye. Upon immunization with CEP, a marked decrease in contrast sensitivity which precedes a loss of visual acuity, was observed, similar to what occurs in many patients with dry AMD.

(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, we 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.

Wet-AMD Market

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

Competitive Landscape in Wet-AMD

The current FDA approved market leaders for the treatment of wet AMD are VEGF inhibitors, including Lucentis®, Eylea® and (off-label) Avastin®. In 2015, annual revenue (worldwide) was more than $3 billion for Lucentis®, despite significant off-label use of Avastin® (estimated to be 45-60% of the overall market). Eylea®, is approved for use in wet-AMD and other retinal indications and achieved 2015 revenues of approximately $4 billion. Both Lucentis® and Eylea® are administered via frequent intravitreal injections directly into the eye. We are developing Squalamine for use in combination with Lucentis® and other anti-VEGF agents to improve visual function beyond that achieved with anti-VEGF therapy alone. There is no assurance that we will receive FDA approval for Squalamine for the treatment of wet-AMD, and if we receive it, there is no assurance we will be able to displace the market leaders as a treatment in a significant percentage of patients.

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

- Fovista®, a PDGF targeting aptamer being developed by Ophthotech in partnership with Novartis and Roche;
- Abicipar Pegol, a VEGF targeting DARPin molecule being developed by Allergan;
- RTH258, an anti-VEGF agent being developed by Alcon/Novartis;
- X-82, an oral tyrosine kinase inhibitor being developed by Tyrogenex;
- ALG-1001, an integrin targeting peptide being developed by Allegro Ophthalmics;
- REG-2176, a combination injection of anti-VEGF and PDGF agents being developed by Regeneron;
- REG-910, an anti-Ang2 agent to be used with Eylea® being developed by Regeneron;

- RG7716, a bispecific antibody to both VEGF-A and Ang2 being developed by Roche;
- OPT-302, an inhibitor of VEGF-C and VEGF-D being developed by Opthea; and
- PAN-90806, a selective inhibitor of VEGF being developed by Panoptica Inc.

All of these products in clinical development, with the exception of X-82 and PAN-90806, use an intravitreal route of administration much like the current standards of care. We believe that squalamine has potential competitive advantages through its intracellular mechanism of action, multiple growth factor inhibition, and non invasive delivery. We also believe we have reduced the risk in our Phase 3 program by utilizing our exploratory Phase 2 trial to identify and enroll a patient population that has the greatest potential for visual acuity benefits with combination therapy.

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

All of these programs are in the preclinical or clinical development stages. Each of these may prove to be effective means to deliver drugs in a sustained manner and we cannot assure that none of them will get to market before us or that the SKS technology will be a better drug delivery approach.

Corporate Strategy

We are currently actively developing our pipeline products for applications in ophthalmology. Beginning in fiscal 2014, we transitioned Ohr to a core focus on ophthalmology indications and building an ophthalmology-focused pipeline, and we expect to continue to see progress in our pipeline and ophthalmology initiatives.

We are in an ongoing business development process to seek and implement strategic alternatives with respect to Squalamine, based on the Phase 2 study demonstrating a visual acuity benefit of Squalamine combination therapy, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. Several third parties with whom we have been in discussions have expressed interest in a potential licensing or partnering transaction for the Squalamine program. We continue to make progress in these discussions.

We are also in preliminary discussions regarding potential collaborations for the SKS sustained release platform technology with potential strategic partners.

As part of this core strategy, on February 26, 2014, we entered into a Joint Venture Agreement and related agreements with Cold Spring Harbor Laboratory ("CSHL") pursuant to which a joint venture, DepYmed Inc. ("DepYmed"), was formed to further preclinical and clinical development of Ohr's Trodusquemine and analogues as PTP1B inhibitors for oncology indications. DepYmed licenses research from CSHL and intellectual property from us. In December 2014, DepYmed hired a full time CEO to run the operations of DepYmed and in October 2016 raised $1 million in a private placement transaction, with an additional $1 million to be received upon the achievement of specific development milestones. The proceeds of the private placement will fund the ongoing operations of DepYmed. Ohr is a passive joint venturer in DepYmed.

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. U.S. patents and U.S. patent applications 7981876, 8716270, 6262283, 7728157, 20130281420 and 20150342874 cover the Squalamine formulations, composition of matter, combination therapy with other agents, methods of manufacture, and uses. Additional patent applications covering 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/macro particle fabrication technology for sustained release of molecules. 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 particulate 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 by the filing of an investigational new drug application. Additional patent applications have been filed that expand on this platform technology and that are specific to our active development programs using the sustained release technology.

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 effective 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 by patent term adjustment when the U.S. Patent Office fails to examine the patent application in a timely manner before issuance of the patent. 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 (the "Hatch-Waxman Act") and the Generic Animal Drug and Patent Term Restoration Act of 1988 (the "GADPTR Act"), 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. Our issued U.S. patents expire between 2017 and 2029, excluding any extensions available under the Hatch-Waxman Act and the GADPTR Act.

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 intellectual property protection via 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 a 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 heading “Intellectual property litigation is increasingly common and increasingly expensive and may result in restrictions on our business and substantial costs, even if we prevail” and 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, we have 14 full-time employees. In addition, we use numerous high level scientific, administrative, operations, and financial consultants, as well as 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 2017 to support the Phase 3 trials for Squalamine and the sustained release platform programs.

ENVIRONMENTAL COMPLIANCE

We are 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 1, trials are conducted with a small number of subjects to determine the early safety profile of the product candidate. In Phase 2, 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 the product candidate. In Phase 3, 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.

AVAILABLE INFORMATION

The Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), are filed with the SEC. The Company is subject to the informational requirements of the Exchange Act and files or furnishes reports, proxy statements and other information with the SEC. Such reports and other information filed by the Company with the SEC are available free of charge on the Company's website at http://ir.ohrpharmaceutical.com/all-sec-filings, as soon as reasonably practicable after we have electronically filed with, or furnished to, the SEC. The public may read and copy any materials filed by the Company with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Room 1580, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. The contents of these websites are not incorporated into this filing. Further, the Company's references to website URLs are intended to be inactive textual references only.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Business and Industry

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

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

We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA, and other regulatory authorities in the 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 reached an agreement on a Special Protocol Assessment with the FDA on the design of the Phase 3 trial for Squalamine in wet-AMD in March 2016, and we initiated the Phase 3 clinical program and began enrolling patients in April 2016. 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, 2016, we had an accumulated deficit of approximately $84.3 million. We expect to incur net losses over the next several years as we advance our programs and incur significant clinical development costs. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We do not expect to receive, for at least the next several years, any revenues from the commercialization of our product candidates.

There is no guarantee that our Phase 3 clinical trials for Squalamine in wet-AMD will be completed, completed in the anticipated timeframe or that they will be successful.

The results of the Phase 2 clinical trial support conducting Phase 3 clinical trials for Squalamine with enrollment criteria for a targeted population, based on the complete analysis of the Phase 2 clinical trial. We reached an agreement on a Special Protocol Assessment with the FDA on the design of the Phase 3 trial in March 2016, and we initiated the Phase 3 clinical program and began enrolling patients in April 2016. However, there can be no assurance that the Phase 3 clinical trials will be completed in the anticipated timeframe, completed at all, or that they will be successful.

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

We reached an agreement on a Special Protocol Assessment with the FDA on the design of the Phase 3 trial in March 2016, and we initiated the Phase 3 clinical program and began enrolling patients in April 2016. The Phase 3 trials for Squalamine are designed to measure the efficacy of combination therapy with Squalamine plus Lucentis® injections compared with Lucentis® monotherapy in treatment naïve patients with wet-AMD. All patients will be followed for safety for two years.

During the first year of the study, patients will be randomized 1:1 to receive monthly Lucentis® plus Squalamine (Squalamine lactate ophthalmic solution, 0.2%) twice a day or Lucentis® plus placebo. During the second year they will receive Lucentis® PRN (as needed) plus Squalamine or placebo twice a day. The primary endpoint will be an improvement in a visual acuity parameter, as measured by a standard ETDRS visual acuity chart.

There can be no assurance that we will meet the goals of the Phase 3 clinical trials or that we will have the same level of success in the Phase 3 clinical trials as we have in our prior clinical trials, or that we will be successful at all. We further believe that Squalamine may also have clinical utility in indications other than wet-AMD. We have completed IST's 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. However, there can be no assurance that Squalamine will realize such potential utility.

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

We will need to raise substantial additional capital to further our drug and delivery platform development programs as well as future trials, including our ongoing Phase 3 clinical program for Squalamine 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 clinical trials. Specifically, we will require significant additional funds to complete our ongoing Phase 3 clinical trials for Squalamine in wet-AMD. In our capital-raising efforts, we may seek to sell additional equity or debt securities, obtain a bank credit facility, or seek a strategic commercial partner or do a combination. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. However, we may not be able to raise additional funds on acceptable terms, or at all. If we raise capital through a strategic commercial partner, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to secure sufficient capital to fund our research and development activities, we may have to delay, reduce or cease operations.

As of September 30, 2016, we had cash and cash equivalents of $12.5 million. With our financing in December 2016, we believe that our cash and cash equivalents will be sufficient to fund our operating expenses into June 2017. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. We are planning to spend significant funds to advance our Phase 3 trials for Squalamine. At this time, we cannot reasonably estimate the remaining costs necessary to complete Phase 3 trials or to complete the development of any other product candidate.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, and strategic partnerships. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as holders of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Our strategy with respect to Squalamine is to seek a strategic commercial partner, or partners, such as large pharmaceutical companies, with extensive experience in the development, commercialization, and marketing of ophthalmic products. Several third parties with whom we have been in discussions have expressed interest in a potential licensing or partnering transaction for the Squalamine program. We continue to make progress in these discussions; however, there is no assurance that the Company will enter into a definitive agreement with respect to such a transaction. If we raise capital through such strategic commercial partner, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

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

Results from our Phase 2 clinical trial for Squalamine in wet-AMD may not necessarily be predictive of the results from required later clinical trials. We may not be able to complete our ongoing Phase 3 clinical program for Squalamine in wet-AMD. Similarly, even if we are able to complete our Phase 3 clinical trials for Squalamine in wet-AMD according to our current development timeline, the results from our Phase 2 clinical trial for Squalamine in wet-AMD may not be replicated in our Phase 3 clinical trial results. Many companies in the pharmaceutical and biotechnology industries, including companies developing combination therapies for wet-AMD, have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, pre-clinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events, and expansion of enrollment eligibility criteria from phase 2 to phase 3 studies. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials nonetheless failed to obtain FDA or foreign regulatory approval. If we fail to produce positive results in our Phase 3 clinical trials for Squalamine in wet-AMD, the development timeline and regulatory approval and commercialization prospects for our leading product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected.

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

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

- delays in demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;

- manufacturing sufficient quantities of a product candidate;
- obtaining clearance from the FDA to commence clinical trials pursuant to an Investigational New Drug application (or IND);
- obtaining clearance from foreign regulatory authorities to commence clinical trials;
- financial or strategic considerations; obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site;
- obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site;
- 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; and
- inability to raise funding necessary to initiate a 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;
- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials; and
- inability to raise funding necessary to continue a clinical trial.

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 and our business and financial prospects would be materially affected.

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

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

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

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

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

For the diseases or disorders that our product candidates are intended to treat, we expect only a subset of the patients with these diseases to be eligible for our clinical trials. Given that each of our product candidates is in preclinical or clinical development, we may not be able to initiate or continue clinical trials for each or all of our product candidates if we are unable to 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 we will continue to rely, on third parties to conduct any future clinical trials for us, including our Phase 3 clinical trial for Squalamine 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. Our CRO running our phase 3 trial has also contracted with Jason S. Slakter, M.D., P.C., d/b/a Digital Angiography Reading Center ("DARC"), a well-known digital reading center, which is owned by Dr. Jason Slakter, our CEO, pursuant to our related party transactions policy, with the review and approval of the Audit Committee, to provide digital reading and imaging services in connection with the Phase 3 study. We are advised that DARC has implemented a standard operating procedure (SOP) to firewall interactions between DARC employees and Dr. Slakter. It is possible that the FDA will investigate and that this related party transaction may impact adversely on its approval of the trials. The parties with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to achieve their research goals or otherwise meet their obligations on a timely basis could adversely affect clinical development of our product candidates.

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

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

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on contract research organizations does not relieve us of our regulatory responsibilities. We and our contract research organizations are required to comply with 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 that, upon inspection, the FDA or any comparable foreign regulatory authority 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 Squalamine in wet-AMD and other drug candidates, contract research organizations conduct all of the clinical trials. As a result, many important aspects of our drug development programs are outside of our direct control. In addition, the contract research organizations may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements, but we remain responsible and are subject to enforcement action that may include civil penalties up to and including criminal prosecution for any violations of FDA or comparable foreign laws and regulations during the conduct of our clinical trials. If the contract research organizations do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of Squalamine in wet-AMD and other drug candidates may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these contract research organizations devote to our program. If we are unable to rely on clinical data collected by our contract research organizations, we could be required to repeat, extend the duration of, or increase the size of our clinical trials and this could significantly delay commercialization and require significantly greater expenditures, and have a material adverse effect on our business.

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

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, other regulatory standards, and similar foreign standards, and we do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our product candidates could be delayed, and have a material adverse effect on our business.

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

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

- the ability to provide acceptable evidence of safety and efficacy;
- pricing and cost effectiveness, which may be subject to regulatory control;
- our ability to obtain sufficient third-party insurance coverage or reimbursement;
- effectiveness of our or our collaborators' sales and marketing strategy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects; and
- availability of alternative treatments.

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

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

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

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

We have no manufacturing facilities and do not have extensive experience in the manufacturing of drugs or in designing drug-manufacturing processes. We have contracted with third-party manufacturers to produce, in collaboration with us, our product candidates, including Squalamine, for clinical trials. If any of our product candidates are approved by the FDA or other regulatory agencies, including foreign regulatory agencies for commercial sale, we may need to amend our contract with our current manufacturer or contract with another third party to manufacture them in larger quantities. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on these third parties for development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations and study and trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study and trial plans and protocols, or if there are disagreements between us and these third parties, we will not be able to initiate, or complete, or may be delayed in completing, the clinical trials required to support future approval of our product candidates. In some such cases, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or with acceptable terms, which would cause additional delay with respect to the approval of our product candidates and would thereby have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

The manufacturers of our product candidates are obliged to operate in accordance with FDA-mandated cGMPs. In addition, the facilities used by our contract manufacturers or other third party manufacturers to manufacture our product candidates must be approved by the FDA or other foreign regulatory authority pursuant to inspections that will be conducted after we request regulatory approval from the FDA or other foreign regulatory authority. A failure of any of our current or future contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates or the ultimate launch of products based on our product candidates into the market. Furthermore, all of our contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks for the production of such materials and products. As a result, failure to satisfy the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our contract manufacturers' facilities generally. Failure by our current or future third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions. Many aspects of the clinical trial and manufacturing process are outside of our control. In addition, the third-party manufacturers may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If a third-party manufacturer breaches its obligations to us or fails to comply with regulatory requirements, the commercialization of Squalamine in wet-AMD and other drug candidates may be delayed or irreversibly harmed.

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

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

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

Our strategy is to seek a strategic commercial partner, or partners, such as large pharmaceutical companies, with extensive experience in the development, commercialization, and marketing of ophthalmic products. We are in an ongoing business development process to seek and implement strategic alternatives with respect to Squalamine, based on the Phase 2 study demonstrating a visual acuity benefit of Squalamine combination therapy, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. Several third parties with whom we have been in discussions have expressed interest in a potential licensing or partnering transaction for the Squalamine program. We continue to make progress in these discussions. We are also in preliminary discussions regarding potential collaborations for the SKS sustained release platform technology with strategic partners. Such anticipated 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, preclinical studies, manufacturing capabilities, and other regulatory requirements concerning future clinical development in the United States and foreign territories.

To date, we have not entered into any strategic partnerships for any of our products. We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships.

While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. We currently lack the resources to 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.

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, including foreign regulatory approvals, of drugs;

- formulating and manufacturing drugs; and

- launching, marketing and selling drugs.

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

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

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

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

Our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates: (1) FDA or any comparable foreign regulatory authority regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or any comparable foreign regulatory authority; (2) manufacturing standards; (3) federal, state and foreign healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA or other regulatory authority debarment could result in a loss of business from our partners and severe reputational harm. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, operating results and financial condition.

Any future acquisitions we make of companies or technologies may result in disruption to our business or distraction of our management, due to difficulties in assimilating acquired personnel and operations.

We may acquire or make investments in complementary businesses, technologies, services or products which complement our pharmaceutical operations if appropriate opportunities arise. From time to time we engage in discussions and negotiations with companies regarding our acquiring or investing in such companies' businesses, products, services or technologies, in the ordinary course of our business. We cannot be assured that we will be able to identify future suitable acquisition or investment candidates, or if we do identify suitable candidates, that we will be able to make such acquisitions or investments on commercially acceptable terms or at all. If we acquire or invest in another company, we could have difficulty in assimilating that company's personnel, operations, technology and software. In addition, the key personnel of the acquired company may decide not to work for us. If we make other types of acquisitions, we could have difficulty in integrating the acquired products, services or technologies into our operations. These difficulties could disrupt our ongoing business, distract our management and employees, increase our expenses and adversely affect our results of operations. Furthermore, we may incur indebtedness or issue equity securities to pay for any future acquisitions. The issuance of equity securities would be dilutive to our existing stockholders. However, we currently do not have any agreement to enter into any material investment or acquisition transaction.

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

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such an event could cause interruption of our operations. For example, the loss of data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs. To the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

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

On June 23, 2016, the U.K. affirmatively voted in a non-binding referendum advising for the exit of the U.K. from the European Union (commonly referred to as the "Brexit"). The referendum is non-binding; however, if passed into law, negotiations would commence to determine the future terms of the U.K.'s relationship with the European Union, including the terms of trade between the U.K. and the European Union. The effects of Brexit will depend on any agreements the U.K. makes to retain access to European Union markets either during a transitional period or more permanently. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which European Union laws to replace or replicate.

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

Risks Related to FDA, Comparable Foreign Regulatory Authority and Healthcare Regulations

We face heavy government regulation. FDA regulatory approval and/or comparable foreign regulatory authority's approval of our products is uncertain.

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

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

- a drug candidate may not be shown to be safe or effective;
- the FDA or any comparable foreign regulatory authority may not approve our manufacturing process;
- the FDA or any comparable foreign regulatory authority may interpret data from preclinical and clinical trials in different ways than we do; and
- the FDA may not meet, or may extend, the Prescription Drug User Fee Act date with respect to a particular NDA.

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

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

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

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

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

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

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

Healthcare costs have risen significantly over the past decade. There have been and continue to be proposals by legislators, regulators and third-party payors to keep these costs down. Certain proposals, if passed, would impose limitations on the prices we will be able to charge for the products that we are developing, or the amounts of reimbursement available for these products from governmental agencies or third-party payors. These limitations could in turn reduce the amount of 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 U.S. patents and patent applications 7981876, 8716270, 6262283, 7728157, 20130281420 and 21050342874 to cover the Squalamine formulations, composition of matter, use in combination with other agents, methods of manufacture, and uses. Nonetheless, the issued patents and patent applications covering our primary technology programs remain subject to uncertainty due to a number of factors, including:

- we may not have been the first to make one or more of the inventions covered by our pending patent applications or issued patents;
- we may not have been the first to file patent applications for one or more of our product candidates or the technologies we rely upon;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- our disclosures in a particular patent application may be determined to be insufficient to meet the statutory requirements for patentability;
- one or more of our pending patent applications may not result in issued patents;
- we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;

- one or more patents issued to us or to our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- we may fail to file for patent protection in all of the countries where patent protection will ultimately be necessary or fail to comply with other procedural, documentary, fee payment or other provisions during the patent process in any such country, and we may be precluded from filing at a later date or may lose some or all patent rights in the relevant jurisdiction;
- one or more of our technologies may not be patentable;
- others may design around one or more of our patent claims to produce competitive products which fall outside of the scope of our patents;
- others may identify prior art which could invalidate our patents; or
- changes to patent laws may limit the exclusivity rights of patent holders.

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

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

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

Some of our research collaborators and scientific advisors have rights to publish data and information to which we have rights. Additionally, employees whose positions may be eliminated may seek future employment with our competitors. Each of our employees is required to sign a confidentiality agreement and invention assignment agreement with us at the time of hire. While such arrangements are intended to enable us to better control the use and disclosure of our proprietary property and provide for our ownership of proprietary technology developed on our behalf, they may not provide us with meaningful protection for such property and technology in the event of unauthorized use or disclosure. In addition, technology that we may in-license may become important to some aspects of our business. We generally will not control all of the patent prosecution, maintenance or enforcement of in-licensed technology.

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

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

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach; or
- our trade secrets or proprietary know-how will otherwise become known.

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

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

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

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others, which could cause us to lose the use of one or more of our drug candidates;
- defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of management resources; or
- pay damages.

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

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

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

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

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

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

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

Changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. In particular, there have been proposals to shorten the exclusivity periods available under U.S. patent law that, if adopted, could substantially harm our business. The product candidates that we are developing are protected by intellectual property rights, including patents and patent applications. If any of our product candidates becomes a marketable product, we will rely on our exclusivity under patents to sell the compound and recoup our investments in the research and development of the compound. If the exclusivity period for patents is shortened, then our ability to generate revenues without competition will be reduced and our business could be materially adversely impacted. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our product candidates. In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect our products or technologies or limit the exclusivity periods that are available to patent holders. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was recently signed into law and includes a number of significant changes to U.S. patent law. These include changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The U.S. Patent and Trademark Office has been in the process of implementing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

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

Risks Related to our Common Stock

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

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

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

- adverse results 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 are in discussion regarding or we may enter into;
- announcements of FDA non-approval of our drug products, or delays in the FDA or other foreign regulatory review process or actions;
- adverse actions taken by regulatory agencies with respect to our drug products, clinical trials, manufacturing processes or sales and marketing activities;
- any lawsuit involving us or our drug products;
- developments with respect to our patents and proprietary rights;
- announcements of technological innovations or new products by our competitors;
- public concern as to the safety of products developed by us or others;
- regulatory developments in the United States and in foreign countries;
- our shares of common stock trading in five- rather than one-cent increments under the SEC's Tick Size Pilot program;
- changes in stock market analyst recommendations regarding our common stock or lack of analyst coverage;
- the pharmaceutical industry conditions generally and general market conditions;
- failure of our results of operations to meet the expectations of stock market analysts and investors;
- sales of our common stock by our executive officers, directors and five percent stockholders or sales of substantial amounts of our common stock;
- changes in accounting principles; and
- loss of any of our key scientific or management personnel.

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

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

- lower trading volume; and
- market conditions.

There is limited trading in our common stock and our security holders may experience wide fluctuations in the market price of our securities. Such price and volume fluctuations have particularly affected the trading prices of equity securities of many pharmaceutical and biotechnology companies. These price and volume fluctuations often appear to have been unrelated to the operating performance of the affected companies. These fluctuations may have an extremely negative effect on the market price of our securities and may prevent a stockholder from obtaining a market price equal to the purchase price such stockholder paid when the stockholder attempts to sell our securities in the open market. In these situations, the stockholder may be required either to sell our securities at a market price which is lower than the purchase price the stockholder paid, or to hold our securities for a longer period of time than planned. An inactive market may also impair our ability to raise capital by selling shares of capital stock or to recruit and retain managers with equity-based incentive plans. Additionally, under the SEC's Tick Size Pilot program, in October 2016, shares of our common stock began trading in five cent rather than one cent increments. The change to five cent increments may result in greater fluctuations in the market price of our common stock and could result in higher trading costs for investors.

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

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

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

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

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

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

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

We are subject to the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and the rules and regulations of the SEC thereunder ("Section 404"). Section 404 requires us to report on the design and effectiveness of our internal controls over financial reporting. In the past, our management has identified certain "material weaknesses" in our internal controls over financial reporting which we believe have been remediated. However, any failure to maintain effective controls could result in significant deficiencies or material weaknesses, and cause us to fail to meet our periodic reporting obligations, or result in material misstatements in our financial statements. We may also be required to incur costs to improve our internal control system and hire additional personnel. This could negatively impact our results of operations.

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

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

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

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

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

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

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

ITEM 2 PROPERTIES

The Company's headquarters are located in New York, New York. Our New York offices are being rented to us on a monthly basis.

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.

ITEM 3 LEGAL PROCEEDINGS

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

ITEM 4 MINE SAFETY DISCLOSURES.

Not applicable.

Part II

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

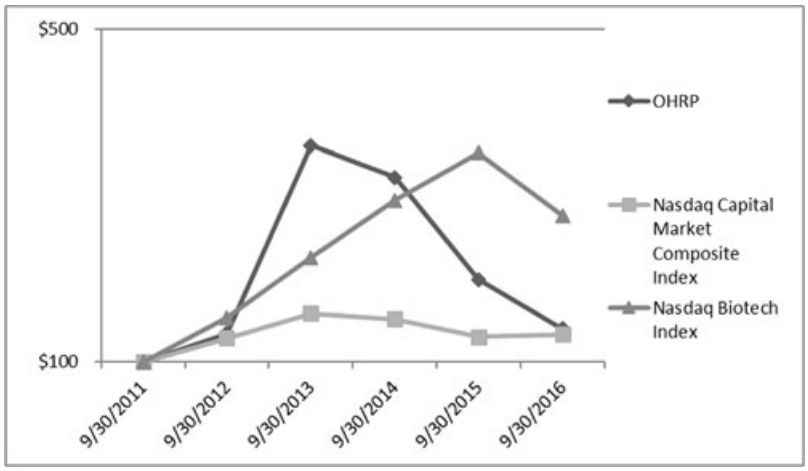
Ohr's shares of common stock are quoted on the Nasdaq Capital Market ("Nasdaq") under the symbol "OHRP." Following is a table of the quotation ranges (high and low trading prices) for its shares for the last two years.

FY 2016	High	Low	FY 2015	High	Low
October 1 - December 31, 2015	$ 6.56	$ 2.72	October 1 - December 31, 2014	$ 9.24	$ 6.69
January 1 - March 31, 2016	$ 6.15	$ 2.65	January 1 - March 31, 2015	$ 12.31	$ 2.51
April 1 - June 30, 2016	$ 4.00	$ 2.57	April 1 - June 30, 2015	$ 3.04	$ 2.35
July 1 -September 30, 2016	$ 2.93	$ 2.44	July 1 - September 30, 2015	$ 4.34	$ 2.02

Performance Graph

The following graph compares our cumulative total stockholder return from October 1, 2011, 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, 2011 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.

	9/30/2011	9/30/2012	9/30/2013	9/30/2014	9/30/2015	9/30/2016
OHRP	$ 100	$ 135	$ 360	$ 322	$ 200	$ 140
Nasdaq Capital Market Composite Index	$ 100	$ 129	$ 159	$ 152	$ 131	$ 133
Nasdaq Biotech Index	$ 100	$ 153	$ 226	$ 295	$ 352	$ 277



Holders

As of December 14, 2016 there were 182 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.

Securities authorized for issuance under equity compensation plans

Information regarding our equity compensation plans is presented below as of September 30, 2016.

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity Compensation Plans Approved by Stockholders	2,411,350	$ 7.59	2,649,475
Total	2,411,350	$ 7.59	2,649,475

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, 2012, 2013, 2014, 2015 and 2016, and for the five years in the period ended September 30, 2016. 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 Annual Report on Form 10-K.

Consolidated Statements of Operations Data:
Year Ended September 30,

	2012	2013	2014	2015	2016
Operating expenses					
General and administrative	$ 989,571	$ 1,775,857	$ 4,287,205	$ 7,509,601	$ 7,656,327
Research and development	2,209,108	2,753,914	4,369,413	8,777,519	16,460,714
Depreciation and amortization	87,729	91,145	466,306	1,179,254	1,189,276
Gain on settlement of accounts payable	—	—	—	—	(710,264)
Impairment of intangibles	—	—	—	338,906	—
Total Operating Expenses	3,286,408	4,620,916	9,122,924	17,805,280	24,596,053
Operating Loss	(3,286,408)	(4,620,916)	(9,122,924)	(17,805,280)	(24,596,053)
Change in derivative liability	1,812,224	(1,117,642)	—	—	—
Change in fair value of contingent consideration	—	—	—	2,637,756	(1,185,667)
Share in losses on investment in joint venture	—	—	(10,643)	(103,143)	—
Other income and expense	19,300	86,070	2,903	72,802	15,522
Total other income (expense)	1,831,524	(1,031,572)	(7,740)	2,607,415	(1,170,145)
Loss from operations	(1,454,884)	(5,652,488)	(9,130,664)	(15,197,865)	(25,766,198)
Provision for income taxes	—	—	—	—	—
Net loss	$ (1,454,884)	$ (5,652,488)	$ (9,130,664)	$ (15,197,865)	$ (25,766,198)
Net loss per basic and diluted share	$ (0.10)	$ (0.30)	$ (0.41)	$ (0.54)	$ (0.82)
Weighted-average shares used to compute net loss per basic and diluted share:	14,242,792	18,707,759	22,141,538	28,404,405	31,349,223
Consolidated Balance Sheet Data:					
Total assets	$ 3,517,420	$ 5,743,865	$ 32,025,144	$ 46,370,807	$ 29,445,013
Total liabilities	1,091,195	479,737	5,273,122	3,880,014	4,481,866
Total stockholders' equity	2,426,225	5,264,128	26,752,022	42,490,793	24,963,147

ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

General

Ohr Pharmaceutical, Inc. ("we," "us," "our," "Ohr" or the "Company") is a pharmaceutical company focused on the development of novel therapeutics and delivery technologies for the treatment of ocular disease. Our development pipeline consists of several programs and indications at various stages of development. Our lead clinical asset, topical Squalamine (also known as squalamine lactate ophthalmic solution, 0.2%, or OHR-102), is a novel therapeutic product which could provide a non-invasive therapy to improve vision outcomes beyond that achieved with current standard of care, without requiring multiple injections per office visit. We are conducting a Phase 3 registration program evaluating Squalamine in combination with Lucentis® injections for the treatment of wet-AMD. This clinical program is proceeding based on the data from a Phase 2 clinical trial in wet-AMD which demonstrated a positive and clinically meaningful treatment effect of Squalamine combination therapy in classic containing choroidal neovascularization (classic CNV) as well as those with occult neovascularization (occult CNV) less than $10mm^2$ in area.

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.

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.

Recent Developments

On December 7, 2016, we entered into a securities purchase agreement (the "Purchase Agreement") with various purchasers set forth on the signatures pages thereto (the "Purchasers"). Pursuant to the Purchase Agreement, we issued and sold to the Purchasers in a registered offering an aggregate of 3,885,000 shares of our common stock, together with Series A common stock purchase warrants ("Series A Warrants") exercisable for up to an aggregate of 1,942,500 shares of common stock and Series B common stock purchase warrants ("Series B Warrants") exercisable for up to an aggregate of 3,885,000 shares of common stock. The offering closed on December 13, 2016 and we received net proceeds of approximately $6.9 million, after deducting placement agent fees and estimated offering expenses payable by us, but excluding the proceeds, if any, from the exercise of the Series A Warrants and Series B Warrants issued in the offering.

The Series A Warrant has an exercise price of $2.75 per share and the Series B Warrant has an exercise price of $3.00 per share. The Series A Warrants will be immediately exercisable and will expire on the five year anniversary of the date of issuance. The Series B Warrants will be immediately exercisable and will expire on the six month anniversary of the date of issuance.

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 decreased from the beginning of the 2016 fiscal year to the end by $16,352,880 (to $8,803,142 from $25,156,022) and increased from the beginning of 2015 fiscal year to the end by $17,075,123 (to $25,156,022 from $8,080,899) primarily due to capital raised through the sale of common stock. At the end of fiscal 2016, our quarterly cash burn increased to approximately $5,000,000, which was higher than in fiscal 2015. We expect our cash burn to increase in fiscal 2017 with the full phase 3 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 the Company 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. Management believes the Company has sufficient capital to meet its planned operating needs into June 2017.

Results of Operations

For the fiscal year ended September 30, 2016, the Company had no revenues and operating expenses of approximately $24,596,053. The loss from operations was comprised of $16,460,714 in research and development costs, $7,656,327 in general and administrative expenses, and $1,189,276 in depreciation and amortization. During the same period, the Company recorded a gain on settlement of accounts payable of $710,264, a decrease in fair value of contingent consideration of $1,185,667 and had other income and expense, net items totaling $15,522. The net loss for the year ended September 30, 2016 was $25,766,198.

For the fiscal year ended September 30, 2015, the Company had no 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 a loss on investment of subsidiary of $103,143, a change in fair value of contingent consideration of $2,637,756 and had other income and expense, net items totaling $72,802. 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 a loss on investment of subsidiary of $10,643 and had other income and expense, net items totaling $2,903. The net loss for the year ended September 30, 2014 was $9,130,664.

As noted above, the Company had no revenues for fiscal year 2016, and does not anticipate that it will have any revenues in fiscal year 2017. The operating expenses of the Company increased from fiscal year 2015 to fiscal year 2016 by $6,790,773. 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 2017, including clinical development costs, again with no offsetting revenues.

Results of operations for the year ended September 30, 2016 reflect the following changes from the prior year period:

	2016	2015	Change
General and administrative	$ 7,656,327	$ 7,509,601	$ 146,726
Research and development	16,460,714	8,777,519	7,683,195
Depreciation and amortization	1,189,276	1,179,254	10,022
Gain on settlement of accounts payable	(710,264)	—	(710,264)
Impairment of intangibles	—	338,906	(338,906)
Total Operating Expenses	24,596,053	17,805,280	6,790,773
Operating Loss	(24,596,053)	(17,805,280)	(6,790,773)
Change in fair value of contingent consideration	(1,185,667)	2,637,756	(3,823,423)
Share in losses on investment in joint venture	—	(103,143)	103,143
Other income and expense, net	15,522	72,802	(57,280)
Net Loss	$ (25,766,198)	$ (15,197,865)	$ (10,568,333)

Results of continuing operations for the year ended September 30, 2015 reflect the following changes from the prior year 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 expense, net	72,802	2,903	69,899
Net Loss	$ (15,197,865)	$ (9,130,664)	$ (6,067,201)

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.

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 $16,460,714, $8,777,519, and $4,369,413 during the years ended September 30, 2016, 2015, and 2014, 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 options and the stock price on the date of the grant for the fair value of restricted stock awards.

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, 2016, 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 14 years. During the years ended September 30, 2016, 2015, and 2014 the Company recognized $1,124,644, $1,138,631, and $448,456 in amortization expense on the patents and license rights, respectively. The amortization expense has been included in depreciation and amortization 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K 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, 2016, 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 (Principal Executive Officer)	Chief Financial Officer (Principal Financial and Accounting Officer)
December 22, 2016	December 22, 2016

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, 2016 and 2015 and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended September 30, 2016. We also have audited the Company's internal control over financial reporting as of September 30, 2016, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for these consolidated financial statements, 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 these consolidated financial statements and an opinion on the Company's internal control over financial reporting 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 and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. 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 audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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 consolidated 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, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2016, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2016, based on the criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ MaloneBailey, LLP
www.malone-bailey.com
Houston, Texas
December 22, 2016

OHR PHARMACEUTICAL, INC.
Consolidated Balance Sheets

	September 30, 2016	September 30, 2015
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 12,546,890	$ 28,697,323
Prepaid expenses and other current assets	738,118	338,713
Total Current Assets	13,285,008	29,036,036
EQUIPMENT, net	198,631	248,753
OTHER ASSETS		
Security deposit	12,243	12,243
Intangible assets, net	15,208,219	16,332,863
Goodwill	740,912	740,912
TOTAL ASSETS	$ 29,445,013	$ 46,370,807
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 4,394,068	$ 1,592,348
Notes payable	87,798	48,063
Contingent consideration	—	2,239,603
Total Current Liabilities	4,481,866	3,880,014
TOTAL LIABILITIES	4,481,866	3,880,014
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, 32,076,396 and 30,331,309 shares issued and outstanding, respectively	3,207	3,033
Additional paid-in capital	109,237,551	100,999,173
Accumulated deficit	(84,277,611)	(58,511,413)
Total Stockholders' Equity	24,963,147	42,490,793
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 29,445,013	$ 46,370,807

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

OHR PHARMACEUTICAL, INC.
Consolidated Statements of Operations

	For the Year Ended September 30,		
	2016	**2015**	**2014**
OPERATING EXPENSES			
General and administrative	$ 7,656,327	$ 7,509,601	$ 4,287,205
Research and development	16,460,714	8,777,519	4,369,413
Depreciation and amortization	1,189,276	1,179,254	466,306
Gain on settlement of accounts payable	(710,264)	—	—
Impairment of Intangibles	—	338,906	—
OPERATING LOSS	24,596,053	17,805,280	9,122,924
OTHER INCOME (EXPENSE)			
Change in fair value of contingent consideration	(1,185,667)	2,637,756	—
Share in losses on investment in joint venture	—	(103,143)	(10,643)
Other income and expense	3,419	42,966	8,479
Interest income (expense), net	12,103	(5,977)	(5,576)
Royalty income	—	35,813	—
Total Other Income (Expense)	(1,170,145)	2,607,415	(7,740)
LOSS FROM OPERATIONS BEFORE INCOME TAXES	(25,766,198)	(15,197,865)	(9,130,664)
PROVISION FOR INCOME TAXES	—	—	—
NET LOSS	$ (25,766,198)	$ (15,197,865)	$ (9,130,664)
BASIC AND DILUTED LOSS PER SHARE	$ (0.82)	$ (0.54)	$ (0.41)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:			
BASIC AND DILUTED	31,349,223	28,404,405	22,141,538

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	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
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 settlement of accounts payable	—	—	5,952	1	49,999	—	50,000
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
Warrants issued for services	—	—	—	—	8,559	—	8,559
Fair value of employee stock options and warrants issued for services	—	—	—	—	3,579,788	—	3,579,788
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
Exercise of warrants for cash	—	—	88,612	8	144,834	—	144,842
Common stock issued for achievement of milestones set in asset acquisition	—	—	995,718	100	3,425,170	—	3,425,270
Common stock issued for services	—	—	660,757	66	1,754,748	—	1,754,814
Fair value of employee stock options and	—	—	—	—	2,913,626	—	2,913,626
Net loss for the year ended September 30, 2016	—	—	—	—	—	(25,766,198)	(25,766,198)
Balance, September 30, 2016	—	$ —	32,076,396	$ 3,207	$ 109,237,551	$ (84,277,611)	$ 24,963,147

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,		
	2016	**2015**	**2014**
OPERATING ACTIVITIES			
Net loss	$ (25,766,198)	$ (15,197,865)	$ (9,130,664)
Adjustments to reconcile net loss to net cash used by operating activities:			
Common stock issued for services	1,754,814	635,288	—
Warrants issued for services	—	8,559	1,177,095
Stock option expense	2,913,626	3,579,788	2,074,487
Change in fair value of contingent consideration	1,185,667	(2,637,756)	—
Share in losses on investment in joint venture	—	103,143	10,643
Depreciation	64,632	40,623	17,850
Amortization of intangible assets	1,124,644	1,138,631	448,456
Impairment of intangibles	—	338,906	—
Gain on settlement of accounts payable	(710,264)	(40,636)	—
Changes in operating assets and liabilities			
Prepaid expenses and deposits	(64,794)	7,214	105,823
Accounts payable and accrued expenses	3,511,984	1,331,120	(63,822)
Net Cash Used in Operating Activities	(15,985,889)	(10,692,985)	(5,360,132)
INVESTING ACTIVITIES			
Acquisition of SKS Ocular's assets	—	—	(3,500,000)
Investment in joint venture	—	(100,000)	(13,786)
Purchase of property and equipment	(14,510)	(184,951)	(1,083)
Net Cash Used in Investing Activities	(14,510)	(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	26,041	80,003	260,752
Repayments of short-term notes payable	(176,075)	(208,236)	(164,152)
Net Cash Provided by/(Used in) Financing Activities	(150,034)	26,454,765	16,972,600
NET CHANGE IN CASH AND CASH EQUIVALENTS	(16,150,433)	15,476,829	8,097,599
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	28,697,323	13,220,494	5,122,895
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 12,546,890	$ 28,697,323	$ 13,220,494
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION	—		
CASH PAID FOR:			
Interest	$ 6,071	$ 5,977	$ 5,576
Income Taxes	—	—	—
NON CASH FINANCING ACTIVITIES:			
Settlement of contingent consideration	$ 3,425,270	$ —	$ —
Financing of insurance premiums through issuance of short term notes	215,810	212,400	194,000
Subscription receivable from exercise of warrants	118,801	—	—
Conversion of preferred for common stock	—	—	50
Noncash exercise of options and warrants	—	—	223
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.

NOTE 1 – DESCRIPTION OF BUSINESS

OHR Pharmaceutical, Inc. ("we", "our," 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, topical Squalamine (also known as Squalamine Lactate Ophthalmic Solution, 0.2% or OHR-102), is being evaluated in a phase 3 clinical program for the treatment of the wet form of age-related macular degeneration ("wet-AMD"). We are also developing a sustained release ocular drug delivery platform technology.

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 a micro-fabrication polymer- based sustained delivery platform related to ocular therapeutics and a dry age-related macular degeneration animal model, together with biomarkers to support such model.

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 liabilities.

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

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

Concentration of Credit Risk
Financial instruments, which potentially subject us to concentrations of credit risk, consist principally of cash. Our cash balances are maintained in accounts held by major banks and financial institutions located in the United States. The Company occasionally maintains amounts on deposit with a financial institution that are in excess of the federally insured limit of $250,000. The risk is managed by maintaining all deposits in high quality financial institutions. The Company had approximately $12,046,890 and $27,947,323 of cash balances in excess of federally insured limits at September 30, 2016 and 2015, 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 $1,000 are capitalized, while expenditures that do not, such as repairs and maintenance, are expensed as incurred.

Valuation of Long-Lived Assets
Long-lived tangible assets and definite-lived intangible assets are reviewed for possible impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The Company uses an estimate of undiscounted future net cash flows of the assets over the remaining useful lives in determining whether the carrying value of the assets is recoverable. If the carrying values of the assets exceed the expected future cash flows of the assets, the Company recognizes an impairment loss equal to the difference between the carrying values of the assets and their estimated fair values. Impairment of long-lived assets is assessed at the lowest levels for which there are identifiable cash flows that are independent from other groups of assets. The evaluation of long-lived assets requires the Company to use estimates of future cash flows. However, actual cash flows may differ from the estimated future cash flows used in these impairment tests. In fiscal 2015, management discontinued development of the OHR/AVR118 program. In connection with this decision, the OHR/AVR118 patent portfolio is no longer being maintained and the remaining $338,906 in unamortized patent costs have been impaired. As of September 2016, 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, 2016 and 2015, on a recurring basis:

Assets and liabilities measured at fair value on a recurring basis at September 30, 2016	Level 1	Level 2	Level 3	Total Carrying Value
Contingent stock consideration	$ —	$ —	$ —	$ —
	$ —	$ —	$ —	$ —

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

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.

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:	Contingent Stock Consideration
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
Purchases, sales, issuances and settlements (net)	(3,425,270)
Mark to market adjustments	1,185,667
Total Level 3 assets and liabilities at September 30, 2016	$ —

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, (hi) 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, 2016, 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, 2016, 2015, and 2014 the Company recognized $1,124,644, $1,138,631, and $448,456 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, manufacturing expenses, consulting fees, and laboratory costs. The Company incurred net research and development expenses of $16,460,714, $8,777,519, and $4,369,413 during the years ended September 30, 2016, 2015, and 2014 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 options and the stock price on the date of issuance to determine the fair value of restricted stock awards.

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.

Stock-based compensation expense is recognized in the Company's financial statements on a straight-line basis over the awards' vesting periods. The stock-based compensation awards generally vest over a period of up to five years.

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. This method requires the reduction of deferred tax assets by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. 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.

As of September 30, 2016 and 2015, the Company's deferred tax assets relate to net operating loss ("NOL") carryforwards that were derived from operating losses from prior years amounting to $40,779,002 and $20,746,188, respectively. A full valuation allowance has been applied to the Company's deferred tax assets. The valuation allowance will be reduced when and if the Company determines it is more likely than not that the related deferred income tax assets will be realized.

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 2013 to 2015 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, 2016, 2015 and 2014, 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 440,449, 1,313,536 and 3,995,343 at September 30, 2016, 2015 and 2014, respectively.

Reclassification of Financial Statement Accounts

Certain amounts in the September 30, 2015 and 2014 financial statements have been reclassified to conform to the presentation in the September 30, 2016 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 a micro-fabrication polymer-based sustained delivery platform related to ocular therapeutics and a dry age-related macular degeneration animal model, together with biomarkers to support such model.

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, 2016 and 2015 consist of:

	2016	2015
Equipment	$ 93,789	$ 91,715
Lab equipment	251,908	239,472
Leasehold improvements	2,181	2,181
Office furniture and fixtures	2,523	2,523
	350,401	335,891
Accumulated depreciation	(151,770)	(87,138)
	$ 198,631	$ 248,753

Depreciation expense for the years ended September 30, 2016, 2015, and 2014 was $64,632, $40,623, and $17,850, respectively.

NOTE 5 – INTANGIBLE ASSETS
Intangible assets at September 30, 2016 and 2015 consist of:

	2016	2015
License rights	$ 17,712,991	$ 17,712,991
Patent costs	200,000	200,000
	17,912,991	17,912,991
Accumulated amortization	(2,704,772)	(1,580,128)
	$ 15,208,219	$ 16,332,863

During the years ended September 30, 2016, 2015, and 2014, the Company recognized $1,124,644, $1,138,631, and $448,456, 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 OHR/AVR118 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
2017	$ 1,120,616
2018	1,117,731
2019	1,116,449
2020	1,119,508
2021	1,115,577
Thereafter	9,618,338
Total	$ 15,208,219

NOTE 6 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES

During the year ended September 30, 2016, the Company realized a gain of $710,264 related to the settlement of an accounts payable balance.

NOTE 7 –NOTES PAYABLE

On February 28, 2016, the Company entered into a premium financing arrangement for its directors' and officers' insurance policy in the amount of $215,810. The financing arrangement bears interest at 7.0% per annum and will be fully paid in ten months from the date of issuance. As of September 30, 2016, the Company had repaid $128,012 of principal and had paid interest of $5,664.

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, 2016, the Company had repaid $212,400 of principal and had paid interest of $5,950.

NOTE 8 – EQUITY

The Company intends to retain cash in order to continue to invest in the development and marketing of the business. Therefore, it does not expect to pay any cash dividends in the foreseeable future.

During fiscal 2016, 2015, and 2014, the Company issued 1,745,087, 5,077,119 and 5,512,649 shares, respectively, of common stock primarily due to stock option exercises, issuance of restricted stock awards for services, acquisition of assets, settlement of accounts payable and capital raised from sale of common stock. Refer to Note 9 for further detail on issuances related to common stock warrants and options.

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 November 13, 2013, two holders of its Series B preferred shares converted an aggregate of 500,000 preferred shares into 166,667 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 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 December 23, 2014, the Company issued 5,952 common shares as settlement of accounts payable in the amount of $50,000.

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 December 11, 2015, the Board approved the achievement of Milestone 1 in connection with the SKS ophthalmology assets acquisition by the Company. As a result, the Company issued 497,859 shares of its common stock to SKS. The value of the stock issued was $2,061,136 as determined by the $4.14 per share closing sale price of the Company's common stock on the date of Board approval. On July 12, 2016, the Board approved the achievement of Milestone 2, and as result, the Company issued an additional 497,859 shares of its common stock to SKS. The value of the stock issued was $1,364,134 as determined by the $2.74 per share closing sale price of the Company's stock on the date of Board approval.

NOTE 9 – STOCK BASED COMPENSATION

The Company's Consolidated 2016 Stock Plan (the "Plan") provides for granting stock options and restricted stock awards to employees, directors and consultants of the Company. A total of 5,833,334 shares have been authorized for issuance under the Plan. At September 30, 2016, the Company had 2,649,475 shares available for future grant. Upon share option exercise or issuance of restricted stock, the Company issues new shares to fulfill these grants. The Company previously maintained a 2014 Stock Incentive Plan and the 2009 Stock Incentive Plan. The 2016 Plan consolidated the 2014 Plan and the 2009 Plan into a new plan.

Common Stock Warrants

For all warrants included within permanent equity, the Company has determined the estimated value of the warrants granted to nonemployees in exchange for services and financing expenses using the Black-Scholes pricing model and the following assumptions: stock price at valuation, $7.85-$7.96; expected term of 2-5 years, exercise price of $7.88-$7.96, a risk free interest rate of 0.38-1.72 percent, a dividend yield of 0 percent and volatility of 98-163 percent.

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 through $2.85 for which $80,003 in cash was received by the Company.

During the year ended September 30, 2016, 15,278 shares of common stock were issued in connection with the exercise of warrants to purchase the Company's common stock. The warrants were exercised at prices ranging from $1.50 through $1.95 per share for which $26,041 in cash was received by the Company. An additional 73,334 shares of common stock were also issued in connection with the exercise of warrants to purchase common stock. These warrants were exercised at a price of $1.62 per share and a receivable for $118,801 was recorded as September 30, 2016 to account for cash proceeds not yet received at September 30, 2016.

Below is a table summarizing the warrants issued and outstanding as of September 30, 2016:

	Number Outstanding	Weighted-Average Exercise Price
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
Granted	—	—
Exercised	(88,612)	1.63
Forfeited	(43,334)	6.55
Outstanding at September 30, 2016	614,923	$ 5.08
Exercisable at September 30, 2016	614,923	$ 5.08

The outstanding warrants as of September 30, 2016 have an intrinsic value of approximately $33,671. For the years ended September 30, 2016, 2015, and 2014, the Company has expensed $0, $8,559, and $1,177,095, respectively, related to the fair value of warrants issued for services.

Stock Options

Stock Options are granted for a term not exceeding five years and the nonvested options are generally forfeited in the event the employee, director or consultant terminates his or her employment or relationship with the Company. Any options that have vested at the time of termination are forfeited to the extent they are not exercised within the applicable post-employment exercise period provided in the option agreements. These options vest over one to five years.

The following assumptions were used to calculate the fair value of the Company's options on the date of grant:

	Year Ended September 30,		
	2016	2015	2014
Expected term	3 to 3.5 years	3 to 3.5 years	2.25 to 3.25 years
Expected volatility	103% - 105%	69% - 73%	56% - 83%
Expected dividends	0%	0%	0%
Risk-free rates	1.04% - 1.22%	1.02% - 1.10%	0.30% - 1%

Below is a table summarizing the options issued and outstanding as of September 30, 2016 ("Price" reflects the weighted average exercise price per share):

	Year Ended September 30,					
	2016		2015		2014	
	Options	Price	Options	Price	Options	Price
Outstanding October 1	2,761,001	$ 7.27	2,048,335	$ 5.43	1,133,335	$ 2.31
Granted	669,275	4.11	1,106,000	9.04	915,000	9.29
Exercised	—	—	—	—	—	—
Forfeited or expired	(572,808)	6.61	(393,334)	2.54	—	—
Outstanding September 30	2,857,468	$ 6.66	2,761,001	$ 7.27	2,048,335	$ 5.43
Exercisable September 30	1,833,712	$ 6.49	1,450,667	$ 5.74	1,103,750	$ 3.53
Weighted average fair value per option granted		$ 2.68		$ 4.77		$ 4.08

As of September 30, 2016, the intrinsic value of both outstanding options and exercisable options was $373,334. There were no options exercised during the years ended September 30, 2016, 2015, and 2014.

The Company recognized stock-based compensation expense from stock options of $2,913,626, $3,579,788, and $2,074,487 during the years ended September 30, 2016, 2015, and 2014, respectively. As of September 30, 2016, there was $2,517,203 of stock-based compensation cost related to unvested shares of stock options which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 1.1 years.

Restricted Stock

The Company has granted restricted stock awards to its employees, directors and consultants under the 2016 Plan and related restricted stock agreements. The restricted stock-based compensation awards generally vest over a period ranging from zero to three years. These common shares are forfeited in the event the recipient's employment or relationship with the Company is terminated prior to the lapse of the restriction.

Below is a table summarizing nonvested restricted stock shares as of September 30, 2016, and changes during the year ended September 30, 2016:

	Shares	Weighted Average Grant Date Fair Value
Nonvested at September 30, 2013	—	$ —
Granted	—	—
Vested	—	—
Forfeited	—	—
Nonvested at September 30, 2014	—	$ —
Granted	111,752	8.89
Vested	(49,072)	7.91
Forfeited	—	—
Nonvested at September 30, 2015	62,680	$ 9.66
Granted	660,757	4.46
Vested	(123,079)	5.45
Forfeited	—	—
Nonvested at September 30, 2016	600,358	$ 4.80

The Company recognized stock-based compensation expense from restricted stock awards of $1,754,814, $635,288, and $0 during the years ended September 30, 2016, 2015, and 2014, respectively. As of September 30, 2016, there was $1,289,333 of stock-based compensation cost related to unvested shares of restricted stock which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 1.27 years.

NOTE 10 – RELATED PARTY TRANSACTIONS

Our Contract Research Organization running our phase 3 trial has contracted with Jason S. Slakter, M.D., P.C., d/b/a Digital Angiography Reading Center ("DARC"), a well-known digital reading center, which is owned by Dr. Jason Slakter, Ohr's CEO, pursuant to our related party transactions policy, with the review and approval of the Audit Committee, to provide digital reading and imaging services in connection with the Phase 3 study. During the years ended September 30, 2016 and 2015, the Company has been invoiced $267,680 and $91,280, respectively, from DARC.

NOTE 11 – COMMITMENTS AND CONTINGENCIES

Legal Proceedings

The Company may become involved in certain legal proceedings and claims which arise in the normal course of business. If an unfavorable ruling were to occur, there exists the possibility of a material adverse impact on the Company's results of operations, prospects, cash flows, financial position and brand. To the best knowledge of the Company's management, at September 30, 2016 and 2015, 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 and laboratory space and associated building expenses. The lease expires in December 2017. As of September 30, 2016, future minimum payments for all lease obligations are as follows:

Year		Amount
Fiscal 2017	$	283,524
Fiscal 2018		70,887
	$	354,411

Rental expense related to the operating lease has been recorded in the consolidated statements of operations in the amounts of $340,064, $305,638, and $83,556 for each of the years ended September 30, 2016, 2015, and 2014, 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 a micro-fabrication polymer- based sustained delivery platforms related to ocular therapeutics and a dry age-related macular degeneration animal model, together with biomarkers to support such model.

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.

On December 11, 2015 and July 12, 2016, the Board approved the achievement of Milestone 1 and Milestone 2, respectively. Consequently, the Company issued 995,718 shares of its common stock to SKS. Milestone 3 is contingent upon the approval of an Investigational New Drug Application ("IND") within three years of the closing date of the SKS acquisition. We do not expect IND approval within this time frame and therefore, do not expect to achieve Milestone 3. As such, there is no related contingent stock consideration recorded in association with Milestone 3.

NOTE 12 – QUARTERLY FINANCIAL DATA (Unaudited)

	First	Second	Third	Fourth	Total
2016					
Total revenue	$ —	$ —	$ —	$ —	$ —
Operating loss	(3,592,148)	(6,596,035)	(7,598,627)	(6,809,243)	(24,596,053)
Net loss	(6,145,462)	(5,284,859)	(7,699,741)	(6,636,136)	(25,766,198)
Net loss per basic and diluted share	$ (0.20)	$ (0.17)	$ (0.24)	$ (0.21)	$ (0.82)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:					
BASIC AND DILUTED	30,472,493	31,344,424	31,501,540	32,016,707	31,349,223
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)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:					
BASIC AND DILUTED	25,259,154	27,713,410	30,323,206	30,331,309	28,404,405

NOTE 13 – SUBSEQUENT EVENTS

In October 2016, $118,801 in cash proceeds were received related to the receivable recorded in connection with the 73,334 common shares issued for warrants exercised in July 2016.

On December 7, 2016, the Company entered into a securities purchase agreement (the "Purchase Agreement") with various purchasers pursuant to which the Company issued and sold to the purchasers in a registered offering an aggregate of 3,885,000 shares of its common stock, together with Series A common stock purchase warrants ("Series A Warrants") exercisable for up to an aggregate of 1,942,500 shares of common stock and Series B common stock purchase warrants ("Series B Warrants") exercisable for up to an aggregate of 3,885,000 shares of common stock. The offering closed on December 13, 2016 and the Company received net proceeds of approximately $6.9 million, after deducting placement agent fees and estimated offering expenses payable by the Company, but excluding the proceeds, if any, from the exercise of the Series A Warrants and Series B Warrants issued in the offering.

The Series A Warrant has an exercise price of $2.75 per share and the Series B Warrant has an exercise price of $3.00 per share. The Series A Warrants will be immediately exercisable and will expire on the five year anniversary of the date of issuance. The Series B Warrants will be immediately exercisable and will expire on the six month anniversary of the date of issuance.

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 the period covered by this Annual Report on Form 10-K, 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

The report of management on our internal control over financial reporting as of September 30, 2016, and the attestation report of our independent registered accounting firm on our internal report on financial reporting are set forth in "Part II. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

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, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B OTHER INFORMATION

None.

ITEM 10 DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Following this table is a brief biographical description for each of Ohr's executive officers and directors, with a brief description of their business experience and present relationship to Ohr as of September 30, 2016, together with all required relevant disclosures for the past five years.

Name	Position	Current Term of Office
Ira Greenstein	Chairman	Director since 2007
Jason S. Slakter, M.D.	Chief Executive Officer, President and Director	Officer since 2014, Director since 2015
Orin Hirschman	Director	Director since 2009
Thomas Riedhammer	Director	Director since 2013
June Almenoff	Director	Director since 2013
Sam Backenroth	CFO and Vice President of Business Development	Officer since 2010
Avner Ingerman, M.D.	Chief Clinical Officer	Officer since 2015

Ira Greenstein, age 56, has served as a Director of Ohr since March 2007. Mr. Greenstein has served as President of Genie Energy Ltd. since December 2011. Mr. Greenstein currently also serves as Counsel to the Chairman of IDT Corporation and General Counsel to various companies, including Ohr and Global Risk Advisors, LLC, an international strategic consulting firm providing clients with innovative security and risk mitigation strategies. Mr. Greenstein had served as the President of IDT from 2001 through 2011 and Counsel to the Chairman of IDT in 2000 and 2001. He has served as a Director of IDT and General Counsel and Secretary of IDT's subsidiary, Net2Phone, Inc. Prior to joining IDT, Mr. Greenstein was a partner in Morrison & Foerster LLP, where he served as the Chairman of that firm's New York Office's Business Department. Mr. Greenstein was an associate in the New York and Toronto offices of Skadden, Arps, Slate, Meagher & Flom LLP and served on the Securities Advisory Committee and as secondment counsel to the Ontario Securities Commission. Mr. Greenstein serves as Chairman of the Board of NanoVibronix, Inc. and on the Boards of Directors of Document Security Systems, Inc., Enerpulse Technologies, Inc. and Regal Bank of New Jersey. Mr. Greenstein received a B.S. from Cornell University and a J.D. from Columbia University Law School where he serves as a member of the Dean's Council.

Dr. Jason S. Slakter, age 58, joined Ohr as Chief Medical Officer in May 2014 and was appointed Director in January 2015. He was appointed Chief Executive Office in September 2015. He was previously Chief Executive Officer and co-founder of SKS Ocular LLC. He is also the Founder and Director of the Digital Angiography Reading Center (DARC) in New York, which is the largest center for ocular image evaluation for clinical trials of posterior segment disease with over 900 certified clinical sites in over 44 countries worldwide. Dr. Slakter has been involved extensively in the design and application of new diagnostic and treatment modalities for ophthalmic diseases. He has played a major role in the discovery, development and commercialization of treatments for age-related macular degeneration, diabetic retinopathy, retinal vascular disease, central serous chorioretinopathy and other retinal diseases. He has provided critical assistance in the design of clinical trials at all stages of development, and has participated in numerous meetings with the FDA. Dr. Slakter served as Chief Medical Officer for Potentia Pharmaceuticals from its inception through its acquisition by Alcon Laboratories, Inc. (Novartis). Dr. Slakter is a member of The American Ophthalmological Society, The Macula Society, The Retina Society, and The American Society of Retina Specialists, and was the founder and first Editor-in-Chief of Retinal Physician journal. He has been the recipient of many awards including The Macula Society's Richard and Hinda Rosenthal Award for outstanding contribution to the treatment of ocular disease by an individual under the age of 45, the 2003 Helen Keller Manhattan League Award, and Life Achievement Honor Award from the American Academy of Ophthalmology. Dr. Slakter is a Clinical Professor of Ophthalmology at New York University School of Medicine and has also practiced at the Vitreous-Retina-Macula Consultants of New York for over 28 years.

Orin Hirschman, age 47, has served as a Director of Ohr since March 2009. Mr. Hirschman has over 25 years of experience in money management, leveraged buyouts, restructuring and venture capital. Mr. Hirshman has been the manager of AIGH Investment Partners, LP since 2011. From 1994 until 2001 Mr. Hirschman served as a co-manager of two private investment funds, Adam Smith Investment Partnerships and Adam Smith Investment Partners, Ltd (the "Adam Smith Funds"). In addition to Mr. Hirschman's private placement investments over the last thirteen years, the Adam Smith Funds, and AIGH Investment Partners, LP, his experience in the securities industry includes tenures with Wesray Capital, the investment firm founded by former U.S. Secretary of the Treasury William E. Simon, and Randall Rose & Company, a $100 million money management firm based in New York. Mr. Hirschman has been actively involved in the financing and structuring of over 70 companies, including many high technology companies. Mr. Hirschman has served as a Director of Novint Technologies Inc. since August 2013. Mr. Hirschman's educational background includes an M.B.A. in Finance from New York University Graduate School of Business and a degree in Biology and Finance from Touro College where he graduated Summa Cum Laude.

Dr. Thomas M. Riedhammer, age 68, has been a Director of Ohr since April 2013, and has been a Director of DepYmed, a joint venture of Ohr, since 2014. He most recently served as Chairman of Sirion Therapeutics Inc, a position he held from 2007 to 2013. Prior to that, Dr. Riedhammer served as Chief Operating Officer of Presby Corp., a medical device company engaged in the research and development of treatments for eye disorders. Prior to Presby Corp., Dr. Riedhammer served as President and Senior Vice President of Worldwide Pharmaceuticals at Bausch and Lomb from 1994 to 2000. He also held various other positions at Bausch and Lomb including: Senior Vice President, and Chief Technical Officer from 1998 to 2000, Senior Vice President and President for Worldwide Pharmaceutical, Surgical, and Hearing Care Products from 1994 to 1998, and Vice President from 1993 to 1994. He was a corporate Vice President of Paco Pharmaceuticals and President of Paco Research Corp from 1984 to 1991. Dr. Riedhammer began his career at Bausch & Lomb as a Research Chemist and was its Director, Lens Care Products R&D. He has served as Chairman and Director of Prevent Blindness Florida, Director of Prevent Blindness America, Sjogren's Syndrome Foundation as secretary and Junior Achievement International. Dr. Riedhammer holds a B.A. in Chemistry and a Ph.D. in Electrochemistry from State University of New York at Buffalo.

Dr. June S. Almenoff, age 59, has been a Director of Ohr since May 2013. Dr. Almenoff is currently an independent biopharma consultant and Board Director. She is the Executive Chair of RDD Pharma and an independent Board Director of Tigenix NV (Nasdaq: TIG). She also serves on the investment advisory board of the Harrington Discovery Institute (University Hospitals, Cleveland), the advisory board of Redhill Biopharma (Nasdaq: RDHL) and of several private companies. Recently, Dr. Almenoff served as President, Principal Executive Officer and Chief Medical Officer at Furiex Pharmaceuticals (Nasdaq). During her four year tenure, the company's valuation increased approximately 10x culminating in its acquisition by Forest Labs/Actavis for approximately $1.2B in 2014. Furiex's lead product, eluxadoline, a novel gastrointestinal drug, received FDA approval in 2015. Prior to joining Furiex, Dr. Almenoff was at GlaxoSmithKline for 12 years, where she held positions of increasing responsibility, including Vice President of the clinical safety organization. She served on the GSK's senior governing medical boards, managed a diverse therapeutic portfolio supporting numerous regulatory approvals, and chaired a Pharma-FDA working group. She led the development of several pioneering systems for minimizing risk in early- and late-stage drug development; these have been widely implemented by pharmaceutical companies and regulatory agencies and were recognized with numerous awards including the Wall Street Journal Technology Innovation Award. Dr. Almenoff also worked in GSK's Scientific Licensing group. Dr. Almenoff received her B.A. cum laude from Smith College and graduated with AOA honors from the M.D.-Ph.D. program at the Icahn (Mt. Sinai) School of Medicine. She completed post-graduate medical training at Stanford University Medical Center and served on the faculty of Duke University School of Medicine. She is an adjunct Professor at Duke and a Fellow of the American College of Physicians.

Sam Backenroth, age 32, has served as Chief Financial Officer and Vice President of Business Development since April 2010, and has been a Director of DepYmed, a joint venture of Ohr, since 2014. Mr. Backenroth has previously worked as an investment banker with The Benchmark Company LLC, an investment banking firm specializing in micro-cap biotech transactions. While at Benchmark, he helped fund numerous small biotech companies raise in excess of $75 million of growth equity capital through a variety of structures. Mr. Backenroth also acted as an advisor to multiple public and private biotech companies in assisting with business development activities, joint ventures, licensing, strategic partnerships, and mergers & acquisitions. He graduated with honors from Touro College with a Bachelors degree in finance.

Dr. Avner Ingerman, age 53, has served as our Chief Clinical Officer since February 2015. Dr. Ingerman is an ophthalmologist, with more than 15 years of pharmaceutical industry product development. He served as vice president of ophthalmology at Regeneron Pharmaceuticals, responsible for the Eylea® development program, and previously served as the clinical leader of the Lastacaft® development program at Johnson and Johnson. Dr. Ingerman has additionally served as an ophthalmology development consultant to numerous companies. Dr. Ingerman received his MD degree from the Tel-Aviv University Sackler School of Medicine. He completed his ophthalmology residency at the Rabin Medical Center in Israel. He was the R&D director of Johnson & Johnson in Israel and the UK, and the clinical leader of Alcaftadine (Lastacaft®) development. He later became the Vice President of Ophthalmology at Regeneron Pharmaceuticals, responsible for the Aflibercept (Eylea®) development program, conducted in collaboration with Bayer Healthcare.

Family Relationships

No family relationships exist between any of the executive officers and directors (or nominees for director) of the Company.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers and persons who own more than 10% of the issued and outstanding shares of our common stock to file reports of initial ownership of common stock and other equity securities and subsequent changes in that ownership with the SEC. To our knowledge, during the fiscal year ended September 30, 2016, all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners were complied with.

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.

Change in Procedures for Recommending Directors

There have been no material changes to the procedures by which our stockholders may recommend nominees to our Board from those procedures set forth in our Proxy Statement for our 2016 Annual Meeting of Stockholders, filed with the SEC on January 29, 2016.

Audit Committee

The Audit Committee's function is to evaluate the adequacy of the Company's internal accounting controls, review the scope of the audit by MaloneBailey, LLP and related matters pertaining to the examination of the financial statements, review the year-end and the quarterly financial statements, review the nature and extent of any non-audit services provided by the Company's independent accountants and make recommendations to the Board of Directors with respect to the foregoing matters as well as with respect to the appointment of the Company's independent accountants. The Audit Committee had four meetings in fiscal 2015, and each member attended all meetings. The members of the Audit Committee are independent with the meaning of the rules of the Nasdaq Stock Market and applicable rules and regulations of the Securities and Exchange Commission. Members of the Audit Committee are Thomas Riedhammer (Chairman), June Almenoff and Orin Hirschman. The Board of Directors has determined that Thomas Riedhammer is a financial expert.

ITEM 11 EXECUTIVE COMPENSATION

Executive Compensation

The table below provides information on the compensation we paid to the named executive officers in fiscal 2016, 2015 and 2014.

Summary Compensation Table

		Annual Compensation				Long-Term Compensation			
Name and Principal Position	Year	Salary	Bonus(2)	Stock Awards	Option Awards(3)	Non- Equity Incentive Plan Compensation	Change in Pension Value and Non-Qualified Deferred Compensation Earnings	All Other Compensation (4)	Total
Jason Slakter	2016	$ 200,000	$ 175,000	$ 1,583,618	$ —	$ —	$ —	$ 195	$ 1,958,813
Chief Executive Officer (1)	2015	$ 200,000	$ —	$ 163,333	$ 247,289	$ —	$ —	$ —	$ 610,622
	2014	$ 38,462	$ —	$ —	$ —	$ —	$ —	$ —	$ 38,462
Sam Backenroth	2016	$ 200,000	$ 107,500	$ 587,600	$ —	$ —	$ —	$ 16,620	$ 911,720
Chief Financial Officer	2015	$ 200,000	$ 150,000	$ —	$ 296,746	$ —	$ —	$ 17,877	$ 664,623
	2014	$ 177,704	$ —	$ —	$ 977,192	$ —	$ —	$ 21,530	$ 1,176,426
Avner Ingerman	2016	$ 244,615	$ 120,000	$ —	$ —	$ —	$ —	$ 16,620	$ 381,235
Chief Clinical Officer	2015	$ 132,692	$ 50,000	$ 586,800	$ 1,128,604	$ —	$ —	$ 12,381	$ 1,910,477
	2014	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —

(1) Dr. Slakter became Chief Executive Officer of the Company on August 7, 2015. Salary for Dr. Slakter includes salary, bonus, and consulting fees for fiscal years 2016, 2015 and 2014.

(2) Cash bonuses for 2014 and 2015 were paid in January of 2015 and 2016, respectively.

(3) The amounts in this column reflect the aggregate grant date fair value of equity awards granted during the applicable fiscal year, calculated in accordance with FASB ASC Topic 718 and using a Black-Scholes valuation model. Assumptions used in the calculation of these amounts are included in Note 9 of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

(4) Consists of the following for each named executive officer:

Name	Year	401(k) Company	Group Term	Health Benefits	Paid Time Off buy Back	Total Other Compensation
Jason Slakter	2016	$ —	$ 195	$ —	$ —	$ 195
Chief Executive Officer	2015	$ —	$ —	$ —	$ —	$ —
	2014	$ —	$ —	$ —	$ —	$ —
Sam Backenroth	2016	$ —	$ 195	$ 16,425	$ —	$ 16,620
Chief Financial Officer	2015	$ —	$ —	$ 17,877	$ —	$ 17,877
	2014	$ —	$ —	$ 21,530	$ —	$ 21,530
Avner Ingerman	2016	$ —	$ 195	$ 16,425	$ —	$ 16,620
Chief Clinical Officer	2015	$ —	$ —	$ 12,381	$ —	$ 12,381
	2014	$ —	$ —	$ —	$ —	$ —

Pension Benefit

The Company has established a 401(k) plan but does not make contributions to it. The Company provides no other pension benefits.

Option Exercises

There were no options exercised by named executive officers in the fiscal year ended September 30, 2016.

Grants of Plan-Based Stock and Option Awards 2016

The following table sets forth information concerning all grants of stock options, restricted stock and other equity awards made to the named executive officers for service during the year ended September 30, 2016:

Name	Grant Date	All other stock awards: Number of shares of stock or units	All other option awards: Number of securities underlying options	Exercise Price(1)	Grant Date Fair Value of Stock and Option Awards(2)
Jason Slakter Chief Executive Officer	1/9/2016	350,358	—	—	$ 1,583,618
Sam Backenroth Chief Financial Officer	1/9/2016	130,000	—	—	$ 587,600
Avner Ingerman Chief Clinical Officer	—	—	—	—	$ —

(1) The exercise price reflects the closing market price of our common stock on the day of the grant.

(2) The grant date fair value of the stock and option awards is calculated in accordance with FASB ASC Topic 718 and using a Black-Scholes valuation model. Assumptions used in the calculation of these amounts are included in Note 9 of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

Employment Agreements

Dr. Jason Slakter

On August 5, 2015, the Company's Board of Directors authorized the restructuring of certain management positions, all of which became effective as of August 7, 2015. Jason S. Slakter, MD was appointed Chief Executive Officer of the Company succeeding Dr. Taraporewala. Dr. Slakter remained a director of the Company. Dr. Taraporewala was appointed Chief Technology Officer of the Company and remained President and a director of the Company. The employment of Dr. Taraporewala was terminated in December 2015 and he no longer holds any position in the Company.

The Company anticipates entering into an employment agreement with Dr. Slakter. Until such time, Dr. Slakter will be paid $8,333.33 bi-monthly and will be eligible for equity grants under stockholder approved equity compensation plans.

Sam Backenroth

On January 6, 2015, the Company amended its employment agreement with Sam Backenroth, Chief Financial Officer and Vice President, Business Development, to extend the term to February 28, 2016, and to provide for automatic one year extensions thereafter absent notice of termination. The employment agreement provides for an annual base salary of $200,000 for Mr. Backenroth.

Avner Ingerman

On February 26, 2015, the Company entered into an employment agreement with Dr. Ingerman, Chief Clinical Officer of the Company. The initial term of the Employment Agreement is until December 31, 2017, subject to automatic renewal for successive one year periods unless either party delivers written notice of non-renewal. Dr. Ingerman will receive (i) a base annual salary of $230,000 during the period from the hire date until December 31, 2015, $250,000 during the 2016 calendar year, and $275,000 during the 2017 calendar year; (ii) a $50,000 sign-on bonus; (iii) five-year options for 200,000 shares of common stock, which will vest over the initial term; (iv) 60,000 shares of restricted stock which will vest over the initial term; and (v) will be eligible to receive a performance bonus of $120,000 for calendar 2015, plus, at the discretion of the Company's Compensation Committee, an additional bonus in the range of $50,000 to $100,000, and, at the end of each of calendar 2016 and 2017, and any subsequent renewal period, a bonus to be awarded at the discretion of the Compensation Committee, expected to be in the range of $100,000 to $300,000. Dr. Ingerman will also receive standard employee benefits during the term of his employment.

The Company's Board of Directors reviews the executives' salaries on an annual basis. Each executive may also receive an annual bonus at the discretion of the Board, in accordance with any bonus plan adopted by the Board, and will participate in the Company's employee benefit programs, stock based incentive compensation plans and other benefits. See "Compensation Committee Report" and "Compensation Discussion and Analysis." See "Annual Incentive Compensation" below concerning discretionary bonuses for fiscal 2016.

Change in Control Benefits

Change in control benefits are intended to diminish the distraction that executives would face by virtue of the personal uncertainties created by a pending or threatened change in control and to assure that the Company will continue to have the executive's full attention and services at all time. Our change in control benefits are designed to be competitive with similar benefits available at companies with which we compete for executives' talent. These benefits, as one element of our total compensation program, help the Company attract, retain and motivate highly talented executives.

Sam Backenroth

Mr. Backenroth is entitled to (1) severance pay and benefits if his employment is terminated, whether at the end of the term of his employment agreement or termination without cause, equal to 50% of his base salary at the time of termination, or (2) alternatively, in the event of a change in control of the Company, upon (i) his termination without cause, (ii) expiration of the term of his employment agreement, or (iii) as a result of a constructive termination (that is, his resignation because he has reasonably determined in good faith that his titles, authorities, responsibilities, salary, bonus opportunities or benefits have been materially diminished, that a material adverse change in his working conditions has occurred, that his services are no longer required in light of the Company's business plan, or the Company has breached his employment agreement) which occurs: (x) concurrently with the change in control, or (y) within 12 months of the change in control, he will be entitled to receive (A) severance pay in an amount equal to $400,000, (B) the value of any accrued but unused vacation time, (C) the amount of all accrued but previously unpaid base salary through the date of termination, and (D) all of his then current employment benefits for the longer of twelve (12) months or the full un-expired term of his employment agreement. Mr. Backenroth has the right, for a period of 30 days following termination of his employment to exercise his Company options to the extent such options are otherwise vested and exercisable as of the date of termination.

Avner Ingerman

Dr. Ingerman is entitled to (1) severance pay and benefits if his employment is terminated, whether at the end of the term of his employment agreement or termination without cause, equal to 50% of his base salary at the time of termination, or (2) alternatively, in the event of a change in control of the Company, upon (i) his termination without cause, or (iii) as a result of a constructive termination (that is, his resignation because he has reasonably determined in good faith that his titles, authorities, responsibilities, salary, bonus opportunities or benefits have been materially diminished, that a material adverse change in his working conditions has occurred, that his services are no longer required in light of the Company's business plan, or the Company has materially breached his employment agreement) which occurs: (x) concurrently with the change in control, or (y) within 12 months of the change in control, he will be entitled to receive (A) severance pay in an amount equal to $350,000, (B) the value of any accrued but unused vacation time, (C) the amount of all accrued but previously unpaid base salary through the date of termination, and (D) all of his then current employment benefits for the longer of twelve (12) months or the full un-expired term of his employment agreement. Dr. Ingerman has the right, for a period of 30 days following termination of his employment to exercise his Company options to the extent such options are otherwise vested and exercisable as of the date of termination.

Equity compensation plans and other benefit plans

Ohr Pharmaceutical, Inc. 2016 Consolidated Stock Incentive Plan

General Information. The Board of Directors adopted the Ohr Pharmaceutical, Inc. 2016 Consolidated Stock Incentive Plan (the "2016 Plan") on January 7, 2016 and the shareholders approved the plan on March 17, 2016 to assist the Company in recruiting and retaining individuals with ability and initiative by enabling them to receive awards and participate in the future success of the Company by associating their interests with those of the Company and its stockholders. The 2016 Plan is intended to permit the grant of stock options (both incentive stock options ("ISOs") and non-qualified stock options ("NQSOs")), stock appreciation rights ("SARs"), restricted stock ("Restricted Stock Awards"), restricted stock units ("RSUs") and other incentive awards ("Incentive Awards").

Prior Plans. We previously maintained each of the Ohr Pharmaceutical, Inc. 2014 Stock Incentive Plan (the "2014 Plan") and the Ohr Pharmaceutical, Inc. 2009 Stock Incentive Plan (the "2009 Plan"). The 2016 Plan is intended to consolidate the 2014 Plan and the 2009 Plan into a new plan, with an aggregate number of shares available for issuance under the 2016 Plan as set forth below under "- Shares Subject to Plan." For Options and Restricted Stock Awards granted under the 2014 Plan and the 2009 Plan prior to January 7, 2016, the terms and conditions of the 2014 Plan and the 2009 Plan and the applicable award agreements will control, except that the our Compensation Committee (the "Committee"), in its discretion may allow a participant to pay all or part of the option price (i) by surrendering shares of common stock to the Company that the participant already owns and, if necessary to avoid adverse accounting consequences, has held for at least six months; (ii) by a cashless exercise through a broker; (iii) by means of a "net exercise" procedure, (iv) by such other medium of payment as the Committee in its discretion shall authorize or (v) by any combination of the aforementioned methods of payment. If shares of common stock are used to pay all or part of the Option price, the sum of the cash and cash equivalent and the fair market value (determined as of the day preceding the date of exercise) of the shares surrendered shall equal the Option price of the shares for which the Option is being exercised.

Written Agreements. All awards granted under the 2016 Plan will be governed by separate written agreements between the Company and the participants. The written agreements will specify when the award may become vested, exercisable or payable, as well as other terms and conditions that may apply to the award. No right or interest of a participant in any award will be subject to any lien, obligation or liability of the participant. The laws of the State of Delaware govern the 2016 Plan.

No awards may be granted after January 7, 2026, the date which is 10 years after the adoption of the 2016 Plan by the Board.

Tax Treatment. It is intended that awards granted under the 2016 Plan shall be exempt from treatment as "deferred compensation" subject to Section 409A of the Internal Revenue Code of 1986 (and any amendments thereto) (the "Code").

Administration. The Company bears all expenses of administering the 2016 Plan. The Committee administers the 2016 Plan. The Committee has the authority to grant awards to such persons and upon such terms and conditions (not inconsistent with the provisions of the 2016 Plan), as it may consider appropriate. The Committee may delegate to one or more officers of the Company all or part of its authority and duties with respect to awards to individuals who are not subject to Section 16 of the Exchange Act.

Eligibility for Participation. Any of the Company's employees or service providers, including any employees or service providers of our Affiliates (as defined in the 2016 Plan), and any non-employee member of our Board of Directors or the boards of directors of our Affiliates, is eligible to receive an award under the 2016 Plan. However, ISOs may only be granted to employees of the Company or an Affiliate.

Shares Subject to Plan. The maximum number of shares of Common Stock that may be issued under the life of the 2016 Plan pursuant to awards will be (a) 5,833,334 shares minus (b) the number of shares of Common Stock that previously have been issued pursuant to the exercise of options under the 2009 Plan or 2014 Plan or the number of shares of restricted stock granted under the 2014 Plan and the 2009 Plan that, as of December 14, 2016 are no longer subject to a substantial risk of forfeiture. One hundred percent (100%) of such shares may be issued pursuant to Options (including Incentive Stock Options), SARs, Restricted Stock Awards, Restricted Stock Units or Incentive Awards or any combination of Awards. Of the 5,833,334 shares, 333,334 previously were authorized under the 2009 Plan and 2,750,000 previously were authorized under the 2014 Plan.

Shares of Common Stock covered by an Award shall only be counted as issued to the extent they are actually issued. A share of Common Stock issued in connection with any Award under the 2016 Plan shall reduce the total number of shares of Common Stock available for issuance under the 2016 Plan by one; provided, however, that a share of Common Stock covered under a stock-settled SAR shall reduce the total number of shares of Common Stock available for issuance under the 2016 Plan by one even though the shares of Common Stock are not actually issued in connection with settlement of the SAR. Except as otherwise provided in the 2016 Plan, any shares of Common Stock related to an Award which terminates by expiration, forfeiture, cancellation or otherwise without issuance of shares of Common Stock, which is settled in cash in lieu of Common Stock or which is exchanged, with the Committee's permission, prior to the issuance of shares of Common Stock, for Awards not involving shares of Common Stock, shall again be available for issuance under the 2016 Plan. The following shares of Common Stock, however, may not again be made available for issuance as Awards under the 2016 Plan: (i) shares of Common Stock not issued or delivered as a result of a net settlement of an outstanding Award, (ii) shares of Common Stock tendered or held to pay the exercise price, purchase price or withholding taxes relating to an outstanding Award, or (iii) shares of Common Stock repurchased on the open market with the proceeds of the exercise price of an Award.

In any calendar year, no participant may be granted options, SARs, Restricted Stock Awards, RSUs, or any combination thereof that relate to more than 500,000 shares of Common Stock. In any calendar year, no participant may be granted an Incentive Award (i) with reference to a specified dollar limit for more than $3,000,000 million and (ii) with reference to a specified number of shares of Common Stock for more than 500,000 shares of Common Stock. The maximum number of shares of Common Stock that may be issued pursuant to awards, the per individual limits on awards and the terms of outstanding awards will be adjusted as the Committee in its sole discretion determines is equitably required in the event of corporate transactions and other appropriate events.

Options. A stock option entitles the participant to purchase from the Company a stated number of shares of Common Stock. The Committee will determine whether the option is intended to be an ISO or a NQSO and specify the number of shares of Common Stock subject to the option. In the case of ISOs, the aggregate fair market value (determined as of the date of grant) of Common Stock with respect to which an ISO may become exercisable for the first time during any calendar year cannot exceed $100,000; and if this limitation is exceeded, the ISOs which cause the limitation to be exceeded will be treated as NQSOs. The exercise price per share of Common Stock may not be less than the fair market value of the Common Stock on the date the option is granted. With respect to an ISO granted to a participant who beneficially owns more than 10% of the combined voting power of the Company or any Affiliate (determined by applying certain attribution rules), the exercise price per share may not be less than 110% of the fair market value of the Common Stock on the date the option is granted. The exercise price may be paid in cash or, if the agreement so provides, the Committee may allow a participant to pay all or part of the exercise price by tendering shares of Common Stock the participant already owns, through a broker-assisted cashless exercise, by means of "net exercise" procedure, any other specified medium of payment or a combination.

Stock Appreciation Rights. ("SARs"). A SAR entitles the participant to receive, upon exercise, the excess of the fair market value on that date of each share of Common Stock subject to the exercised portion of the SAR over the fair market value of each such share on the date of the grant of the SAR. A SAR can be granted alone or in tandem with an option. A SAR granted in tandem with an option is called a Corresponding SAR and entitles the participant to exercise the option or the SAR at which time the other tandem award expires. The Committee will specify the number of shares of Common Stock subject to a SAR and whether the SAR is a Corresponding SAR. No participant may be granted Corresponding SARs in tandem with ISOs which are first exercisable in any calendar year for shares of Common Stock having an aggregate fair market value (determined as of the date of grant) that exceeds $100,000; and if this limitation is exceeded the tandem option will be treated as NQSOs. A Corresponding SAR may be exercised only to the extent that the related option is exercisable and the fair market value of the Common Stock on the date of exercise exceeds the exercise price of the related option. As set forth in the agreement, the amount payable as a result of the exercise of a SAR may be settled in cash, shares of Common Stock or a combination of each.

Restricted Stock Awards. A Restricted Stock Award is the grant or sale of shares of Common Stock, which may be subject to forfeiture restrictions. The Committee will prescribe whether the Restricted Stock Award is forfeitable and the conditions to which it is subject. If the participant must pay for a Restricted Stock Award, payment for the award generally shall be made in cash or, if the agreement so provides, by surrendering shares of Common Stock the participant already owns or any other medium of payment. Prior to vesting or forfeiture, a participant will have all rights of a shareholder with respect to the shares underlying the Restricted Stock Award, including the right to receive dividends and vote the underlying shares; provided, however, the participant may not transfer the shares. The Company may retain custody of the certificates evidencing the shares until they are no longer forfeitable.

RSUs. An RSU entitles the participant to receive shares of Common Stock when certain conditions are met. The Committee will prescribe when the RSUs shall become payable. The Company will pay the participant one share of Common Stock for each RSU that becomes earned and payable.

Incentive Awards. An Incentive Award entitles the participant to receive cash or Common Stock or a combination of each when certain conditions are met. The Committee will prescribe the terms and conditions of the Incentive Award. As set forth in the participant's agreement, an Incentive Award may be paid in cash, shares of Common Stock or a combination of each.

Performance Objectives. The Committee has discretion to establish objectively-determinable performance conditions for when awards will become vested, exercisable and payable. Objectively-determinable performance conditions are performance conditions (i) that are established in writing (a) at the time of grant (b) no later than the earlier of (x) 90 days after the beginning of the period of service to which they relate and (y) before the lapse of 25% of the period of service to which they relate; (ii) that are uncertain of achievement at the time they are established; and (iii) the achievement of which is determinable by a third party with knowledge of the relevant facts. These performance conditions may include any or any combination of the following: (a) gross, operating or net earnings before or after taxes; (b) return on equity; (c) return on capital; (d) return on sales; (e) return on investments; (f) return on assets or net assets; (g) earnings per share; (h) cash flow per share; (i) book value per share; (j) gross margin; (k) customers; (l) cash flow or cash flow from operations; (m) fair market value of the Company or any Affiliate or shares of Common Stock; (n) share price or total shareholder return; (o) market share; (p) level of expenses or other costs; (q) gross, operating or net revenue; (r) earnings before interest and taxes; (s) adjusted earnings before interest and taxes; (t) profitability; (u) earnings before interest, taxes, depreciation and amortization; (v) adjusted earnings before interest, taxes, depreciation and amortization; (w) adjusted earnings before interest, taxes, depreciation and amortization less capital expenditures; (x) research and development milestones; (y) business development objectives, partnerships and other collaborations; or (z) peer group comparisons of any of the aforementioned performance conditions. Performance conditions may be related to a specific customer or group of customers or geographic region. The form of the performance conditions also may be measured on a Company, Affiliate, division, business unit, service line, segment or geographic basis or a combination thereof. Performance goals may reflect absolute entity performance or a relative comparison of entity performance to the performance of a peer group of entities or other external measure of the selected performance conditions. Profits, earnings and revenues used for any performance condition measurement may exclude any extraordinary or nonrecurring items. The performance conditions may, but need not, be based upon an increase or positive result under the aforementioned performance criteria and could include, for example and not by way of limitation, maintaining the status quo or limiting the economic losses (measured, in each case, by reference to the specific business criteria). An award that is intended to become exercisable, vested or payable on the achievement of performance conditions means that the award will not become exercisable, vested or payable solely on mere continued employment or service. However, such an award, in addition to performance conditions, may be subject to continued employment or service by the participant. Additionally, the vesting, exercise or payment of an award can be conditioned on mere continued employment or service if it is not intended to qualify as qualified performance-based compensation under Section 162(m) of the Code.

Change in Control. In the event of or in anticipation of a "Change in Control" (as defined in the 2016 Plan), the Committee in its discretion may terminate outstanding awards (i) by giving the participants an opportunity to exercise the awards that are then exercisable and then terminating, without any payment, all awards that have not been exercised (including those that were not then exercisable) or (ii) by paying the participant the value of the awards that are then vested, exercisable or payable without payment for any awards that are not then vested, exercisable or payable or that have no value. Alternatively, the Committee may take such other action as the Committee determines to be reasonable under the circumstances to permit the participant to realize the vested value of the award. The Committee may provide that a participant's outstanding awards become fully exercisable or payable on and after a Change in Control or immediately before the date the awards will be terminated in connection with a Change in Control. Awards will not be terminated to the extent they are to be continued after the Change in Control.

Stockholder Rights. No participant shall have any rights as a shareholder of the Company until the award is settled by the issuance of Common Stock (other than a Restricted Stock Award or RSUs for which certain shareholder rights may be granted).

Transferability. An award is non-transferable except by will or the laws of descent and distribution, and during the lifetime of the participant to whom the award is granted, the award may only be exercised by, or payable to, the participant. The holder of the transferred award will be bound by the same terms and conditions that governed the award during the period that it was held by the participant.

Maximum Award Period. No award shall be exercisable or become vested or payable more than ten years after the date of grant. An ISO granted to a participant who beneficially owns more than 10% of the combined voting power of the Company or any Affiliate (determined by applying certain attribution rules) or a Corresponding SAR that relates to such an ISO may not be exercisable more than five years after the date of grant.

Compliance With Applicable Law. No award shall be exercisable, vested or payable except in compliance with all applicable federal and state laws and regulations (including, without limitation, tax and securities laws), any listing agreement with any stock exchange to which the Company is a party, and the rules of all domestic stock exchanges on which the Company's shares may be listed.

Amendment and Termination of Plan. The Board of Directors may amend or terminate the 2016 Plan at any time; provided, however, that no amendment may adversely impair the rights of a participant with respect to outstanding awards without the participant's consent. An amendment will be contingent on approval of the Company's shareholders, to the extent required by law, by the rules of any stock exchange on which the Company's securities are then traded or if the amendment would (i) increase the benefits accruing to participants under the 2016 Plan, including without limitation, any amendment to the 2016 Plan or any agreement to permit a repricing or decrease in the exercise price of any outstanding options or SARs, (ii) increase the aggregate number of shares of Common Stock that may be issued under the 2016 Plan, (iii) modify the requirements as to eligibility for participation in the 2016 Plan or (iv) change the stated performance conditions for qualified performance-based compensation under Section 162(m) of the Code. Additionally, to the extent the Board deems necessary for the 2016 Plan to continue to grant awards that are intended to comply with the performance-based exception to the deduction limits of Code Section 162(m), the Board will submit the material terms of the stated performance conditions to the Company's shareholders for approval no later than the first shareholder meeting that occurs in the fifth year following the year in which the shareholders previously approved the material terms of the performance goals.

Notwithstanding any other provision of the 2016 Plan, the Committee may amend any outstanding award without participant's consent if, as determined by the Committee in its sole discretion, such amendment is required either to (i) confirm exemption from Section 409A of the Code, (ii) comply with Section 409A of the Code or (iii) prevent the Participant from being subject to any tax or penalty under Section 409A of the Code.

Forfeiture Provisions. Awards do not confer upon any individual any right to continue in the employ or service of the Company or any Affiliate. All rights to any award that a participant has will be immediately forfeited if the participant is discharged from employment or service for "Cause" (as defined in the 2016 Plan).

Material U.S. Federal Income Tax Consequences

The following discussion summarizes the material United States federal income tax consequences associated with awards granted under the 2016 Plan to U.S. citizens. The discussion is based on laws, regulations, rulings and court decisions currently in effect, all of which are subject to change.

ISOs. A participant will not recognize taxable income on the grant or exercise of an ISO. A participant will recognize taxable income when he or she disposes of the shares of Common Stock acquired under the ISO. If the disposition occurs more than two years after the grant of the ISO and more than one year after its exercise (the "ISO holding period"), the participant will recognize long-term capital gain (or loss) to the extent the amount realized from the disposition exceeds (or is less than) the participant's tax basis in the shares of Common Stock. A participant's tax basis in shares of the Common Stock generally will be the amount the participant paid for the shares.

If Common Stock acquired under an ISO is disposed of before the expiration of the ISO holding period described above, the participant will recognize as ordinary income in the year of the disposition the excess of the fair market value of the Common Stock on the date of exercise of the ISO over the exercise price. Any additional gain will be treated as long-term or short-term capital gain, depending on the length of time the participant held the shares. A special rule applies to such a disposition where the amount realized is less than the fair market value of the Common Stock on the date of exercise of the ISO. In that case, the ordinary income the participant will recognize will not exceed the excess of the amount realized on the disposition over the exercise price. If the amount realized is less than the exercise price, the participant will recognize a capital loss (long-term if the stock was held more than one year and short-term if held one year or less). A participant will receive different tax treatment if the exercise price is paid by delivery of Common Stock the participant already owns.

Neither the Company nor any of its Affiliates will be entitled to a federal income tax deduction with respect to the grant or exercise of an ISO. However, in the event a participant disposes of Common Stock acquired under an ISO before the expiration of the ISO holding period described above, the Company or its Affiliate will be entitled to a federal income tax deduction equal to the amount of ordinary income the participant recognizes.

NQSOs. A participant will not recognize any taxable income on the grant of a NQSO. On the exercise of a NQSO, the participant will recognize as ordinary income the excess of the fair market value of the Common Stock acquired over the exercise price. A participant's tax basis in the Common Stock is the amount paid plus any amounts included in income on exercise. The participant's holding period for the stock begins on acquisition of the shares. Any gain or loss that a participant realizes on a subsequent disposition of Common Stock acquired on the exercise of a NQSO generally will be treated as long-term or short-term capital gain or loss, depending on the length of time the participant held such shares. The amount of the gain (or loss) will equal the amount by which the amount realized on the subsequent disposition exceeds (or is less than) the participant's tax basis in his or her shares. A participant will receive different tax treatment if the exercise price is paid by delivery of Company Stock the participant already owns.

The exercise of a NQSO will entitle the Company or its Affiliate to claim a federal income tax deduction equal to the amount of ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

SARs. A participant will not recognize any taxable income at the time the SARs are granted. The participant at the time of receipt will recognize as ordinary income the amount of cash and the fair market value of the Common Stock that he or she receives. The Company or its Affiliate will be entitled to a federal income tax deduction equal to the amount of ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Restricted Stock Awards. A participant will recognize ordinary income on account of a Restricted Stock Award on the first day that the shares are either transferable or not subject to a substantial risk of forfeiture. The ordinary income recognized will equal the excess of the fair market value of the Common Stock on such date over the amount, if any, the participant paid for the Restricted Stock Award. However, even if the shares under a Restricted Stock Award are both nontransferable and subject to a substantial risk of forfeiture, the participant may make a special "83(b) election" within 30 days of the grant date to recognize income, and have his or her tax consequences determined, as of the date the Restricted Stock Award is made. The participant's tax basis in the shares received will equal the income recognized plus the price, if any, paid for the Restricted Stock Award. Any gain (or loss) that a participant realizes upon the sale of any Common Stock acquired pursuant to a Restricted Stock Award will be equal to the amount by which the amount realized on the disposition exceeds (or is less than) the participant's tax basis in the shares and will be treated as long-term (if the shares are held for more than one year) or short-term (if the shares are held for one year or less) capital gain or loss. The participant's holding period for the stock begins on the date the shares are either transferable or not subject to a substantial risk of forfeiture, except that the holding period will begin on the date of grant if the participant makes the special "83(b) election." The Company or its Affiliate will be entitled to a federal income tax deduction equal to the ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

RSUs. The participant will not recognize any taxable income at the time the RSUs are granted. When the terms and conditions to which the RSUs are subject have been satisfied and the RSUs are paid, the participant, at the time of receipt, will recognize as ordinary income the fair market value of the Common Stock he or she receives. The participant's holding period in the Common Stock will begin on the date the stock is received. The participant's tax basis in the Common Stock will equal the amount he or she includes in ordinary income. Any gain or loss that a participant realizes on a subsequent disposition of the shares will be treated as long-term or short-term capital gain or loss, depending on the participant's holding period for the stock (long-term if the shares are held for more than one year; short-term if one year or less). The amount of the gain (or loss) will equal the amount by which the amount realized on the disposition exceeds (or is less than) the participant's tax basis in the Common Stock. The Company or its Affiliate will be entitled to a federal income tax deduction equal to the ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Incentive Awards. A participant will not recognize any taxable income at the time an Incentive Award is granted. When the terms and conditions to which an Incentive Award is subject have been satisfied and the award is paid, the participant, at the time of receipt, will recognize as ordinary income the amount of cash and the fair market value of the Common Stock he or she receives. The participant's holding period in any Common Stock received will begin on the date of receipt. The participant's tax basis in the Common Stock will equal the amount he or she includes in ordinary income with respect to such shares. Any gain or loss that a participant realizes on a subsequent disposition of the Common Stock will be treated as long-term or short-term capital gain or loss, depending on the participant's holding period for the Common Stock (long-term if the shares are held for more than one year; short-term if one year or less). The amount of the gain (or loss) will equal the amount by which the amount realized on the disposition exceeds (or is less than) the participant's tax basis in the Common Stock. The Company or its Affiliate will be entitled to a federal income tax deduction equal to the amount of ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Limitation on Deductions. The deduction for a publicly-held corporation for otherwise deductible compensation to a "covered employee" generally is limited to $1 million per year. An individual is a covered employee if he or she is the chief executive officer or one of the other three highest compensated officers for the year (other than the chief executive officer or chief financial officer). The $1 million limit does not apply to compensation payable solely because of the attainment of performance conditions that meet the requirements set forth in Section 162(m) of the Code and the regulations thereunder. Compensation is considered performance-based only if (a) it is paid solely on the achievement of one or more performance conditions; (b) two or more "outside directors" set the performance conditions; (c) before payment, the material terms under which the compensation is to be paid, including the performance conditions, are disclosed to, and approved by, the shareholders and (d) before payment, two or more "outside directors" certify in writing that the performance conditions have been met. The 2016 Plan has been designed to enable the Committee to structure awards that are intended to meet the requirements for qualified performance-based compensation that would not be subject to the $1 million per year deduction limit under Section 162(m) of the Code.

Any grant, exercise, vesting or payment of an award may be postponed if the Company reasonably believes that its or any applicable Affiliate's deduction with respect to such award would be limited or eliminated by application of Code Section 162(m) to the extent permitted by Section 409A of the Code; provided, however, such delay will last only until the earliest date at which the Company reasonably anticipates the deduction will not be limited or eliminated under Code Section 162(m).

Other Tax Rules. The 2016 Plan is designed to enable the Committee to structure awards that are intended to not be subject to Code Section 409A, which imposes certain restrictions and requirements on deferred compensation.

2014 Stock Incentive Plan

The Ohr Pharmaceutical, Inc. 2014 Stock Incentive Plan (the "2014 Plan") was first adopted by the Board on January 31, 2014, and by the shareholders on March 31, 2014, as amended by the Board on January 6, 2015, and by the shareholders on March 10, 2015.

The 2014 Plan is designed to advance the Company's interests by enhancing its ability to attract and retain employees and others in a position to make significant contributions to the success of the Company through ownership of shares of common stock. The 2014 Plan provides for the grant of ISOs, NQSOs, restricted stock, and combinations of the above. Awards under the 2014 Plan may also include provision for payment of dividend equivalents with respect to the shares subject to the award.

The 2014 Plan is administered by the Compensation Committee. All employees of the Company and any of its subsidiaries and other persons or entities (including non-employee directors of the Company and its subsidiaries) who, in the opinion of the Board, are in a position to make a significant contribution to the success of the Company or its subsidiaries are eligible to participate in the 2014 Plan.

Summary of the 2014 Plan. The exercise price of an ISO granted under the 2014 Plan may not be less than 100% (110% in the case of 10% stockholders) of the fair market value of the common stock at the time of grant. The exercise price of a NQSO granted under the 2014 Plan is determined by the Board. The term of each option may be set by the Board but cannot exceed ten years from grant (five years from grant in the case of an incentive stock option granted to a 10% stockholder), and each option will be exercisable at such time or times as the Board specifies. The option price may be paid in cash or check acceptable to the Company or, if permitted by the Board and subject to certain additional limitations, by tendering shares of common stock, by using a promissory note, by delivering to the Company an unconditional and irrevocable undertaking by a broker promptly to deliver sufficient funds to pay the exercise price, or a combination of the foregoing.

Except as otherwise provided by the Board, if a participant dies, options held by such participant immediately prior to death, to the extent then exercisable, may be exercised by the participant's executor, administrator or transferee during a period of one year following such death (or for the remainder of their original term, if less). Except as otherwise determined by the Board, options not exercisable at a participant's death terminate. Outstanding awards of restricted common stock must be transferred to the Company upon a participant's death except as otherwise determined by the Board.

In the case of termination of a participant's association with the Company for any reason other than death, options remain exercisable, to the extent they were exercisable immediately prior to termination, for 30 days (or for the remainder of their original term, if less), and shares of restricted common stock must be resold to the Company, unless otherwise determined by the Board. If any such association is terminated due to the participant's discharge for cause which, in the opinion of the Board, casts such discredit on the participant as to justify immediate termination of any award under the 2014 Plan, such participant's options may be terminated immediately.

In the event of a consolidation or merger in which the Company is not the surviving corporation or which results in the acquisition of substantially all of the Company's outstanding Common Stock by a single person or entity or by a group of persons and/or entities acting in concert or in the event of the sale or transfer of substantially all of the Company's assets, the Board may determine that (i) each outstanding option will become immediately exercisable unless otherwise provided at the time of grant, and (ii) each outstanding share of restricted Common Stock will immediately become free of all restrictions and conditions. The Board may also arrange to have the surviving or acquiring corporation or affiliate assume any award held by a participant or grant a replacement award. If the optionee is terminated after a change in control by the Company without cause, or in the case of certain officers designated from time to time by the Board resigns under certain circumstances, within two years following the change in control, all unvested options will vest and all options will be exercisable for the shorter of four years or their original duration and all other awards will vest. If the option committee makes no such determination, outstanding awards to the extent not fully vested will be forfeited.

2009 Stock Incentive Plan

The Ohr Pharmaceutical, Inc. 2009 Stock Incentive Plan (the "2009 Plan") was first adopted by the Board in June 2009 and by the shareholders effective as of July 13, 2009.

The 2009 Plan was designed to encourage ownership of common stock by employees, consultants and directors of the Company and its affiliates and to provide additional incentive for them to promote the success of the Company's business. The 2009 Plan provided for the grant of ISOs, NQSOs, restricted stock, and combinations of the above.

The 2009 Plan is administered by the Compensation Committee. An award under the 2009 Planmay grant to any employee of or consultant to one or more of the Company and its affiliates or to any non-employee member of the Board or of any board of directors (or similar governing authority) of any affiliate.

Summary of the 2009 Plan. If any Option expires, terminates, or is cancelled for any reason without having been exercised in full, or if any award of restricted stock is forfeited by the recipient, the shares not purchased by the optionee or forfeited by the recipient shall again be available for awards to be granted under the 2009 Plan.

The exercise price of an ISO granted under the 2009 Plan may not be less than 100% (110% in the case of 10% stockholders) of the fair market value of the common stock at the time of grant. The exercise price of a NQSO granted under the 2009 Plan is determined by the Board. The term of each option may be set by the Board but cannot exceed ten years from grant (five years from grant in the case of an incentive stock option granted to a 10% stockholder), and each option will be exercisable at such time or times as the Board specifies. The option price may be paid in cash or check acceptable to the Company or, if permitted by the Board and subject to certain additional limitations, by tendering shares of common stock, by using a promissory note, by delivering to the Company an unconditional and irrevocable undertaking by a broker promptly to deliver sufficient funds to pay the exercise price, or a combination of the foregoing.

The option price may be paid in cash or check acceptable to the Company or, if permitted by the Board and subject to certain additional limitations, by (i) shares of stock having a market value equal to the exercise price of the shares to be purchased, or (ii) by using a promissory note.

If a participant's employment or other association with the Company and its affiliates ends for any reason, any outstanding option of the participant will cease to be exercisable in any respect not later than 30 days following that event and, for the period it remains exercisable following that event, will be exercisable only to the extent exercisable at the date of that event. Military or sick leave or other bona fide leave will not be deemed a termination of employment or other association.

Unless the Compensation Committee provided otherwise for any award of restricted stock, upon termination of a participant's employment or other association with the Company and its affiliates for any reason during the restriction period, all shares of restricted stock subject to forfeiture will be forfeited or otherwise subject to return to or repurchase by the Company on the terms specified in the award agreement.

In the event of a Change in Control (as defined in the 2009 Plan), any restricted stock award still then subject to a forfeiture and any outstanding option not then exercisable in full shall vest under the terms of the award. The Compensation Committee shall have the discretion, exercisable either in advance of a change in control or at the time thereof, to provide (upon such terms as it may deem appropriate) for (i) the automatic acceleration of one or more outstanding options that do not otherwise accelerate by reason of the change in control, and/or (ii) the subsequent termination of one or more of the Company's repurchase rights with respect to restricted stock awards that do not otherwise terminate at that time, in the event that the employment of the respective grantees of such awards should subsequently terminate following such change in control.

Material U.S. Federal Income Tax Consequences For the 2014 Plan and the 2009 Plan

The following discussion summarizes the principal United States federal income tax consequences associated with awards granted under the 2014 Plan and 2009 Plan to U.S. citizens. The discussion is based on laws, regulations, rulings and court decisions currently in effect, all of which are subject to change.

ISOs. A participant will not recognize taxable income on the grant or exercise of an ISO. A participant will recognize taxable income when he or she disposes of the shares of Common Stock acquired under the ISO. If the disposition occurs more than two years after the grant of the ISO and more than one year after its exercise (the "ISO holding period"), the participant will recognize long-term capital gain (or loss) to the extent the amount realized from the disposition exceeds (or is less than) the participant's tax basis in the shares of Common Stock. A participant's tax basis in shares of the Common Stock generally will be the amount the participant paid for the shares.

If Common Stock acquired under an ISO is disposed of before the expiration of the ISO holding period described above, the participant will recognize as ordinary income in the year of the disposition the excess of the fair market value of the Common Stock on the date of exercise of the ISO over the exercise price. Any additional gain will be treated as long-term or short-term capital gain, depending on the length of time the participant held the shares. A special rule applies to such a disposition where the amount realized is less than the fair market value of the Common Stock on the date of exercise of the ISO. In that case, the ordinary income the participant will recognize will not exceed the excess of the amount realized on the disposition over the exercise price. If the amount realized is less than the exercise price, the participant will recognize a capital loss (long-term if the stock was held more than one year and short-term if held one year or less). A participant will receive different tax treatment if the exercise price is paid by delivery of Common Stock the participant already owns.

Neither the Company nor any of its Affiliates will be entitled to a federal income tax deduction with respect to the grant or exercise of an ISO. However, in the event a participant disposes of Common Stock acquired under an ISO before the expiration of the ISO holding period described above, the Company or its Affiliate will be entitled to a federal income tax deduction equal to the amount of ordinary income the participant recognizes.

NQSOs. A participant will not recognize any taxable income on the grant of a NQSO. On the exercise of a NQSO, the participant will recognize as ordinary income the excess of the fair market value of the Common Stock acquired over the exercise price. A participant's tax basis in the Common Stock is the amount paid plus any amounts included in income on exercise. The participant's holding period for the stock begins on acquisition of the shares.

Any gain or loss that a participant realizes on a subsequent disposition of Common Stock acquired on the exercise of a NQSO generally will be treated as long-term or short-term capital gain or loss, depending on the length of time the participant held such shares. The amount of the gain (or loss) will equal the amount by which the amount realized on the subsequent disposition exceeds (or is less than) the participant's tax basis in his or her shares. A participant will receive different tax treatment if the exercise price is paid by delivery of Company Stock the participant already owns.

The exercise of a NQSO will entitle the Company or its Affiliate to claim a federal income tax deduction equal to the amount of ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Restricted Stock Awards. A participant will recognize ordinary income on account of a Restricted Stock Award on the first day that the shares are either transferable or not subject to a substantial risk of forfeiture. The ordinary income recognized will equal the excess of the fair market value of the Common Stock on such date over the amount, if any, the participant paid for the Restricted Stock Award. However, even if the shares under a Restricted Stock Award are both nontransferable and subject to a substantial risk of forfeiture, the participant may make a special "83(b) election" to recognize income, and have his or her tax consequences determined, as of the date the Restricted Stock Award is made. The participant's tax basis in the shares received will equal the income recognized plus the price, if any, paid for the Restricted Stock Award. Any gain (or loss) that a participant realizes upon the sale of any Common Stock acquired pursuant to a Restricted Stock Award will be equal to the amount by which the amount realized on the disposition exceeds (or is less than) the participant's tax basis in the shares and will be treated as long-term (if the shares are held for more than one year) or short-term (if the shares are held for one year or less) capital gain or loss. The participant's holding period for the stock begins on the date the shares are either transferable or not subject to a substantial risk of forfeiture, except that the holding period will begin on the date of grant if the participant makes the special "83(b) election." The Company or its Affiliate will be entitled to a federal income tax deduction equal to the ordinary income the participant recognizes. If the participant is an employee, that ordinary income will constitute wages subject to withholding and employment taxes.

Any grant, exercise, vesting or payment of an award may be postponed if the Company reasonably believes that its or any applicable Affiliate's deduction with respect to such award would be limited or eliminated by application of Code Section 162(m) to the extent permitted by Section 409A of the Code; provided, however, such delay will last only until the earliest date at which the Company reasonably anticipates the deduction will not be limited or eliminated under Code Section 162(m).

Other Tax Rules. The Incentive Plan is designed to enable the Compensation Committee to structure awards that are intended to not be subject to Code Section 409A, which imposes certain restrictions and requirements on deferred compensation.

Outstanding Equity Awards at Fiscal Year-End

The following table provides certain information with respect to outstanding individual grants through the fiscal year ended September 30, 2016 to each of our named executive officers of common share purchase options relating to our common shares:

	Option Awards				Stock Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested (9)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested
Jason Slakter	25,000(1)	25,000(1)	$ 10.14	3/10/2020	—	$ —	—	$ —
	—	—	$ —	—	350,358(2)	$ 1,583,618	—	$ —
Sam Backenroth	133,333(3)	—	$ 1.71	3/9/2017	—	$ —	—	$ —
	187,500(4)	62,500(4)	$ 10.11	2/3/2017	—	$ —	—	$ —
	30,000(5)	30,000(5)	$ 10.14	3/10/2020	—	$ —	—	$ —
	—	—	$ —	—	130,000(6)	$ 587,600	—	$ —
Avner Ingerman	100,000(7)	100,000(7)	$ 7.06	3/1/2020	—	$ —	—	$ —
	—	—	$ —	—	30,000(8)	$ 293,400(8)	—	$ —

(1) One quarter of the options vested immediately and on March 10, 2016, and one quarter of the options will vest on each of March 10, 2017 and March 10, 2018.

(2) 175,000 shares of restricted stock vest on January 9, 2017 and 175,358 shares of restricted stock vest on January 9, 2018.

(3) One quarter of the options vested immediately, and one quarter of the options vested on each of March 9, 2013, March 9, 2014 and March 9, 2015.

(4) One quarter of the options vested on each of February 3, 2014 and February 3, 2015, and February 3, 2016 and one quarter of the options will vest on February 3, 2017.

(5) One quarter of the options vested immediately and on March 10, 2016, and one quarter of the options will vest on each of March 10, 2017 and March 10, 2018.

(6) One half of the shares of restricted stock vest on January 9, 2017 and one half of the shares of restricted stock vest on January 9, 2018.

(7) One quarter of the options vested on each of March 1, 2015 and December 31, 2015, and one quarter of the options will vest on each of December 31, 2016, and December 31, 2017.

(8) 30,000 restricted stock units vested on January 1, 2016 and 15,000 restricted stock units will vest on each of January 1, 2017 and January 1, 2018.

(9) The amounts in this column reflect the aggregate grant date fair value of equity awards, calculated in accordance with FASB ASC Topic 718.

Compensation of Directors

During the fiscal year 2016, the following options were granted to directors serving in fiscal 2016:

Name	Grant Date	All other stock awards: Number of shares of stock or units	All other option awards: Number of securities underlying options	Exercise Price(1)	Grant Date Fair Value of Stock and Option Awards(2)
Ira Greenstein	1/7/2016	—	60,000	$ 5.14	$ 201,678
Chairman	1/22/2016	—	80,000	$ 3.62	$ 189,708
Orin Hirschman	1/7/2016	—	60,000	$ 5.14	$ 201,678
Director					
Thomas Riedhammer	1/7/2016	—	60,000	$ 5.14	$ 201,678
Director					
June Almenoff	1/7/2016	—	60,000	$ 5.14	$ 201,678
Director					

(1) The exercise price reflects the closing market price of our common stock on the day of the grant.

(2) The grant date fair value of the option grants is calculated in accordance with FASB ASC Topic 718 and using a Black-Scholes valuation model. Assumptions used in the calculation of these amounts are included in Note 9 of the audited financial statements included elsewhere in this Annual Report on Form 10-K.

The following table shows the number of outstanding options held by our non-executive directors at the end of fiscal 2016:

	Number of Securities Underlying Unexercised Options (#)(1)				
	Exercisable	Unexercisable	Unearned	Option Exercise Price	Option Expiration Date
Ira Greenstein	100,000	—	—	$ 1.71	3/8/2017
Chairman	42,000	42,000	—	$ 10.14	3/10/2020
	20,000	40,000	—	$ 5.14	1/6/2021
	26,666	53,334	—	$ 3.62	1/21/2021
Orin Hirschman	100,000	—	—	$ 1.71	3/8/2017
Director	42,000	42,000	—	$ 10.14	3/10/2020
	20,000	40,000	—	$ 5.14	1/6/2021
Thomas Ricdhammer	116,667	—	—	$ 4.74	4/29/2018
Director	42,000	42,000	—	$ 10.14	3/10/2020
	20,000	40,000	—	$ 5.14	1/6/2021
June Almenoff	116,667	—	—	$ 4.68	5/16/2018
Director	42,000	42,000	—	$ 10.14	3/10/2020
	20,000	40,000	—	$ 5.14	1/6/2021

(1) The Option numbers represent options to acquire shares of common stock.

The following table shows the compensation of our non-executive directors for fiscal 2016:

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Change in Pension Value and Non-Qualified Deferred Compensation Earnings	All Other Compensation	Total
Ira Greenstein Chairman	$ 10,000	$ —	$ 391,386	$ —	$ —	$ —	$ 401,386
June Almenoff Director	$ 10,000	$ —	$ 201,678	$ —	$ —	$ —	$ 211,678
Orin Hirschman Director	$ 10,000	$ —	$ 201,678	$ —	$ —	$ —	$ 211,678
Thomas Reidhammer Director	$ 10,000	$ —	$ 201,678	$ —	$ —	$ —	$ 211,678

Compensation Committee Report

Notwithstanding anything to the contrary set forth in any of our previous or future filings under the Securities Act of 1933 or the Securities Exchange Act of 1934 that might incorporate this Annual Report on Form 10-K, in whole or in part, the following report of the Compensation Committee shall not be deemed to be incorporated by reference into any such filings and shall not otherwise be deemed filed under such Acts.

The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis contained in this Annual Report on Form 10-K with management and, based on that review and discussion, the Compensation Committee recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this Annual Report on Form 10-K.

Submitted by: The Compensation Committee

Thomas Riedhammer, Chairman
June Almenoff
Ira Greenstein

Compensation Discussion and Analysis

Compensation Program Objectives

The Company's compensation programs are competitive, designed to attract and retain highly qualified directors, officers and employees, encourage high performance, promote accountability and assure that employee interests are aligned with the interests of the Company's stockholders.

To achieve these objectives, we seek to design our executive compensation program and set compensation levels that are comparable to those of other companies that compete with us for executive talent. We use both objective and subjective criteria to evaluate Company and individual performance. This approach should allow the Compensation Committee to exercise discretion and not rely solely on rigid formulas and quantitative analyses. We historically provided long-term compensation in the form of stock options that generally vest over a two to three-year period and restricted stock that vest over a period of up to three years. We believe these awards allow the executive officers and all employees to participate in the long-term success of the Company, to align their interests with those of our stockholders, and to incentivize future performance, helping us retain talented executive management personnel.

We believe that the Company's compensation program for its executive officers is competitive and appropriately designed to attract and retain key employees, reward superior performance and promote long-term stockholder value. The Compensation Committee plans to continue to review the compensation payable to the Company's executive officers, periodically evaluate the Company's compensation practices, and make any changes it deems appropriate to the Company's compensation structure to ensure that the programs are designed and implemented to achieve the Committee's stated goals.

We rely on various sources of information to assist us in evaluating the competitiveness of the Company's executive compensation program, setting compensation levels for the executive officers and meeting the Compensation Committee's stated compensation objectives and the experience and knowledge of our Compensation Committee and senior management. We have not retained an independent third party compensation consultant.

Highlights of Company Performance in 2016

In fiscal 2016, the Company made important progress toward achieving its goals. The Company has achieved the following milestones:

- Obtained FDA agreement on a Special Protocol Assessment for the Phase 3 clinical program for Squalamine in combination with Lucentis® for patients with exudative AMD. The first Phase 3 trial began enrollment in April 2016.
- Appointed David Brown, MD, as Chairman of the Steering Committee overseeing the Phase 3 trial.
- Demonstrated in vivo sustained release of a novel small molecule anti-angiogenic compound (OHR3031) in a pharmacokinetic study in December 2015.
- In May 2016, demonstrated sustained pharmacological anti-angiogenic activity of OHR3031 in a rabbit model of laser-induced CNV which was comparable to that seen with a currently approved anti-VEGF agent conducted in a previous study.
- Multiple posters and presentations at major medical meetings for both Squalamine as well as the sustained release platform technology. Advanced ex-US regulatory discussions to facilitate the second Phase 3 Squalamine study.
- Continued progress on our ongoing discussions with several parties regarding a potential partnership transaction for Squalamine.
- Significant progress with our active sustained release programs.

Peer Group Analysis

In reviewing fiscal 2016, the Compensation Committee reevaluated the Company's peer group of companies and benchmarked executive compensation against this group. The objective of this reevaluation and analysis was to develop a peer group of companies in line with our revenue, market capitalization and phase of clinical trials and to compare our executive compensation practices to those of our peer companies. The Compensation Committee believes that it is important when making its compensation decisions to be informed as to the current practices of comparable, publicly held companies headquartered in the United States. To that end, we monitor developments in the Company, including growth in its products under development and market capitalization, and in the market generally that might change the selection of companies we consider comparable and benchmark our executive compensation against the most recently applicable companies. While benchmarking might not always be appropriate as a stand-alone tool for setting compensation due to the aspects of our business and objectives that might be unique to us, we generally believe that gathering this information is an important part of our compensation-related decision-making process.

We recognize that to attract, retain and motivate key individuals, such as our named executive officers, the Compensation Committee might determine that it is in our best interests to negotiate total compensation packages with our executive management that may deviate from the general principle of targeting total compensation at the median level for the peer group. Actual pay for each named executive officer is determined around this structure, driven by the performance of the executive over time, as well as our annual performance.

For purposes of compensation decisions based on 2016 performance and compensation, our peer group of companies consisted of the following: Eleven Biotherapeutics, Inc., Inotek Pharmaceuticals, Corp., Alimera Sciences, Inc., Ocular Therapeutix, Inc., and pSivida Corp. These companies were chosen based on their comparable profile, stage of development, market capitalization, and therapeutic area of focus.

Say-on-Pay and Say-on-Frequency Feedback from Stockholders

The Board and the Compensation Committee value the opinions of our stockholders, and consider the outcome of advisory stockholder votes when making future compensation decisions for our named executive officers. At our 2014 annual meeting, 99.06% of the votes cast approved our advisory resolution regarding the compensation of our named executive officers. In addition, 86.93% of the votes cast voted that an advisory vote on executive compensation should occur every three years; consequently, the Company's next advisory vote on executive compensation will occur at our next annual meeting of stockholders. With stockholders showing strong support of our executive compensation program, the Compensation Committee continued its regular practice of evaluating the program to reflect continued linkage between pay and company performance and carefully considered actual compensation payouts, seeking to provide compensation that follows our compensation philosophy and meets our compensation objectives described above. In light of all pertinent considerations, the Compensation Committee believes that the Company's compensation programs embody a pay-for-performance philosophy that is well suited for these purposes.

Executive Compensation Policy

The principal components of compensation for the Company's executive officers are base salary, discretionary annual cash incentive awards and long-term incentive compensation in the form of options, restricted common stock or other forms of equity.

The Company also provides severance benefits upon a change in control of the Company, a 401(k) plan and a group health plan. The Company does not maintain supplemental retirement programs for its executive officers because we believe that the existing compensation arrangements enable the Company's executive officers to adequately plan for their retirement.

Compensation Program Elements

Base Salary. Ohr's base salary is designed to recognize the duties and responsibilities of each executive officer and the experience, knowledge, ability and skill of the executive officer that holds each such position. We believe that base salaries are an important component of the Company's executive compensation program and are critical in attracting and retaining executive talent. The Compensation Committee reviews base salaries of the Company's executive officers on an annual basis. In setting annual base salaries, the Compensation Committee considers the Company's overall financial and operating performance in the prior year, the Company-wide target for base salary increases for all employees, market and competitive salary information, including for our peer companies as noted above, inflation, changes in the scope of an executive officer's job responsibilities, other components of compensation and other relevant factors. The Compensation Committee also reviews the executive officer's individual performance.

Annual Incentive Cash Compensation. This component of compensation provides an incentive to the executive officers to achieve both Company and individual performance objectives and to be rewarded for those achievements.

Our plan is that after each fiscal year, the Compensation Committee will determine the bonus for the named executive officers, for that year. In all cases, the Committee seeks to establish bonuses that are designed to ensure that total cash compensation is competitive and reflects performance in that year.

The size of the final discretionary bonuses paid to the named executive officers are not based on a specific formula or level of achievement, but rather at the discretion of the Compensation Committee taking into account the factors discussed above.

Based on the Company's corporate and operational performance in fiscal year 2016 and the individual performance of each named executive officer, in January 2017 the Compensation Committee will convene to determine executive bonuses. In determining the amounts of these payments, the Compensation Committee will consider the importance of retaining our key employees and motivating them to implement our long-term strategic plan to develop additional products and to acquire potential products.

The Compensation Committee believes its approach to cash incentive awards properly motivates and rewards the Company's executive officers and provides the Compensation Committee with appropriate discretion and flexibility to set awards that reflect both the Company's performance and each named executive officer's contributions for the given year.

Perquisites and Other Benefits. The Company's philosophy is not to provide executive perquisites or other special benefits. Instead, we maintain broad-based benefits that we provide to all employees, including our executive officers. These benefits include a 401(k) retirement savings plan (without matching contributions from the Company) and a group health plan.

Stock-Based Awards. Stock-based awards under our 2016 Consolidated Stock Incentive Plan are the primary form of long-term compensation offered to our named executive officers. Under our 2016 Consolidated Stock Incentive Plan, the Compensation Committee may grant named executive officers and other employees eligible to participate in the Plan, incentive and nonqualified stock options and restricted stock awards.

The Compensation Committee grants option awards to named executive officers and other employees eligible to participate in our 2016 Consolidated Stock Incentive Plan. Typically, a small portion of the option awards vest immediately and the remaining portions vest over time, subject to continued employment.

The Compensation Committee believes its option and stock award program is consistent with its stated objective of establishing a performance-based executive compensation system to reward and incentivize the named executive officers and other employees and consultants because the value of the options and stock generally will be tied to the Company's financial and operating performance over time. The Compensation Committee believes this link to longer-term performance aligns the interests of the named executive officers, employees and consultants with the interests of our stockholders. In addition, the vesting schedule for most option or stock awards helps the Company retain executive talent because unvested options or stock awards are automatically forfeited upon the termination of an executive officer's employment. Thus, the recipient of an option or stock award is incentivized to remain with the Company during the vesting period.

Policy on Timing of Equity Grants

We do not have any formal plan or practice to time equity grants in coordination with our public release or disclosure of material nonpublic information, but we generally only make grants at times when we do not have any material nonpublic information about our Company. We also do not time our release of material nonpublic information for purposes of affecting the value of compensation to employees, including our officers.

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

The following table provides information about the beneficial ownership of our common stock as of December 14, 2016.

- each person or entity known by us to own beneficially more than five percent of our common stock;
- the named executive officers;
- each of our directors; and
- all of our directors and executive officers as a group.

In accordance with Securities and Exchange Commission rules, beneficial ownership includes any shares for which a person or entity has sole or shared voting power or investment power and any shares for which the person or entity has the right to acquire beneficial ownership within 60 days after December 14, 2016 through the exercise of any option, warrant or otherwise. Except as noted below, we believe that the persons named in the table have sole voting and investment power with respect to the shares of common stock set forth opposite their names. Percentage of beneficial ownership is based on 35,961,396 shares of common stock outstanding as of December 14, 2016, plus any shares of common stock issuable upon exercise of presently exercisable common stock options or common stock warrants held by such person or entity. All shares included in the "Right to Acquire" column represent shares subject to outstanding stock options or warrants that are exercisable within 60 days after December 14, 2016. The address of each of our directors and executive officers is c/o Ohr Pharmaceutical, Inc., 800 Third Avenue, 11th Floor, New York, New York 10022.

Name and Address of Beneficial Owner	Shares Owned	Right to Acquire (1)	Common and Warrant Shares Owned Beneficially	Fully Diluted Ownership Percentage (2)
Orin Hirschman (3)	2,376,939	333,000	2,709,939	7.5%
Jason Slakter (4)	2,120,764	25,000	2,145,764	6.0%
Ira Greenstein (5)	331,051	235,334	566,385	1.6%
Sam Backenroth (6)	141,167	413,333	554,500	1.5%
Thomas Riedhammer (7)	8,000	198,667	206,667	*
June Almenoff (8)	16,900	198,667	215,567	*
Avner Ingerman (9)	61,000	100,000	161,000	*
All Officers and Directors as a Group	5,055,821	1,504,001	6,559,822	17.5%

* Less than 1%.

(1) Only includes vested and exercisable securities, including securities exercisable within 60 days after December 14, 2016.

(2) Calculated on the basis of shares of Common Stock outstanding plus the number of shares such holder has the right to acquire.

(3) Mr. Hirschman is the sole member of AIGH Investment Partners LLC ("AIGH") and directly determines investment and voting decisions, and AIGH directly owns shares and warrants to purchase common stock. Mr. Hirschman indirectly owns shares as custodian of accounts for the benefit of his minor children. Mr. Hirschman shares voting and dispositive power over shares and warrants held by The Tzedakah Fund.

(4) Consists of 925,000 shares of common stock held by Dr. Slakter directly and 1,195,724 shares of common stock held by SKS Ocular I LLC, an affiliate of Dr. Slakter. Dr. Slakter has sole voting and dispositive power over shares and options held by Dr. Slakter personally. Dr. Slakter shares voting and dispositive power over shares held by SKS Ocular I LLC. Dr. Slakter disclaims any beneficial ownership of the 1,195,724 shares of common stock held by SKS Ocular I LLC except to the extent of his pecuniary interest therein.

(5) Includes shares currently issuable upon exercise of options granted to Mr. Greenstein.

(6) Includes shares currently issuable upon exercise of options granted to Mr. Backenroth.

(7) Includes shares currently issuable upon exercise of options granted to Dr. Riedhammer.

(8) Includes shares currently issuable upon exercise of options granted to Dr. Almenoff.

(9) Includes shares currently issuable upon exercise of options granted to Dr. Ingerman.

ITEM 13 CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Policies and procedures for related person transactions

Our Board has adopted a written related policy with respect to related person transactions. This policy governs the review, approval or ratification of covered related person transactions. The Audit Committee of our Board manages this policy.

For purposes of this policy, a "related person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we (or any of our subsidiaries) were, are or will be a participant, and the amount involved exceeds $120,000 and in which any related person had, has or will have a direct or indirect interest. For purposes of determining whether a transaction is a related person transaction, the Audit Committee relies upon Item 404 of Regulation S-K, promulgated under the Securities Exchange Act of 1934, as amended.

A "related person" is defined as:

- any person who is, or at any time since the beginning of our last fiscal year was, one of our directors or executive officers or a nominee to become one of our directors;
- any person who is known to be the beneficial owner of more than five percent of any class of our voting securities;
- any immediate family member of any of the foregoing persons, which means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law of the director, executive officer, nominee or more than five percent beneficial owner, and any person (other than a tenant or employee) sharing the household of such director, executive officer, nominee or more than five percent beneficial owner; and

- any firm, corporation, or other entity in which any of the foregoing persons is employed or is a general partner or principal or in a similar position or in which such person has a ten percent or greater beneficial ownership interest.

The policy generally provides that we may enter into a related person transaction only if:

- the Audit Committee pre-approves such transaction in accordance with the guidelines set forth in the policy;
- the transaction is on terms comparable to those that could be obtained in arm's length dealings with an unrelated third party and the Audit Committee (or the chairperson of the Audit Committee) approves or ratifies such transaction in accordance with the guidelines set forth in the policy;
- the transaction is approved by the disinterested members of the Board; or
- the transaction involves compensation approved by the Compensation Committee of the Board.

In the event a related person transaction is not pre-approved by the Audit Committee and our management determines to recommend such related person transaction to the Audit Committee, such transaction must be reviewed by the Audit Committee. After review, the Audit Committee will approve or disapprove such transaction. When our Chief Financial Officer in consultation with our Chief Executive Officer, determines that it is not practicable or desirable for us to wait until the next Audit Committee meeting, the chairperson of the Audit Committee possesses delegated authority to act on behalf of the Audit Committee. The Audit Committee (or the chairperson of the Audit Committee) may approve only those related person transactions that are in, or not inconsistent with, our best interests and the best interests of our shareholders, as the Audit Committee (or the chairperson of the Audit Committee) determines in good faith.

The Audit Committee has determined that certain types of related person transactions are deemed to be pre-approved by the Audit Committee. Our related person transaction policy provides that the following transactions, even if the amount exceeds $120,000 in the aggregate, are considered to be pre-approved by the Audit Committee:

- any employment of certain named executive officers that would be publicly disclosed;
- director compensation that would be publicly disclosed;
- transactions with other companies where the related person's only relationship is as a director or owner of less than ten percent of said company (other than a general partnership), if the aggregate amount involved does not exceed the greater of $200,000 or five percent of that company's consolidated gross revenues;

- transactions where all shareholders receive proportional benefits;
- transactions involving competitive bids;
- transactions with a related person involving the rendering of services at rates or charges fixed in conformity with law or governmental authority; and
- transactions with a related person involving services as a bank depositary of funds, transfer agent, registrar, trustee under a trust indenture or similar services.

In addition, the Audit Committee will review the policy at least annually and recommend amendments to the policy to the Board from time to time.

The policy provides that all related person transactions will be disclosed to the Audit Committee, and all material related person transactions will be disclosed to the Board. Additionally, all related person transactions requiring public disclosure will be properly disclosed, as applicable, on our various public filings.

The Audit Committee will review all relevant information available to it about the related person transaction. The policy provides that the Audit Committee may approve or ratify the related person transaction only if the Audit Committee determines that, under all of the circumstances, the transaction is in, or is not inconsistent with, our best interests. The policy provides that the Audit Committee may, in its sole discretion, impose such conditions as it deems appropriate on us or the related person in connection with approval of the related person transaction.

Interest of Management in Certain Transactions

In May 2014, the Company acquired certain assets of SKS Ocular (and affiliates; collectively referred to as "SKS"), which is a related person of Dr. Slakter, currently a director of the Company and its Chief Executive Officer. In consideration thereof, the Company paid $3.5 million in cash and 1,194,862 shares of the Company's common stock. Dr. Slakter was not a director of the Company at the time of the transaction. In the acquisition, the Company entered into a consulting agreement with Dr. Slakter, and agreed to appoint a designee of SKS as a director of the Company. The Company is also obliged to grant to SKS Ocular up to an aggregate of 1,493,577 shares of the common stock upon reaching certain milestones. In December 2015, milestone 1 was achieved, and in May 2016, milestone 2 was achieved, resulting in the issuance of 995,718 shares of Ohr common stock to SKS Ocular 1 LLC. The Company also indirectly paid a total of $91,280 in fiscal year 2015, and was invoiced $267,680 in fiscal 2016, from Digital Angiography Reading Center, an affiliate of Dr. Slakter, for services rendered to the Company. In addition, in fiscal year 2015, the Company paid a total of $172,308 to Dr. Slakter in consulting fees.

Our CRO running our phase 3 trial has contracted with Jason S. Slakter, M.D., P.C., d/b/a Digital Angiography Reading Center ("DARC"), a well-known digital reading center, which is owned by Dr. Jason Slakter, our CEO, pursuant to our related party transactions policy, with the review and approval of the Audit Committee, to provide digital reading and imaging services in connection with the Phase 3 study. We are advised that DARC has implemented a standard operating procedure (SOP) to firewall interactions between DARC employees and Dr. Slakter.

ITEM 14 PRINCIPAL ACCOUNTANT FEES AND SERVICES

The Board of Directors has selected MaloneBailey as the Company's independent auditors for the fiscal year ended September 30, 2016. MaloneBailey, LLP has audited Ohr Pharmaceutical's financial statements since 2012.

Principal Accountant Fees and Services.

For fiscal year 2016, MaloneBailey charged the Company a total of $59,000 for independent accounting and review fees. For fiscal year 2015, MaloneBailey charged the Company a total of $92,500 for independent accounting and review fees.

	Fiscal Year Ended	
	September 30, 2016 (1)	**September 30, 2015 (2)**
Audit Fees & Audit-Related Fees	$ 59,000	$ 92,500
Tax Fees	$ 8,124	3,500
All Other Fees	—	—
Total Fees	$ 67,124	$ 96,000

(1) Fees billed to the Company through September 30, 2016.

(2) Fees billed to the Company through September 30, 2015.

Pre-Approval of Audit and Non-Audit Services

The Board has not approved any formal policy concerning pre-approval of the auditors to perform both audit and non-audit services (services other than audit, review and attest services). Instead, on a case by case basis, any audit or non-audit services proposed to be performed are considered by and, if deemed appropriate, approved by the Board in advance of the performance of such services.

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
4.3	Form of Series A Warrant	December 8, 2016, Form 8-K, Exhibit 4.1
4.4	Form of Series B Warrant	December 8, 2016, Form 8-K, Exhibit 4.2
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 Sam Backenroth	January 10, 2014, Form 8-K, Exhibit 10.38

Exhibit Number	Description of Exhibit	The filings referenced for incorporation by reference are Ohr Pharmaceutical, Inc. (File No. 001-35963)
10.2(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
10.2(c)*	Proprietary Information and Inventions Agreement, dated April 10, 2010, between Ohr Pharmaceutical, Inc. and Sam Backenroth	September 30, 2015, form 10-K, Exhibit 10.3(c)
10.3*	Employment Agreement, dated as of February 24, 2015, between Ohr Pharmaceutical, Inc. and Avner Ingerman	February 26, 2015, Form 8-K, Exhibit 10.52
10.4	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
10.5	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
10.6	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
10.7	Securities Purchase Agreement, dated December 7, 2016, by and among Ohr Pharmaceuticals, Inc. and to purchasers listed therein	December 8, 2016, Form 8-K, Exhibit 10.1
10.8	Letter Agreement, dated December 2, 2016, by and betweeen Ohr Pharmaceutical, Inc. and H.C. Wainwright & Co., LLC	December 8, 2016, Form 8-K, Exhibit 10.2
10.9	Ohr Pharmaceutical, Inc. 2016 Consolidated Stock Incentive Plan	March 21, 2016, Form 8-K, Exhibit 10.1
10.10(a)*	The Ohr Pharmaceutical, Inc. 2014 Stock Incentive Plan	April 14, 2014, Form 8-K, Exhibit 10.42
10.10(b)*	Amendment to Ohr Pharmaceutical, Inc. 2014 Stock Incentive Plan	September 30, 2015, Form 10-K, Exhibit 10.8(b)
10.11*	Form of Stock Option Agreement	March 31, 2015, Form 10-Q, Exhibit 10.53
10.12*	Ohr Pharmaceutical, Inc. 2009 Stock Incentive Plan	March 31, 2010, Form 10-Q, Exhibit 10.1

Exhibit Number	Description of Exhibit	The filings referenced for incorporation by reference are Ohr Pharmaceutical, Inc. (File No. 001-35963)
14	Code of Ethics	September 30, 2015, Form 10-K, 10.8(b)
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 22, 2016

By: */s/* JASON SLAKTER
Jason Slakter, CEO (Principal Executive Officer)

Dated: December 22, 2016

By: /s/ SAM BACKENROTH
Sam Backenroth, CFO
(Principal Accounting and Financial Officer)

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

Dated: December 22, 2016

By: /s/ JASON SLAKTER
Jason Slakter, Director

Dated: December 22, 2016

By: /s/ IRA GREENSTEIN
Ira Greenstein, Director

Dated: December 22, 2016

By: /s/ ORIN HIRSCHMAN
Orin Hirschman, Director

Dated: December 22, 2016

By: /s/ JUNE ALMENOFF
June Almenoff, Director

Dated: December 22, 2016

By: /s/ THOMAS RIEDHAMMER
Thomas Riedhammer, Director

Exhibit 21
List of Subsidiaries of Ohr Pharmaceutical. Inc.

1. Ohr Opco, Inc. (incorporated in Delaware)
2. Ohr Pharma, LLC (organized in Delaware)

Exhibit 23
Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-201368) of Ohr Pharmaceutical, Inc. of our report dated December 22, 2016, relating to the consolidated financial statements for the year ended September 30, 2016 and the effectiveness of internal control over financial reporting as of September 30, 2016, which report appears in this Annual Report on Form 10-K for the fiscal year ended September 30, 2016.

/s/ MaloneBailey, LLP
www.malone-bailey.com
Houston, Texas
December 22, 2016

Exhibit 31.1
Certification of Chief Executive Officer
Pursuant to Section 302 of the
Sarbanes-Oxley Act of 2002

I, Jason Slakter, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated: December 22, 2016

/s/ Jason Slakter
Jason Slakter
Chief Executive Officer

Exhibit 31.2
Certification of Chief Financial Officer
Pursuant to Section 302 of the
Sarbanes-Oxley Act of 2002

I, Sam Backenroth, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated: December 22, 2016

/s/ *Sam Backenroth*
Sam Backenroth
Chief Financial Officer and Principal Accounting Officer

Exhibit 32.1
Certification of Chief Executive Officer
Pursuant to 18 U.S.C Section 1350,
As Adopted Pursuant to Section 906 of the
Sarbanes-Oxley Act of 2002

Not Filed Pursuant to the Securities Exchange Act of 1934

In connection with the Annual Report of Ohr Pharmaceutical, Inc. (the *"Company"*) on Form 10-K for the fiscal year ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the *"Report"*), I, Jason Slakter, Chief Executive Officer, of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: December 22, 2016

/s/ Jason Slakter
Name: Jason Slakter
Title: Chief Executive Officer

Exhibit 32.2
Certification of Chief Financial Officer
Pursuant to 18 U.S.C Section 1350,
As Adopted Pursuant to Section 906 of the
Sarbanes-Oxley Act of 2002

Not Filed Pursuant to the Securities Exchange Act of 1934

In connection with the Annual Report of Ohr Pharmaceutical, Inc. (the "*Company*") on Form 10-K for the fiscal year ended September 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the *"Report"*), I, Sam Backenroth, Chief Financial Officer, of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: December 22, 2016

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