UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended December 31, 2014

or

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from to

Commission File Number 000-55362

EYEGATE PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**98-0443284**
(State or other jurisdiction of Incorporation or organization)	(I.R.S. Employer Identification No.)

271 Waverley Oaks Road
Suite 108
Waltham, MA 02452
(Address of Principal Executive Offices, including zip code)

(781) 788-9043
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:
None
Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.01 par value

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 Section 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 the past 90 days.
YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 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. ☐

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 filer ☐	(Do not check if a smaller reporting company)	Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act. YES ☐ NO ☒

As the last day of the registrant's most recently completed second fiscal quarter, the registrant's common stock was not publicly traded. The registrant's common stock began trading on the OTCQB Venture Marketplace on February 13, 2015. As of March 25, 2015, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $4.85 million, based on the closing price of the registrant's common stock on March 25, 2014.

At March 27, 2015, there were 6,333,579 shares of the registrant's common stock issued and outstanding.

EYEGATE PHARMACEUTICALS, INC.
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ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2014

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This Annual Report on Form 10-K contains statements that are not statements of historical fact and are 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 (the "Exchange Act"), each as amended.. The forward-looking statements are principally, but not exclusively, contained in "Item 1: Business" and "Item 7: Management's Discussion and Analysis of Financial Condition and Results of Operations." These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about management's confidence or expectations, and our plans, objectives, expectations and intentions that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "goals," "sees," "estimates," "projects," "predicts," "intends," "think,""potential," "objectives," "optimistic," "strategy," and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in detail under the heading "Item 1A. Risk Factors" beginning on page 25 of this Annual Report on Form 10-K. You should carefully review all of these factors, as well as other risks described in our public filings, and you should be aware that there may be other factors, including factors of which we are not currently aware, that could cause these differences. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this report. We may not update these forward-looking statements, even though our situation may change in the future, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information.

Eyegate Pharmaceuticals, Inc. is referred to herein as "we," "our," "us," and "the Company."

PART I

Item 1. ***Business.***

Overview

We are a clinical-stage specialty pharmaceutical company that is focused on developing and commercializing therapeutics and drug delivery systems for treating diseases of the eye. EGP-437, our first and only product in clinical trials, incorporates a reformulated topically active corticosteroid, dexamethasone phosphate, that is delivered into the ocular tissues through our proprietary innovative drug delivery system, the EyeGate® II Delivery System. EGP-437 is being developed under the 505(b)(2) New Drug Application, or NDA, regulatory pathway for drugs submitted for approval to the U.S. Food and Drug Administration, or FDA, which enables an applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its NDA. An example of an existing product on which we believe that we can rely, in part, for a 505(b)(2) NDA filing is Decadron®, a topical dexamethasone formulation. An Investigational New Drug application, or IND (IND 77,888), for EGP-437 was submitted to the FDA on April 28, 2008, which was subsequently amended as described below in this "Business" section under the heading "Clinical Trial Results."

The EyeGate® II Delivery System and EGP-437, are designed to address two major issues in ophthalmic medicine: lack of patient compliance and safety. The EyeGate® II Delivery System features a compact, elegant, and easy-to-use device that we believe has the potential to deliver drugs non-invasively and quickly into the ocular tissues through the use of iontophoresis, which can accelerate the onset of action, dramatically reduce treatment frequency versus eye drops and sustain therapeutic effect. Iontophoresis employs the use of a low electrical current that promotes the migration of a charged drug substance across biological membranes. The current produces ions, which through electrorepulsion, drive a like-charged drug substance into the tissues. The EyeGate® II Delivery System is easy-to-use, only takes a few minutes to employ and has been utilized to administer more than 1,700 experimental treatments. We hold worldwide commercialization rights to the EyeGate® II Delivery System.

We are developing EGP-437 for the treatment of various inflammatory conditions of the eye, including uveitis, a debilitating form of intraocular inflammation of the anterior portion of the uvea, such as the iris and/or ciliary body and macular edema, an abnormal thickening of the macula associated with the accumulation of excess fluids in the extracellular space of the neurosensory retina.

The EyeGate® II Delivery System has the potential to offer a non-invasive method of drug delivery as an alternative to the current delivery modalities used for treating ocular diseases, such as eye drops and ocular injections. In-office preparation is simple and efficient and can be completed by nursing or other office staff. Utilizing the EyeGate® II Delivery System, we have demonstrated in vivo (preclinical) the ability to deliver EGP-437 to the back-of-the-eye.

Program	Indication	Current Status	Contemplated Near Term Milestones
EGP-437	Macular Edema		• Initiate and complete Phase 2 proof of concept trial for macular edema
	Anterior Uveitis	• Phase 1-2 dose ranging trial completed • First non-inferiority trial completed	• No further trials are anticipated prior to raising additional funds
	Dry Eye	• Two trials completed (Phase 2 & Phase 3) (Stress Environment - placebo controlled)	
	Cataract Surgery	• Phase 2 proof of concept trial completed (prophylactic - placebo controlled)	

Our Strategy

Our goal is to become a leading specialty pharmaceutical company focused on developing and commercializing therapeutics and drug delivery systems for treating diseases of the eye. The key elements of this strategy are to:

- *Complete trials for back-of-the-eye delivery with our EGP-437 Combination Product.* As an anti-inflammatory agent, our EGP-437 Combination Product has the potential to be used to treat back-of-the-eye diseases that have an inflammatory component, like macular edema. We are planning on initiating a dose curve trial to determine the optimum dose for back-of-the-eye delivery followed by a Phase 2 proof-of-concept trial for macular edema, a disease affecting the back-of-the-eye. We have begun preparatory work and plan to enroll the first subject by the end of the second quarter of 2015 for the dose curve trial. We expect to have top-line data from the Phase 2 proof-of-concept trial treating macular edema by the end of 2015.

- *Seek to continue clinical development of and obtain marketing approval for our EGP-437 Combination Product for the treatment of non-infectious anterior uveitis in the future.* Currently, we are devoting most of our efforts to the proof-of-concept trial for macular edema with our EGP-437 Combination Product. We will seek to continue development of our EGP-437 Combination Product for the treatment of non-infectious anterior uveitis in the future once we have raised additional funds.

- *Maximize commercial potential of our EGP-437 Combination Product.* We believe that medical specialists in the U.S. who treat macular edema or anterior uveitis patients are sufficiently concentrated that if our EGP-437 Combination Product receives marketing approval in the U.S., we could effectively promote our EGP-437 Combination Product to these specialists with a specialty sales and marketing group. Therefore, we may decide to build our own focused, specialty pharmaceutical sales force in order to commercialize our EGP-437 Combination Product in the U.S. We intend to enter into strategic collaborations for the development and commercialization of our EGP-437 Combination Product outside of the U.S.

- *Pursue other strategic collaborations.* We plan to evaluate opportunities to enter into collaborations that may contribute to our ability to advance our drug delivery platform and product candidates and to progress concurrently a range of discovery and development programs. We also plan to evaluate opportunities to in-license or acquire the rights to other products, product candidates or technologies for the treatment of eye diseases.

Ophthalmic Market Opportunity

Ophthalmology is a specialty market with commercial and regulatory dynamics that make it possible for small or medium sized companies like us to develop and commercialize products on our own. We believe that the specialists in the U.S. who treat ocular diseases are sufficiently concentrated that we could effectively promote our products with a specialty sales and marketing group.

Our Lead Product: EGP-437

Back-of-the-eye

We have demonstrated in clinical trials the effect of utilizing iontophoresis to deliver drugs into the eye. Our non-invasive and proprietary EyeGate® II Delivery System is designed to deliver optimal quantities of drugs to the anterior or posterior segments of the eye. Although, our initial clinical development has been for treating a disease at the front-of-the-eye, non-infectious anterior uveitis, with a corticosteroid, EGP-437, we have demonstrated in vivo (preclinical studies) that the delivery system is capable of delivering EGP-437 to the back-of-the-eye.

We have performed numerous preclinical biodistribution studies that have shown the successful delivery of significant quantities of some of the previously mentioned drug types in various ocular tissues including the retina, vitreous and choroid.

To achieve adequate therapeutic levels of dexamethasone in the posterior segment in patients while at the same time minimizing systemic distribution, we have developed an ocular iontophoresis device that we believe is designed to more effectively provide adequate drug levels in the posterior segment of the eye than conventional methods. Delivery of therapeutic agents using ocular iontophoresis has been of interest as a means of non-invasively achieving higher drug levels within the eye by promoting the migration of a charged drug substance across biological membranes with a low electrical current. The current produces ions, which via electrorepulsion, drive a like-charged drug substance into the ocular tissues.

The EyeGate® II Delivery System applicator utilizes an inert electrode, which stimulates the electrolysis of water to produce ions (hydroxide or hydronium) that are required to deliver charged molecules. The EyeGate® II Delivery System delivery platform requires custom pharmaceutical formulations to enable delivery efficiency and safety while allowing for potential novel intellectual property. The data from multiple clinical trials suggests that EGP-437 does not significantly raise mean IOP at the time points evaluated during the study period.

The Unmet Need

Currently, the only primary route of administration for drugs treating retinal diseases is through intravitreal injection into the vitreous of the eye. These injections must be given as frequently as once per month when treating chronic diseases like macular degeneration. Unfortunately, there are known drawbacks associated with administering intravitreal injections such as:

- Safety risks
- Adverse patient experience
- Physician practice

Safety Risks

The American Academy of Ophthalmology has published a policy statement stating that intravitreal injections of various agents have been studied extensively, and the overall risk of complications is low when the injection is administered by experienced ophthalmologists. However, per this policy statement, known risks of intravitreal injections can be vision threatening and require prompt diagnosis and treatment, and possibly surgical intervention. The most serious but rarely occurring injection-related complications include acute-onset endophthalmitis, pseudo-endophthalmitis, cataract development/progression, retinal detachment and hemorrhage.

Additional infrequent complications include hypotony, angle closure, hemiretinal vein occlusion, retinal pigment epithelial tears, iritis/uveitis, optic disc atrophy, corneal epitheliopathy, maculopathy, and anaphylactic reaction to the agent injected in the vitreous.

Patient Experience

Other than the aforementioned risks associated with an intravitreal injection in the eye there are other factors influencing the patient experience, such as:

- Travel time — There are a limited number of ophthalmologists that provide the treatment which means limited number of facilities where treatment can be given which can result in significant travel time for some patients.
- Companion required — Invasive procedures prevent patients from travelling home alone.
- Extended office time — Additional assessments and monitoring are required prior to discharge.

With monthly injections, a 75 year old patient with a life expectancy of another additional 13 years would need approximately 150 intravitreal injections.

Physician Practice

Because of the potential safety issues, intravitreal injections can be time and labor intensive and should be administered by an experienced ophthalmologist. Combined, these factors limit the number of patients that can be treated and strains the resources of physician offices. The increased number of indications being approved for treatment by intravitreally injected drugs and the aging population will dramatically increase this strain.

The EyeGate® II Delivery System could potentially reduce the impact of the issues described above by providing eye care practitioners and patients with a non-invasive solution for treating retinal diseases like age-related macular degeneration. The treatment with our EyeGate® II Delivery System can be administered by a wider group of eye care practitioners than currently giving intravitreal injections and reduces the risks associated with invasive procedures. In-office preparation is simple and efficient and can be completed by nursing or other office staff with actual dosing taking approximately three minutes and total treatment time including preparation taking about seven minutes per eye.

Front-of-the-eye

Many front of the eye diseases such as non-infectious anterior uveitis and seasonal allergic conjunctivitis are acute inflammatory conditions. The current standard of care to treat ocular surface and anterior segment inflammation is patient administered corticosteroids in the form of eye drops. Topical corticosteroids suffer from a number of drawbacks including low ocular bioavailability, rapid clearance and steroid-related side effects including elevated intraocular pressure, or IOP, or cataract formation.

For example, to achieve a successful therapeutic outcome when treating non-infectious anterior uveitis, patients must follow a rigorous dosing schedule for four to six weeks. At a minimum, patients are required to give themselves at least 154 treatments of the standard of care over this period. Given this heavy burden, patient non-compliance is prevalent and is the main cause of treatment failure. Treatment failures may lead to complications causing temporary or permanent loss of vision. When topical treatments fail due to lack of compliance or inadequate response, the alternative is more aggressive steroid therapy, such as ocular and intravenous injections, which is often associated with steroid-related adverse effects such as elevated IOP and cataract formation. Thus, the significant unmet needs in this treatment category include:

- Improving patient compliance which is the main cause of treatment failure which can lead to temporary or permanent loss of vision;
- Eliminating the patient treatment burden of at least 154 eye drops or more for many patients over four to six weeks; and
- Reducing treatment related side effects including elevated IOP.

We believe that our EGP-437 Combination Product has the potential to address these unmet needs by only requiring two or three in-office treatments provided by the eye care provider thereby mitigating the patient compliance issues and substantially reducing the burden of care. Additionally, our clinical trials to date appear to demonstrate a good safety profile, including minimal impact on IOP, and a reduction of inflammation that was demonstrated in four randomized, double-masked clinical studies using our EGP-437 Combination Product.

We recently announced results from a Phase 3 trial of the EGP-437 Combination Product in the lead indication of non-infectious anterior uveitis. The study suggests that two iontophoretic treatments of our EGP-437 Combination Product over a 4-week period achieved the same response rate as 154 drops of PA, and with fewer incidences of elevated IOP. Although we achieved the same response rate in our Phase 3 trial, the dose of the EGP-437 Combination Product tested was just outside the pre-set non-inferiority margin and did not achieve statistical significance as compared to the positive control based on the primary efficacy endpoint.

Targeted Indications

EGP-437: Macular Edema

Broadly defined, macular edema is an abnormal thickening of the macula associated with the accumulation of excess fluid in the extracellular space of the neurosensory retina. Several basic pathophysiologic processes may contribute to the development of macular edema, which occurs in association with a wide variety of pathologic conditions. As a final common pathway in numerous prevalent retinal disorders, macular edema in its various forms can be considered the leading cause of central vision loss in the developed world, and is therefore of enormous medical and socioeconomic importance.

As stated above, the EyeGate® II Delivery System has shown the potential to deliver significant quantities of EGP-437 to the back-of-the-eye tissues including the retina, vitreous and choroid. The risks, the patient experience and the physician practice inefficiencies associated with intravitreal injections provides an opportunity for the EyeGate® II Delivery System to play a role in treating retinal diseases, like macular edema.

EGP-437: Non-Infectious Anterior Uveitis

Uveitis is a general term for inflammation of the uveal tract and encompasses a wide range of etiologies. It may be iodiopathic, associated with systemic diseases or result from a variety of infectious agents. An annual estimated 17.6% of active uveitis patients experience transient or permanent loss of vision. Uveitis is responsible for more than 2.8% of cases of blindness in the U.S., making this disorder an important cause of vision loss and impairment. Non-infectious anterior uveitis is a debilitating form of intraocular inflammation of the anterior portion of the uvea, such as the iris and/or ciliary body and is the most common form of uveitis. Incidence in the U.S. ranges from approximately 26.6 – 102 per 100,000 adults annually with recent reports indicating occurrence in all age groups with the highest incidence in those over age 65 years. Chronic or recurrent, anterior uveitis may lead to complications such as posterior subcapsular cataract, glaucoma and macular edema.

Inflammation can be classified as either acute or chronic. Acute inflammation is the initial response of the body to harmful stimuli and is achieved by the increased movement of plasma and white blood cells from the blood into the injured tissues, in this case the uvea. Sometimes, the inflammation associated with anterior uveitis is in response to a real infection. This is known as infectious anterior uveitis. However, anterior uveitis often occurs for no apparent reason as the result of the immune system malfunctioning and triggering the process of inflammation even though no infection is present. This is known as non-infectious anterior uveitis. Patients that have anterior uveitis, exhibit a large number of white blood cells in the anterior chamber of the eye. In order to count these cells in the anterior chamber, the physician uses a slit lamp, an instrument consisting of a high-intensity light source that can be focused to shine a thin sheet of light into the eye. The treatment objective is to eliminate the inflammation of the uvea which can be confirmed by an anterior chamber cell count of zero.

EGP-437: Dry Eye

Dry eye syndrome (DES), is the most prevalent form of ocular discomfort and irritation. In the U.S., it has been estimated that as many as approximately 3.2 million women and approximately 1.7 million men over the age of 50 have dry eye. In addition, tens of millions more experience a mild form of dry eye or episodic problems with dry eye, usually associated with external stimuli. With the aging population in the U.S. and other countries of the developed world, and with increasing computer use, dry eye is expected to become more prevalent.

While intermittent DES can be related to external environmental factors, the chronic condition is related to internal factors, such as hormonal imbalance, autoimmune disease, the use of many widely prescribed systemic medications, anatomical changes or trauma, and aging. The fundamental (and most likely the causative) problem behind chronic DES is deficiency in either the volume or composition of the tear film. Problems related to the tear film produce an immune-based inflammation of the ocular surface. Symptoms of chronic DES can range from a mildly irritating condition to loss of function and productivity, pain, light sensitivity, and the misery that accompanies significantly impaired vision and decreased quality of life.

Increasing evidence suggests that ocular surface inflammation is present in all chronic dry eye patients. As a consequence, anti-inflammatory ophthalmic solutions are being intensively evaluated for the prolonged clinical use required to treat chronic DES. Restasis® (0.05% topical Cyclosporine A suspension, Allergan) is the only FDA-approved therapeutic agent for dry eye disease; however, it has proven effective in treating only 15% of all dry eye patients. Restasis® has been shown to be safe for long-term use, but may take several weeks to produce a therapeutic effect, and up to six months for maximal effectiveness. Thus, the need for more-effective therapies to treat DES remains substantial. Topical corticosteroids are used off-label to reduce signs and symptoms of dry eye. While corticosteroid eye drops are widely used to treat dry eye, their low ocular bioavailability (estimated to be 1 – 10%) may limit their effectiveness. Therefore, alternative corticosteroid dosing techniques, such as iontophoresis, that enhance drug bioavailability in the eye may be a viable therapeutic option.

EGP-437: Cataract Surgery

Cataract is the leading cause of blindness worldwide, and there are more than 24 million people age 40 and older who have cataract in the U.S. alone, according to the Vision Problems in the U.S. report from Prevent Blindness. A cataract is a clouding of the lens in the eye that affects vision. Most cataracts are related to aging and are very common in older people. By age 80, more than half of the U.S. population either have a cataract or have had cataract surgery. Cataract surgery is the most common surgical procedure in the population aged over 65 years. There are approximately 3 million cataract surgeries performed per year in the U.S. As the technology of cataract surgery has progressed, so too, has the increased patient demand for excellent vision and safety after the procedure, but visual rehabilitation after cataract surgery is sometimes delayed by the inflammatory processes that are induced by phacoemulsification where the eye's internal lens is emulsified with an ultrasonic handpiece and aspirated from the eye. Inflammation is induced in all cataract surgery by the mechanical transmission of energy into the eye, disruption of cell membranes, and the normal healing process. Postoperative topical corticosteroids are used routinely to reduce inflammation and improve visual outcomes after cataract surgery. Despite their use, transient corneal edema is one of the major factors hindering the improvement of vision in the first days after surgery, and cystoid macula edema may reduce quality of vision for weeks and months after the procedure. Therefore, reducing inflammation and its potential damage to the corneal endothelium and retina is a high priority for the ophthalmic surgeon.

Clinical Trial Results:

We submitted an IND for EGP-437 to the FDA on April 28, 2008. The initial protocol submitted as part of the IND application was for our Phase 1/2 non-infectious anterior uveitis trial. Subsequently, we submitted amendments to our IND for protocols for additional trials that we have since completed on September 12, 2008, April 6, 2010, October 18, 2011 and April 13, 2012. An IND application (IND 107,846) referencing our IND (IND 77,888) was submitted by the University of Pennsylvania, School of Medicine on January 29, 2010 with a protocol for the treatment of anterior scleritis.

We have completed five clinical trials under IND 107,846 for the EGP-437 Combination Product. The first two trials were executed in parallel — a Phase 1/2 non-infectious anterior uveitis trial and a Phase 2 dry eye trial. These two trials were followed by a Phase 3 dry eye trial. Subsequently, we completed our first Phase 3 trial for non-infectious anterior uveitis. During the time that we executed the Phase 3 non-infectious anterior uveitis trial we completed a Phase 2 proof-of-concept cataract surgery trial, with prophylactic treatment of the EGP-437 Combination Product.

Protocol	Indication	Phase	No. Subjects Randomized	Control Arm
EGP-437-001	Anterior Uveitis	1/2	40	None
EGP-437-002	Dry Eye	2	105	Placebo
EGP-437-003	Dry Eye	3	198	Placebo
EGP-437-004	Anterior Uveitis	3	193	Standard of care
EGP-437-005	Cataract Surgery	2 POC	45	Placebo

Non-infectious Anterior Uveitis: Phase 1/2 Trial

Our first clinical trial initiated with the EGP-437 Combination Product was a Phase 1/2 trial for subjects with non-infectious anterior uveitis, which was defined as having anterior chamber cell (ACC) scores ≥ 1.5, i.e., cell counts ≥ 11 cells. Subjects who have anterior uveitis, exhibit a large number of white blood cells in the anterior chamber of the eye. The treatment objective is to eliminate the inflammation which can be visually confirmed when all white blood cells have been cleared from the anterior chamber. The degree of intraocular inflammation is based on a grading scheme or score that uses an ordinal scale ranging from 0 to 4, as set forth in the table below.

Grade (Score)	Cells
0	≤ 4
0.5	5 to 7
1.0	8 to 10
1.5	11 to 15
2.0	16 to 20
2.5	21 to 30
3.0	31 to 40
3.5	41 to 50
4.0	> 50

The primary objective of this exploratory study was to define a safe and effective dose of EGP-437 in subjects with non-infectious anterior segment uveitis. The secondary objective was to evaluate the systemic pharmacokinetic profile of EGP-437 (dexamethasone and dexamethasone phosphate) following ocular dosing.

This multi-site, randomized, double-masked, parallel group, dose comparison, exploratory study comprised five visits conducted over 28 days. The study population was comprised of 40 eyes of 40 subjects. Enrolled subjects were randomly assigned to receive one of four iontophoresis dose levels of EGP-437 for approximately 4 minutes with up to 10 subjects per treatment arm. Subjects received a single treatment only, at Day 0, subjects returned for examination on Days 1, 7, 14, and 28. Eligible subjects received one of the following four iontophoresis dose levels of EGP-437 (dexamethasone phosphate ophthalmic solution (40mg/mL)) for approximately 4 minutes:

- Treatment Group A: 1.6 mA-min at 0.4 mA
- Treatment Group B: 4.8 mA-min at 1.2 mA
- Treatment Group C: 10.0 mA-min at 2.5 mA

- Treatment Group D: 14.0 mA-min at 3.5 mA

Following the single treatment with the EGP-437 Combination Product, 48% of the subjects achieved an ACC score of zero within two weeks. By Day 28, 60% of the subjects achieved an ACC score of zero and required no further treatment. At Day 14, in the lowest treatment group, the proportion of subjects with an ACC count of zero was 4/10 (40%) and for all treatment groups was 7/40 (18%). At Day 28, in the lowest treatment group, the proportion of subjects with an ACC count of zero was higher at 6/10 (60%) and for all treatment groups was 14/40 (35%). The highest proportion of subjects with an ACC score or ACC count of zero was in the 1.6 mA-min at 0.4 mA treatment group at both Days 14 and 28.

		Treatment Group				
Characteristic	Statistic or Category	1.6 mA-min (N = 10)	4.8 mA-min (N = 10)	10.0 mA-min (N = 10)	14.0 mA-min (N = 10)	Total (N = 40)
ACC **Score** of Zero	Day 14	8 (80%)	6 (60%)	2 (20%)	3 (30%)	19 (48%)
	Day 28	8 (80%)	6 (60%)	5 (50%)	5 (50%)	24 (60%)
ACC **Count** of Zero	Day 14	4 (40%)	1 (10%)	1 (10%)	1 (10%)	7 (18%)
	Day 28	6 (60%)	2 (20%)	1 (10%)	5 (50%)	14 (35%)

The median time in days to an ACC score of zero ranged from a minimum of 11.5 days in the 1.6 mA-min dose group to a maximum of 31.0 days in the 14.0 mA-min dose group. The proportion of patients with an ACC score reduction of 0.5 or more on Day 28 was 80% (eight) in the 1.6 mA-min dose group and 60% (six) in the other three dose groups. The mean change in ACC score from baseline to Day 28 ranged from a maximum of -2.25 in the 1.6 mA-min dose group to a minimum of -2.00 in the 14.0 mA-min dose group. The relatively short mean times to reach an ACC score of zero in each dose group suggest that the treatment has a rapid onset of action.

The results from this trial appeared to demonstrate that the most effective EGP-437 dose level are in the 1.6 mA-min at 0.4 mA dose level. The level of association between the iontophoresis treatments and achieving an ACC Score of zero was assessed and the association was estimated to be statistically significant at a 5% level of significance (p-value = 0.032) on Day 14, suggesting that the treatment differences are larger than would be expected by chance alone. The probability-value or p-value is a number between 0.00 and 1.00, and is used to demonstrate the strength of a conclusion drawn from clinical trial data. Essentially the p-value measures consistency between the results actually obtained in the trial and the “pure chance” explanation for those results. A statement and corresponding p-value are considered of strong significance if the probability of the same reaction occurring randomly or by chance is less than 5%, corresponding to a p-value of $p<0.05$.

This trial showed low short-term systemic exposure to dexamethasone following ocular iontophoresis delivery of dexamethasone phosphate, and no corticosteroid mediated effects were observed.

While this dose-ranging study did not include positive or negative controls, the results demonstrated that a single treatment with the EGP-437 Combination Product: (1) lowered ACC scores in the majority of patients without requiring additional treatment and (2) produced low short-term systemic exposure to dexamethasone and dexamethasone phosphate.

Non-infectious Anterior Uveitis: Phase 3 Clinical Trial

Our previous Phase 1/2 non-infectious anterior uveitis clinical trial, and two dry eye clinical trials, showed that the EGP-437 dose selected for the Phase 3 non-infectious anterior uveitis trial was well tolerated and demonstrated positive activity. The Phase 3 non-infectious anterior uveitis clinical trial was conducted to assess safety and efficacy of the EGP-437 Combination Product and evaluate its non-inferiority status to a standard of care, PA. Communication received from the FDA, dated December 3, 2007, stated that the FDA recommends that PA, administered at least four times per day (q.i.d.), be the positive control agent for the treatment of anterior uveitis. Our trial utilized a more stringent regimen for the positive control of eight times per day in week one and six times per day in week two before going to four times per day in weeks three and four. Patients had to agree to comply with dosing regimen to be included in the trial.

The recently completed Phase 3 non-inferiority study in patients with non-infectious anterior uveitis, appeared to demonstrate that two iontophoretic treatments with our EGP-437 Combination Product achieved the same response rate as the positive control for the primary efficacy endpoint, a complete clearing of anterior chamber cells, by day 14. The control is the current standard of care, PA, which was administered multiple times daily as eye drops. Although we achieved the same response rate in our Phase 3 clinical trial, the dose of the EGP-437 Combination Product tested was just outside the pre-set non-inferiority margin for intent-to-treat and per protocol populations and did not achieve statistical significance in the intent-to-treat population as compared to the positive control based on the primary efficacy endpoint.

- The EGP-437 Combination Product produced the same outcomes compared to PA while eliminating the need to apply up to 8 eye drops a day, for a total of 154 drops over a four week period — eight times per day for week one, six times per day for week two and four times per day for weeks three and four.

- This was achieved with a lower incidence of increased IOP, which is characterized as an increase of six mm Hg or more from baseline; in the EGP-437 Combined Product group, 14 subjects had 17 occurrences while 24 subjects had 41 occurrences in the PA arm.

In this randomized, double-masked placebo-controlled non-inferiority study conducted at 45 clinical sites in the U.S., a total of 193 patients were randomly assigned into one of two treatment arms. One arm received two iontophoretic treatments of EGP-437, one at day 0 and one at day 7 along with placebo drops and the other arm received 154 treatments of PA over a 28 day period along with two placebo iontophoretic treatments. The primary efficacy endpoint is the proportion of patients with anterior chamber cell (ACC) count of zero on day 14, which is defined as a complete response.

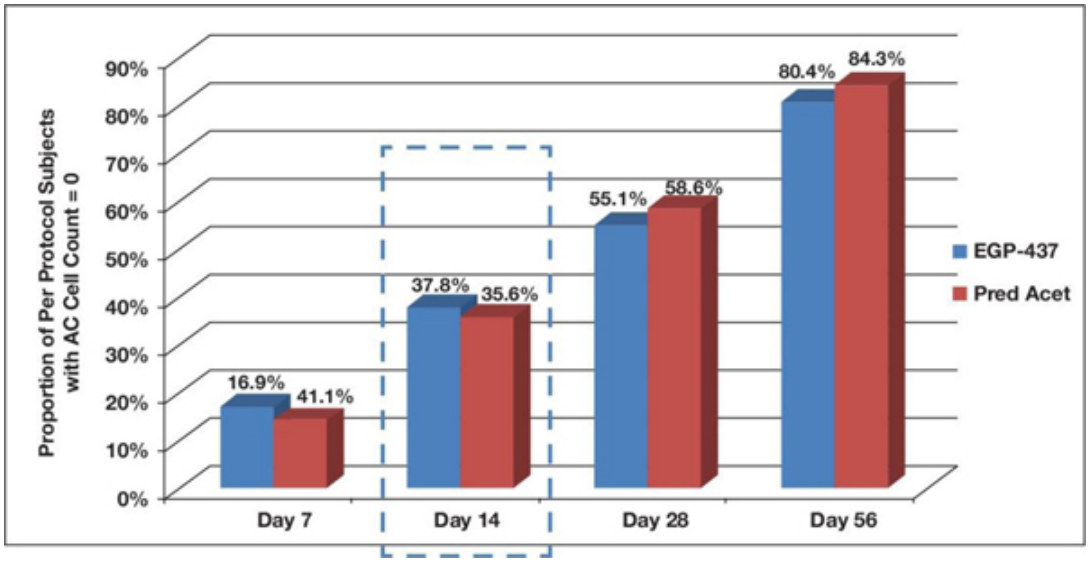
The following results are based on two different patient populations, the intent to treat, or ITT, and the per protocol, or PP:

- ITT population (193 patients): all randomized patients who have been treated with at least one dose of study medication, have a valid baseline efficacy and at least one valid post-randomization efficacy measurement and all data associated with these subjects, until the visit following initiation of any rescue therapy; therefore, the number of subjects for this population dwindles over-time.

- PP population (169 patients): all ITT patients for whom there exists a Day 14 value of ACC count (inclusive of zero anterior chamber cells) and without any significant protocol deviations. The protocol deviations are determined prior to unmasking the data so that we are unable to determine which arm the subject is in. Twenty-four subjects had significant protocol deviations occurring at or before Day 14: Fourteen in the EGP-437 Combination Product arm and ten in the PA arm. Ten of the fourteen subjects in the EGP-437 Combination Product arm and eight of the ten subjects in the PA arm were either rescued and/or did not receive a second iontophoresis treatment or full amount of study drug. In the EGP-437 Combination Product arm, one subject had non-ocular surgery, two subjects were unable to continue with follow-up visits and one subject withdrew consent. In the PA arm two subjects had their Day 14 visit 12 and 30 days outside of the visit window.

Regarding the primary efficacy endpoint for the ITT population, the EGP-437 Combination Product arm resulted in 32/96 complete responses; the PA arm yielded a similar result, 32/97 complete responses. While there is no difference in response rates, at the 95% confidence interval, the non-inferiority margin is -12.94%, which is just outside the pre-set non-inferiority margin of -10% (p-value = 0.06).

In the PP population, the EGP-437 Combination Product arm resulted in 31 complete responses out of 82 patients (37.8%) on day 14; and the PA arm also yielded 31 complete responses out of 87 patients (35.6%). At the 95% confidence interval, the non-inferiority margin is -12.37%, which is just outside the pre-set non-inferiority margin of -10% (p-value = 0.05).



In order to be randomized into the study, a subject required 11 cells or greater in the anterior chamber. In the EGP-437 Combination Product arm 52 of 96 subjects (54.2%) had a baseline ACC count greater than 25, versus the PA arm which had 40 of 97 subjects (41.2%). Given the imbalance in this uveitis severity at baseline, a post-hoc analysis was performed on subjects stratified by baseline ACC counts of 11 to 25 or greater than 25. In the more severe uveitis subgroup (ACC count of greater than 25), which may be more difficult to treat than the subgroup of ACC count 11 to 25, better efficacy was seen with our EGP-437 Combination Product compared with the PA arm.

Population	EGP-437 Combination Product	PA
ITT	25%	20%
PP	27%	22%

Some secondary endpoints include the following:

1. Time to ACC count of zero

In spite of the difference in baseline severity, both the EGP-437 Combination Product arm and the PA arms are consistent and clinically comparable in their efficacy as shown by time to achieving an ACC count of zero. From baseline to Day 28 both arms show a gradual increase in the probability of AC cell count of zero and by Day 28 the probability of reaching an ACC count of zero is approximately 45% for both the EGP-437 Combination Product arm and the PA arm. Statistical analysis was not performed.

2. Proportion of subjects with ACC count of zero at visits 2, 4, 5 (Days 7, 28, 56)

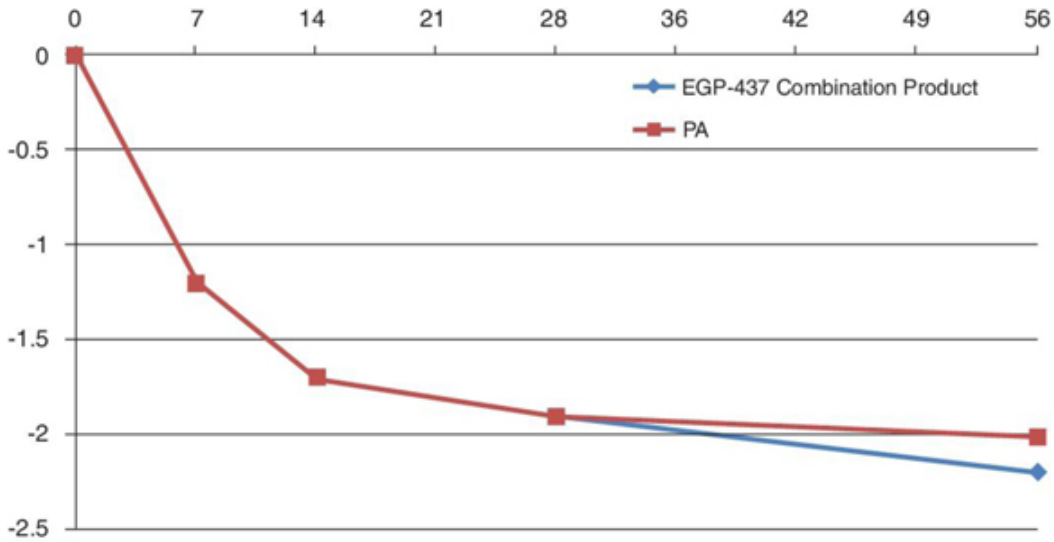
Of particular interest was the onset of apparent efficacy. This was assessed by the number of subjects with an ACC count of zero as early as Day 7, i.e. after just one iontophoresis. The EGP-437 Combination Product was found to be better than PA, especially at Day 7, where the percentage of subjects achieving ACC count of zero is compared: 16.9% and 14.1% at Day 7 in the ITT population in EGP-437 Combination Product and PA, respectively. The difference between the two arms was 2.72%. At the 95% confidence interval, the non-inferiority margin is -7.82%, which is better than the pre-set non-inferiority margin of -10%.

3. Proportion of subjects with a reduction in ACC score from baseline of one or more units at all study visits

The Standardization of Uveitis Nomenclature (SUN) working group of 2004 agreed that although inactive disease (ACC count of zero) is the goal of therapy, for the short-term evaluation of new therapies a two-step increase or decrease in the level of inflammation may be a better criterion than one-step changes. Consequently, an additional secondary analysis, the proportion of subjects with reduction in ACC count, represented here by reduction in cell “Score”, from baseline of one or more units, at study visits, was performed. In this analysis the two treatments arms appear similar, especially by Day 14. The difference between the two arms at Day 14 was -3.042%. At the 95% confidence interval, the non-inferiority margin is -13.97%, which is just outside the pre-set non-inferiority margin of -10%.

4. Mean change from baseline in ACC score at all study visits 2 – 5

The mean changes from baseline scores for both study arms are identical through Day 28 (Day 7: -1.2, Day 14: -1.7 and Day 28: -1.9), and differ only slightly at Day 56 in favor of the EGP-437 Combination Product. (-2.2 in EGP-437 Combination Product arm; -2.0 in PA arm). Statistical analysis was not performed.



Phase 3 Safety Discussion

Our EGP-437 Combination Product appears to be clinically comparable to PA topical drops. With regard to elevated IOP, no subjects in the EGP-437 Combination Product treatment arm experienced any significant increase in IOP (greater than 20mmHg), whereas the PA treatment arm had one subject with a reported IOP increase of 27mmHg. With regard to IOP-related adverse events, one subject in the EGP-437 Combination Product treatment group reported an adverse event (seen approximately three weeks after rescue was initiated) and six subjects in the PA treatment arm reported adverse events related to IOP.

Phase 3 Clinical Trial Conclusion

Topical corticosteroid therapy administered as frequently as every hour with tapering over the treatment period has been the mainstay for uveitis treatment since the 1950s. In this unique Phase 3 randomized, double-masked, positive-controlled clinical trial in subjects with non-infectious anterior uveitis, two treatments with ocular iontophoretic delivery of EGP-437 appears to be clinically comparable to PA topical drops administered with a tapering schedule from eight drops per day to four drops per day over 28 days.

By days seven and fourteen, the proportion of subjects reaching ACC counts of zero was slightly greater in the EGP-437 Combination Product arm than the PA arm. This effect was more noticeable in the subgroup of subjects with a higher baseline ACC count; a higher proportion of subjects in the EGP-437 Combination Product arm reached an ACC count of zero by Days 7 and 14 in this sub-group of subjects. Safety findings were comparable for both study arms.

Dry Eye: Phase 2 Trial

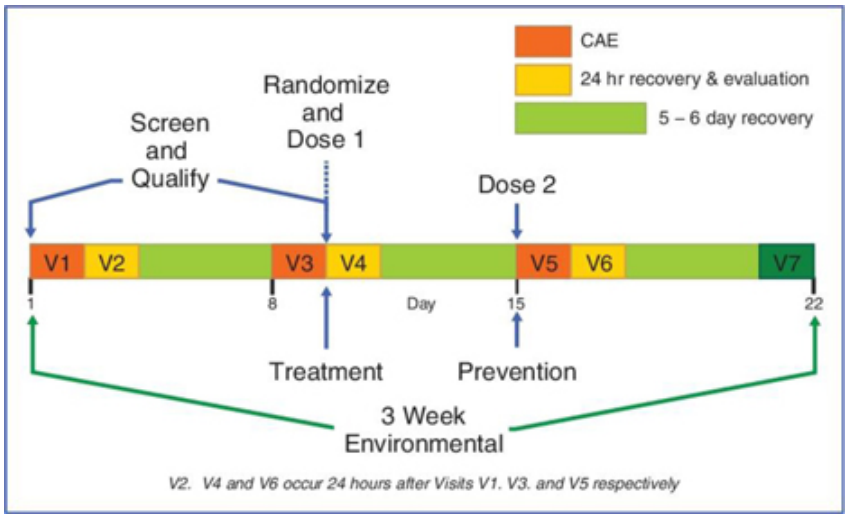
105 subjects were randomized into this 3-armed, single-center, randomized, double-masked, placebo-controlled trial comprised seven visits conducted over three weeks. The objective of this trial was to assess the safety and efficacy of the EGP-437 Combination Product for the treatment of the signs and symptoms of dry eye. Two sets of iontophoresis conditions (7.5 mA-min at 2.5 mA and 10.5 mA-min at 3.5 mA) to create a low-dose and a high-dose group. The control group received ocular iontophoresis of 100 mM sodium citrate buffer (10.5 mA-min at 3.5 mA).

Treatment Group			
7.5 mA-min at 2.5 mA	**10.5 mA-min at 3.5 mA**	**Placebo**	**Total**
41	38	26	105

The controlled adverse environmental (CAE) system was used to reproducibly exacerbate the signs and symptoms of dry eye disease. The CAE is a clinical model emulating some environmental conditions (low humidity, high temperature, visual tasking) that contribute to drying the ocular surface. The CAE system exacerbates the signs and symptoms of dry eye in a reproducible manner. The CAE model has been shown to correlate with accepted murine models of dry eye and has been used extensively in ophthalmic clinical trials. The main objective of the CAE system is for screening and eligibility purposes. A baseline reading of various signs and symptoms of the disease are taken prior and post to exacerbation by the CAE system. A week later this is repeated and the subjects that acted in a reproducible manner are enrolled into the study. This is important as dry eye is a syndrome that is caused by many different etiologies and one treatment may not be sufficient for all.

The trial was designed to evaluate effects among different clinical scenarios, including: Treatment, the effects of treatment with the EGP-437 Combination Product following CAE-induced signs and symptoms; Prevention, the effects of treatment with the EGP-437 Combination Product prior to CAE exposure; Recovery, the effects of treatment with the EGP-437 Combination Product on recovery towards baseline at follow-up visits (24 hours and 7 days after CAE); and Environmental (periods of time not directly influenced by the CAE), the ability of the EGP-437 Combination Product to improve dry eye signs and symptoms over the entire 3-week study period.

The trial included seven visits over three weeks: subjects were exposed to the CAE for 90 minutes at three visits (visits 1, 3, and 5 — CAE visits), and the remaining visits (visits 2, 4, 6, 7) were conducted for follow-up.



At each trial visit (both pre- and post-CAE at Visits 1, 3 and 5), dry eye signs (corneal and conjunctival staining, conjunctival redness, tear film break-up time, or TFBUT, blink rate, ocular protection index (OPI), and corneal sensitivity) and symptoms (ocular discomfort before, during, and after the CAE exposure, several symptom questionnaires) were evaluated. Subjects also recorded morning, afternoon and evening dry eye symptoms in a diary on each day of the trial.

Signs

The low dose treatment group of the EGP-437 Combination Product when compared to placebo demonstrated on a statistically significant basis less lissamine green corneal staining pre- to post-CAE at visit 5 in the superior region ($p = 0.039$). Statistically significant improvements in TFBUT were also observed for the low dose treatment group of the EGP-437 Combination Product relative to placebo at visit 5 pre- and post-CAE ($p = 0.034$, 0.049, respectively) and at visit 7 ($p = 0.042$). Statistically significant improvements in OPI were also observed for the low dose treatment relative to placebo at visit 5 post-CAE ($p = 0.048$).

At visit 7, statistically significant differences between the low dose treatment and placebo groups were documented, including TFBUT ($p = 0.042$). When comparing endpoints across the entire trial's duration ("environmental"), for example, the changes in fluorescein staining from visit 1 pre-CAE to visit 7 fluorescein staining, a statistically significant decrease in the inferior region was revealed for the low dose treatment group over placebo ($p = 0.038$). Fluorescein staining in the inferior region is recognized as an important sign of dry eye disease, because this area represents a region specifically vulnerable to exacerbation by stress conditions, including those presented in the CAE model.

Symptoms

The differences in the mean ocular discomfort scores (for low dose treatment group of the EGP-437 Combination Product versus placebo) at several discrete time points during the visit 5 CAE exposure were statistically significant. In order to determine if the subjects reporting lower ocular discomfort scores during the visit 5 CAE experienced improvements in any relevant dry eye signs, two sub-groups of subjects were evaluated: those demonstrating ocular discomfort scores of < 3 and those demonstrating ocular discomfort scores < 4 at all time points between 50 and 90 minutes during visit 5 CAE exposure. Interestingly, the visit 6 and 7 data for subjects in the sub-group scoring < 4 at all time points between 50 and 90 minutes during visit 5 CAE exposure demonstrated significantly longer mean TFBUTs for both active treatment groups compared to the placebo group. In addition, ocular discomfort at visits 4 and 6 was statistically significantly lower in the low dose treatment group versus placebo ($p = 0.032$ and $p = 0.0032$, respectively).

In this exploratory study, the EGP-437 Combination Product suggested potential improvements in a variety of signs and symptoms of dry eye relative to placebo. Some positive effects were observed within 24 hours of treatment and over the three-week study period, which suggest a rapid onset of action and the potential for long-term effectiveness. Since multiple statistically significant observations were made across a variety of visits and endpoints, it appears that the effects are treatment related (i.e., the probability of incorrectly identifying statistical significance via the α level of 0.05). Based on all endpoints analyzed, it appears that the lower dose is more beneficial than the higher dose.

Dry Eye: Phase 3 Trial

The Phase 3 trial design is similar to the Phase 2 trial design. However, the Phase 2 trial comprised seven visits conducted over three weeks while the Phase 3 trial comprised nine visits conducted over nine weeks. The Phase 3 trial was intended to confirm and extend the results from the Phase 2 trial. The Phase 3 trial was designed to assess the safety and efficacy of the EGP-437 Combination Product under conditions of 4.0 mA-min at 1.5 mA (low dose treatment group) and 6.5 mA-min at 2.5 mA (high dose treatment group) compared to ocular iontophoresis with placebo for the treatment of the signs and symptoms of dry eye. There were 198 subjects enrolled in the trial with 66 subjects assigned to the low dose treatment group, 66 subjects assigned to high dose treatment group, and 66 subjects were assigned to the placebo group.

This was a multi-center, randomized, double masked, placebo-controlled study which comprised nine visits conducted over approximately nine weeks using the CAE chamber. The CAE chamber was used at visit 1 (Day -7), visit 2 (Day 0), and visit 4 (Day +7) to reproducibly exacerbate dry eye signs and symptoms in a subject population selected for evidence of ongoing moderate to severe dry eye disease. Each subject received two sessions of iontophoresis (both eyes treated in each session): the first at 60 minutes after the CAE exposure at visit 2, and the second at 60 minutes before the CAE exposure at visit 4. Visits 3 and 5 took place 24 hours after visits 2 and 4, respectively, as follow-up evaluations. Visits 7, 8, and 9, took place on days 21, 28, and 56, respectively, and served to evaluated duration of action and long-term safety. At all visits (both pre- and post-CAE at visits 1, 2 and 4), dry eye signs (corneal and conjunctival staining, conjunctival redness, TFBUT, blink rate, ocular protection index (OPI), and corneal sensitivity) and symptoms (ocular discomfort before, during, and after the CAE exposure, several symptom questionnaires) were evaluated. Subjects also recorded morning, afternoon, and evening dry eye symptoms in a diary on each day of the study.

The study design allowed the effectiveness of the EGP-437 Combination Product to be assessed in different clinical scenarios: treatment, the effects of the EGP-437 Combination Product following the CAE-induced dry eye signs and symptoms; prevention, the effects of the EGP-437 Combination Product prior to the CAE-induced dry eye signs and symptoms; recovery, the effects of the EGP-437 Combination Product on the recovery towards baseline at 24 hours and 7 days post-CAE; and Environmental, the ability of the EGP-437 Combination Product to improve baseline dry eye signs and symptoms over the study period. Improvements in the EGP-437 Combination Product treatment groups relative to the placebo group at the 24-hour follow-up visits (visits 3 and 5), or post-CAE at visit 4, would be evidence of a rapid onset of action. Improvements relative to the placebo group pre-CAE at visit 4 or at visit 6 through visit 9 would be interpreted as evidence of a long duration of action.

Signs

Although, statistical significance was not met for the primary endpoint for a sign, which was fluorescein staining of the inferior region of the cornea at visit 6 (day 14), statistical significance for the high dose treatment group relative to the placebo group was demonstrated at visit 3 and for change from baseline to visit 3 ($p=0.0366$ and $p=0.0084$ respectively). Fluorescein staining of the total cornea at visit 3 and for change in baseline to visit 3 was also statistically significant with $p=0.05$ for both. Other signs also showed statistical significance at various visits, including lissamine green staining, conjunctival redness and TFBUT.

Conjunctival Redness

Time Point	p-value
Visit 3	0.0004
Visit 3 Change from baseline	0.0038
Visit 4: Post CAE	0.0077
Visit 4: Change from pre CAE to post CAE	0.0080

Symptoms

Although the primary endpoint for symptom of ocular discomfort at visit 5 (Day 8) compared to placebo was not statistically significant, the ocular discomfort score at visit 4 showing the change from 0 to 90 minutes while in the CAE was statistically significant for both the low and high treatment dose groups as compared to the placebo group (p=0.0003 and p=<0.0001 respectively). Also, the ocular surface disease index (OSDI) was statistically significant for the low dose treatment group as compared to placebo at visit 4 and visit 6 for change from baseline (p=0.0266 and p=0.0247 respectively). Other symptoms also showed statistical significance at various visits, including a 4 symptom questionnaire and the diary data assessing dryness.

Questionnaire: Burning

Time Point	p-value
Visit 4 Change from baseline	0.0034
Visit 7 Change from baseline	0.0130
Visit 8 Change from baseline	0.0181

The improvements documented in dry eye signs and symptoms relative to the placebo group indicate that the treatments with the EGP-437 Combination Product had both a rapid onset of action and a long-term effectiveness.

Rapid Onset: Statistically significant improvements for the following endpoints were noted at a 24-hour follow-up visit (visit 3 or visit 5), or post-CAE at visit 4, and are interpreted as evidence for a rapid onset of action.

- Fluorescein staining (inferior, superior, temporal, corneal sum, conjunctival sum)
- Lissamine green staining (inferior, nasal, total sum)
- Conjunctival redness
- TFBUT
- 4-Symptom questionnaire (burning, dryness, grittiness)

Long-term Effectiveness: The EGP-437 Combination Product treatment groups showed statistically significant improvements over the placebo group in the following endpoints pre-CAE at visit 4, at visits 6, 7, 8, or 9, or in the changes from baseline to visits 6, 7, 8, or 9, and are interpreted as evidence for a long duration of action.

- Fluorescein staining (nasal conjunctival region)
- Lissamine green staining (nasal, temporal conjunctival, corneal sum, conjunctival sum)
- Conjunctival redness
- 4-Symptom questionnaire (burning, stinging)
- OSDI Questionnaire
- Diary data (dryness)

The 24-hr follow-up visits evaluate the effectiveness of the EGP-437 Combination Product in treatment mode (visit 3) or in prevention mode (visit 5). Improvements observed in dry eye signs (corneal staining, conjunctival staining and conjunctival redness) at visits 3 and 5, and in the changes from baseline to visits 3 or 5, demonstrate that the two EGP-437 Combination Product treatments may aid healing in these regions.

The improvements in dry eye symptoms (burning, stinging, dryness) demonstrated at visit 6, 7, 8, or 9, and in the changes from baseline to visits 6, 7, 8, or 9, demonstrate that the 2 EGP-437 Combination Product treatments have a long duration of action in relief of these symptoms.

Clinical Development Plan

Our main focus will be the completion of two back-of-the-eye trials, a dose curve trial followed by a macular edema trial using the EGP-437 Combination Product. We estimate that we will have top-line data for the macular edema trial by the end of the year 2015.

We have completed two trials (Phase 1/2 and Phase 3) for anterior uveitis and have demonstrated in a completed Phase 3 non-inferiority study that two iontophoretic treatments with our EGP-437 Combination Product achieved the same response rate as the positive control for the primary efficacy endpoint, a complete clearing of anterior chamber cells, by day 14. This was achieved with a lower incidence of increased IOP, which is characterized as an increase of six mm Hg or more from baseline. We believe that one more Phase 3 clinical trial demonstrating non-inferiority against PA will be sufficient for NDA submission and will seek to initiate this trial once we raise additional funds.

We have completed two trials (Phase 2 and Phase 3) for dry eye and have demonstrated significant improvements in a variety of signs and symptoms of dry eye relative to placebo. Dry eye is a syndrome with many different etiologies and with a pathology that is multifactorial making it difficult to enroll a homogenous group of patients for a trial, hence why we used the CAE system. We believe that dry eye fulfills our criteria and will be one of the indications on our priority list for further development. If we move forward with another trial for dry eye, we will seek an alternative way to determine eligibility for enrollment, without the assistance of the CAE system.

We have completed a proof-of-concept study for the treatment of inflammation post cataract surgery. In this exploratory study we utilized the EGP-437 Combination Product in a prophylactic manner, by providing the treatment one day prior to the surgery. There is a large market opportunity in being able to eliminate the requirement of anti-inflammatory eye drops post-surgery for this elderly patient population. The decision was made for prophylactic treatment to avoid placing the device on an open wound post-surgery. Unfortunately, the surgical procedure eliminates or washes out any remaining drug product from the ocular tissue that becomes inflamed post-surgery. If we are able to determine a way of providing the treatment while keeping intact the economic proposition for us (i.e. reimbursement separate from the surgical procedure) then this indication will be considered for further development.

Easy-to-Use Ocular Delivery System

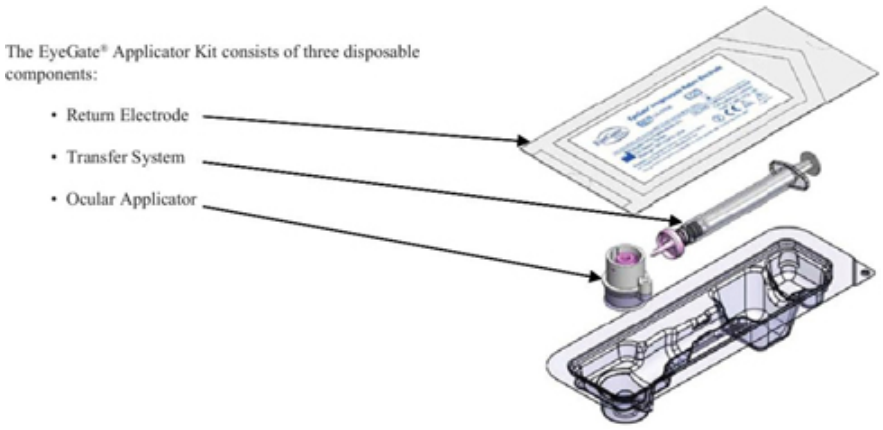
The EGP-437 Combination Product utilizes a proprietary transscleral iontophoresis delivery system, the EyeGate® II Delivery System, which was originally designed at the Bascom Palmer Eye Institute at the University of Miami. Through animal studies and eventually a proof-of-concept clinical study in humans the original prototype was optimized and ultimately became the Eyegate® II Delivery System. We hold worldwide commercialization rights to the EyeGate® II Delivery System. The system utilizes a low electrical current to deliver a specified amount of drug for each treatment. The system used in clinical trials consists of: a reusable battery-powered generator, a disposable applicator kit and a vial that contains the drug. Over 1,700 experimental treatments have been performed with the system with more than 1,000 of these experimental treatments delivering the EGP-437 Combination Product during the development program.

The EyeGate® II Delivery System consists of the following key components:

- An applicator kit that includes:
    - An applicator used to deliver the drug product to the eye;
    - A syringe and adapter transfer system for transferring the drug product from a vial to the applicator; and
    - A return electrode to complete the continuous current circuit;

- A vial containing the drug product; and
- A generator that provides a constant current to the electrode of the applicator.

Applicator Kit



Ocular Applicator

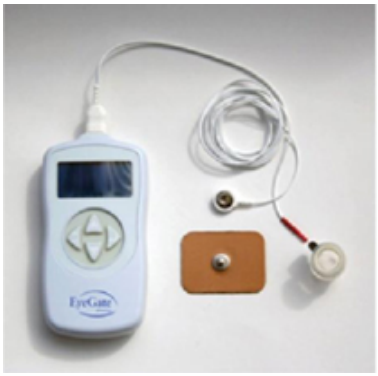
The iontophoresis applicator is annular in shape, and designed to fit over the sclera of the eye, to allow direct delivery of drug to the eye. The inner diameter of the applicator is the same diameter as the average cornea to help facilitate the centering of the device on the eye.

The contact between the eye and the applicator consists of soft foam; this foam serves as the reservoir for the drug product to be delivered during treatment.

The applicator is provided as a sterile, single-use, disposable device.

EyeGate Generator

The EyeGate generator is a hand-held battery powered device designed to deliver a constant current to the applicator. The display shows real time delivery of the current, the amount of dose delivered, and the time remaining in the treatment.



Intellectual Property and Proprietary Rights

Overview

We are building an intellectual property portfolio for our EGP-437 Combination Product, as well as other devices and product candidates for treatment of ocular indications in the U.S. and abroad. We currently seek, and intend to continue to seek, patent protection in the U.S. and internationally for our product candidates, methods of use, and processes for manufacture, and for other technologies, where appropriate. Our current policy is to actively seek to protect our proprietary position by, among other things, filing patent applications in the U.S. and abroad relating to proprietary technologies that are important to the development of our business. We also rely on, and will continue to rely on, trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for the technologies that we consider important to our business, our ability to defend our patents, and our ability to preserve the confidentiality of our trade secrets and operate our business without infringing the patents and proprietary rights of third parties.

Patent Portfolio

Our patent portfolio includes drug delivery device patents directed to the EyeGate® II Delivery System and other drug delivery devices, drug composition patent applications directed to EGP-437 and other product candidates, and patent applications directed to methods of treatment utilizing EGP-437, as well as the other product candidates. These patents and patent applications, if they were to issue, are expected to expire between 2018 and 2029.

We have been developing drugs and drug delivery systems for non-invasive treatment on the eye for several years. These delivery systems include various patented and patent pending iontophoretic drug delivery devices that have been individually designed to treat components of the eye, such as the cornea, sclera, and combinations thereof. These devices have been further improved to provide better patient comfort levels as well as treatment times. The ever growing delivery system patent portfolio consists of eight Patent families, which includes thirteen U.S. Patents, fifty-nine corresponding International Patents, three pending U.S. Patent Applications, and fifteen corresponding pending International Patent Applications. We hold three patents and seventy-one of our patents are held by our subsidiary, EyeGate Pharma S.A.S., a French corporation, or EyeGate S.A.S.

We have also developed patent pending drug compositions that work with our patented delivery systems and treatments utilizing these drug compositions and patent delivery systems. This includes two Patent families with two International Patents, three U.S. Patent Applications and five corresponding International Patent Applications.

License Agreements

Eyegate S.A.S., is party to a certain Amended and Restated License Agreement with the University of Miami and its School of Medicine, dated as of December 16, 2005. This license agreement grants us the right to use certain French, European, Canadian, Japanese, American, Mexican, Korean, Brazilian and Israeli patents in our EGP-437 Combination Product. Under this agreement, we are obligated to pay an annual license fee of $12,500, certain milestone payments pertaining to EGP-437 Combination Product development milestones, and following the commercialization of EGP-437 Combination Product, royalties based on percentages (in the low single digits) of the net sales of any products we sell that are subject to the license agreement, which would include our EGP-437 Combination Product relating to its incorporation of the EyeGate® II Delivery System. All annual license fee and milestone payments have been paid to date. The total amount of milestone payments paid to date under this license agreement is $30,000 and there are potential aggregate additional amounts of up to $150,000 due on certain milestones being met. On July 7, 2014, we entered into an amendment to such license agreement, whereby the parties agreed to eliminate the minimum royalty provisions and related obligations in exchange for the increase of certain future milestone payments as well as the issuance of 15,036 shares of our common stock to the licensor. This license agreement remains in effect until the later of twelve (12) years after the date of the first commercial sale of the applicable product or the date of the last to expire patent relating to the patent rights under the Agreement. Upon such expiration and assuming it was not terminated earlier in accordance with its terms, we retain a fully paid up and perpetual license to the product and certain intellectual property. The license agreement also provides that it may be terminated by either party in the case of continued material breach or provision of false reports, by the licensor pertaining to certain bankruptcy or insolvency circumstances regarding our company or by us upon ninety (90) days prior written notice.

EyeGate S.A.S. is also party to a certain perpetual Transaction Protocol agreement with Francine Behar-Cohen, dated as of July 23, 1999. This agreement acknowledges our right to use certain patents that Ms. Behar-Cohen had certain ownership rights with respect to and which are used in our EGP-437 Combination Product. The agreement also provides for us to pay Ms. Behar-Cohen a fee based on a percentage (in the low single digits) of the pre-tax turnover generated from sales of our EGP-437 Combination Product relating to its inclusion of the EyeGate® II Delivery System. The fees due under the agreement are required to be paid until January 2018.

Confidential Information and Inventions Assignment Agreements

We currently require and will continue to require each of our employees and consultants to execute confidentiality agreements upon the commencement of such individual's employment, consulting or collaborative relationships with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not disclosed to third parties except in specific circumstances.

In the case of employees, the agreements provide that all inventions resulting from such individual's work performed for us, utilizing our property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law. Our consulting agreements also provide for assignment to us of any intellectual property resulting from services performed by a consultant for us.

Sales and Marketing

In light of our stage of development, we have not yet established a commercial organization or distribution capabilities. We generally expect to retain commercial rights in the U.S. for our product candidates for which we may receive marketing approvals and which we believe that we can commercialize through a focused, specialty sales force. We expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize the EGP-437 Combination Product and any other products that we develop in markets outside the U.S.

We hold worldwide commercialization rights to EGP-437 and the EyeGate® II Delivery System. We believe that specialists in the U.S. who treat most of the non-infectious anterior uveitis patients are sufficiently concentrated that if our EGP-437 Combination Product receives marketing approval in the U.S. we could effectively promote the EGP-437 Combination Product to these specialists with a specialty sales and marketing group. Therefore, we may decide to build our own focused, specialty sales force in order to commercialize the EGP-437 Combination Product in the U.S.

We also plan to build key capabilities, such as marketing, market access, sales management and medical affairs, to implement marketing and medical strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with thought leaders in relevant fields of medicine.

Manufacturing

We do not have, and do not intend to establish an in-house manufacturing capability for our products and as a result we will depend heavily on third-party contract manufacturers to produce and package our products. We currently do not have any contractual relationships with third-party manufacturers. We intend to rely on third-party suppliers that we have used in the past for the manufacturing of various components that comprise our EGP-437 Combination Product that will be used in our confirmatory Phase 3 trial and other contemplated clinical trials.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Our potential competitors include large pharmaceutical and biotechnology companies, and specialty pharmaceutical and generic drug companies. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of each of our product candidates, if approved for marketing, are likely to be its efficacy, safety, method of administration, convenience, price, the level of generic competition and the availability of coverage and adequate reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors' establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third party payors seeking to encourage the use of generic products. Generic products currently being used for the indications that we may pursue, and additional products are expected to become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

Our competitors in the treatment of non-infectious anterior uveitis include Durezol® (Novartis AG), Lotemax® (Valeant Pharmaceuticals International, Inc.), Pred Forte® (Allergan, Inc.) and prednisolone acetate ophthalmic suspension (1%) (Novartis AG).

Government Regulation

FDA Approval Process

In the U.S., pharmaceutical products are subject to extensive regulation by the FDA. The Food Drug and Cosmetic Act, or FDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, a clinical hold, warning letters, recall or seizure of products, partial or total suspension of production, withdrawal of the product from the market, injunctions, fines, civil penalties or criminal prosecution.

FDA approval is required before any new drug, can be marketed in the U.S. The process required by the FDA before a new drug product may be marketed in the U.S. generally involves:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulation;
- submission to the FDA of an IND for human clinical testing which must become effective before human clinical trials may begin in the U.S.;
- approval by an independent institutional review board, or IRB, at each site where a clinical trial will be performed before the trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed product candidate for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's cGMP regulations;
- submission to the FDA of a new drug application, or NDA, which must be accepted for filing by the FDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- payment of user fees, if applicable; and
- FDA review and approval of the NDA.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources. Pre-clinical tests include laboratory evaluation of product chemistry, formulation, manufacturing and control procedures and stability, as well as animal studies to assess the toxicity and other safety characteristics of the product. The results of preclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A clinical hold may occur at any time during the life of an IND and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the results of the clinical trials must be submitted at least annually. In addition, timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- *Phase 1:* The product is initially introduced into healthy human patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.

- *Phase 2:* The product is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive clinical trials.

- *Phase 3:* These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product appears to be effective and has an acceptable safety profile, trials are undertaken in large patient populations to further evaluate dosage, to obtain additional evidence of clinical efficacy and safety in an expanded patient population at multiple, geographically-dispersed clinical trial sites, to establish the overall risk-benefit relationship of the product and to provide adequate information for the labeling of the product.

- *Phase 4:* In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials to further assess the product's safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase 4 studies.

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

Section 505(b)(2) New Drug Applications

According to section 505 of the FDCA, there are three types of new drug applications: (1) an application that contains full reports of investigations of safety and effectiveness (section 505(b)(1)); (2) an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference from the entity that performed the studies (section 505(b)(2)); and (3) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product (section 505(j)). We intend to submit a 505(b)(2) NDA for our EGP-437 Combination Product.

Section 505(b)(2) of the FDCA enables an applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its NDA. Using this approval pathway may allow us to rely in part on information in the public domain to support the safety and effectiveness of EGP-437. The FDA may also require sponsors to perform additional clinical trials, measurements, or other types of studies or assessments (e.g., bridging studies) to support any change from the previously approved product. The review process is lengthy and often difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA or an approved letter following satisfactory completion of all aspects of the review process. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured.

To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the 505(b)(2) applicant must submit patent certifications in its 505(b)(2) application with respect to any patents listed for the approved product on which the application relies in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the Orange Book). Specifically, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA application until all the unchallenged listed patents claiming the referenced product have expired. Further, the FDA will also not accept or approve, as applicable, a Section 505(b)(2) NDA application until any non-patent exclusivity, such as exclusivity for obtaining approval of a New Chemical Entity, listed in the Orange Book for the referenced product, has expired.

If the 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the referenced NDA for the previously approved product and relevant patent holders within 20 days after the 505(b)(2) NDA has been accepted for submission by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months, or until a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. Moreover, in cases where a 505(b)(2) application containing a Paragraph IV certification is submitted during a previously approved drug's five year exclusivity period, the 30-month period is automatically extended to prevent approval of the 505(b)(2) application until the date that is seven and one-half years after approval of the previously approved reference product. The court also has the ability to shorten or lengthen either the 30 month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA applicant or relevant patent holder does not file a patent infringement lawsuit within the specified 45 day period, the 30 month stay will not prevent approval of the 505(b)(2) application.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDAs that we submit.

In the NDA submissions for our product candidates, we intend to follow the development and approval pathway permitted under the FDCA that we believe will maximize the commercial opportunities for these product candidates.

Combination Product Regulations

Medical products containing a combination of new drugs, biological products, or medical devices may be regulated as "combination products" in the U.S. A combination product generally is defined as a product comprised of components from two or more regulatory categories, such as drug/device, device/biologic, or drug/biologic. Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic, or device. In order to facilitate premarket review of combination products, the FDA designates one of its centers to have primary jurisdiction for the premarket review and regulation of both components. We expect that the Center for Drug Evaluation and Research will have primary jurisdiction over out EGP-437 Combination Product. The determination whether a product is a combination product or two separate products is made by the FDA on a case-by-case basis. We have had discussions with the FDA about the status of our EGP-437 Combination Product as a combination product and we have been told that the FDA considers our product a combination drug/device.

We will be subject to regulations governing medical devices separate from those governing drugs. After the FDA permits a device to enter commercial distribution, however, numerous regulatory requirements apply. These include:

- product labeling regulations;
- general prohibition against promoting products for unapproved or "off-label" uses;
- corrections and removals (e.g., recalls);
- establishment registration and device listing;
- general prohibitions against the manufacture and distribution of adulterated and misbranded devices; and
- the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

Failure to comply with these regulatory requirements could result in civil fines, product seizures, injunctions, and/or criminal prosecution of responsible individuals and us.

Approval or Clearance of Medical Devices

Medical devices, such as our EyeGate® II Delivery System, may be evaluated either through the premarket approval, or PMA process, or the 510(k) clearance process, depending on the classification of the device. The regulatory classification for the Eyegate® II Delivery System is defined under Code of Federations Regulations 21, Part 890, section 5525 (21 CFR 890.5525). The FDA has confirmed that the EyeGate® II Delivery System will be submitted under the 510(k) clearance process. The FDA has further clarified the Code to state that an iontophoresis device intended for use with a specific drug that has been approved for delivery by iontophoresis is a class II device. The Eyegate® II Delivery System will be indicated for use with a specific drug (EGP-437) that will be approved through the NDA process and therefore classified as a class II device. Gathering clinical evidence for devices is subject to FDA's good clinical practice regulations, including requirements for IRB approval and informed consent. Significant risk devices require an approved investigational device exemption application before studies may begin. PMA approval typically requires, among other things, the submission of valid scientific evidence in the form of preclinical and clinical data, and a pre-approval inspection to determine if the manufacturing facility complies with cGMP practices under the quality system regulation that governs the design and all elements of the manufacture of devices. For clearance, a 510(k) must demonstrate substantial equivalence, i.e., must show that the device is as safe and effective as an already legally marketed device, also known as a predicate device. The evaluation of the newer device must not raise different questions of safety and effectiveness than that of the predicate device. 510(k)s normally do not, but sometimes do, require clinical data for clearance.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to product/device listing, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. While physicians may prescribe for off label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability, both at the federal and state levels.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for extension must be made prior to expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Manufacturing Requirements

We and our third party manufacturers must comply with applicable FDA regulations relating to FDA's cGMP regulations. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, extensive records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and our third party manufacturers and certain key component suppliers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including untitled letters, warning letters, determinations of product adulteration, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. Such perceived problems concerning safety or efficacy may arise in the context of clinical studies continued as a result of our post-marketing obligations, reports we or FDA receive from patients and healthcare providers, or literature published by third parties regarding our products or similar products.

Third Party Payor Coverage and Reimbursement

Reimbursement is expected to use standard approaches for Ophthalmology with EGP-437 reimbursed as a physician-administered drug using a drug code (J-code) and the procedure reimbursed via a CPT code in addition to the standard reimbursement for office visits. The commercial success of our EGP-437 Combination Product and, if and when commercialized, our other product candidates will depend, in part, upon the availability of coverage and reimbursement from third party payors at the federal, state and private levels, including U.S. Government payor programs, such as Medicare and Medicaid, private health care insurance companies and managed care plans have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The U.S. Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products profitably. Ongoing federal and state government initiatives directed at lowering the total cost of health care will likely continue to focus on healthcare reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid payment systems.

We expect that the pharmaceutical industry will continue to experience pricing pressures due to these initiatives and the trend toward managed healthcare and the increasing influence of managed care organizations. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our EGP-437 Combination Product and operate profitably.

Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the applicable regulatory agency will have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, operating results and financial condition.

Business Segment and Geographical Information

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business in one operating segment. The Company operates in one geographic segment.

Our Corporate Information

The Company was formed as a Delaware corporation on December 26, 2004. We were originally incorporated in 1998 under the name of Optis France S.A. in Paris France. At that time, the name of the French corporation was changed to EyeGate Pharma S.A.S. and became a subsidiary of Eyegate Pharmaceuticals, Inc. Our principal executive offices are located at 271 Waverley Oaks Road, Suite 108, Waltham, MA 02452, and our telephone number is (781) 788-9043.

Available Information and Website

We maintain an internet website at *www.eyegatepharma.com* and make available free of charge through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the United States Securities and Exchange Commission, or the SEC. You can find, copy and inspect information we file at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. You can review our electronically filed reports and other information that we file with the SEC on the SEC's web site at http://www.sec.gov. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. The information on our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be a part of this Annual Report on Form 10-K. Our website address is included in this Annual Report on Form 10-K as an inactive technical reference only.

Item 1A. ***Risk Factors.***

Risks Related to Our Financial Position and Need For Additional Capital

We have incurred significant operating losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was approximately $1.6 million for the year ended December 31, 2014 and $3.7 million for the year ended December 31, 2013, $5.8 million for the year ended December 31, 2012, and $56.9 million from the period of inception (December 26, 2004) through December 31, 2014. To date, we have financed our operations primarily through private placements of our preferred stock and convertible promissory notes. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and, beginning in 2008, clinical trials. We are still in the early stages of development of our product candidates, and we have not completed development of any drugs. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2014 with respect to this uncertainty.

We anticipate that our expenses will continue to be significant with our planned clinical trial for our EGP-437 Combination Product, which consists of EGP-437 and our EyeGate® II Delivery System, including a dose curve trial and a macular edema trial. We expect to begin randomizing and treating patients in the dose curve trial by the end of the second quarter of 2015.

Our expenses will also increase if and as we:

- pursue a confirmatory Phase 3 clinical trial evaluating the safety and efficacy of the EGP-437 Combination Product, for the treatment of non-infectious anterior uveitis;
- Pursue a safety clinical trial evaluating corneal endothelial cell counts over a six-month period with the EGP-437 Combination Product;
- Seek marketing approval for the EGP-437 Combination Product for anterior uveitis or any other indication in the U.S. whether alone or in collaboration with third parties;
- pursue the development of the EGP-437 Combination Product for the treatment of additional indications or for use in other patient populations or, if it is approved, seek to broaden the label for the EGP-437 Combination Product;
- continue the research and development of our other product candidates;
- Seek to develop additional product candidates;
- in-license or acquire the rights to other products, product candidates or technologies for the treatment of ophthalmic diseases;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish sales, marketing and distribution capabilities and scale up and validate external manufacturing capabilities to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific and management personnel;
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and planned future commercialization efforts and our operations as a public company; and
- increase our insurance coverage as we expand our clinical trials and commence commercialization of the EGP-437 Combination Product.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase if:

- we are required by the U.S. Food and Drug Administration, or FDA, or foreign equivalents, to perform studies or clinical trials in addition to those currently expected;

- if there are any delays in receipt of regulatory clearance to begin our planned dose curve trial or macular edema clinical trial; or

- if there are any delays in enrollment of patients in or completing our clinical trials or the development of the EGP-437 Combination Product or any other product candidates that we may develop.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we obtain marketing approval for, and commercialize, the EGP-437 Combination Product, which may never occur. This will require us to be successful in a range of challenging activities, including:

- raising additional funds to initiate and obtain favorable results from a confirmatory Phase 3 clinical trial for the EGP-437 Combination Product for the treatment of non-infectious anterior uveitis and for the endothelial cell count safety trial;

- subject to obtaining favorable results from a confirmatory Phase 3 clinical trial for the EGP-437 Combination Product treating anterior uveitis patients, applying for and obtaining marketing approval for the EGP-437 Combination Product;

- establishing sales, marketing and distribution capabilities, either ourselves or through collaboration or other arrangements with third parties, to effectively market and sell the EGP-437 Combination Product in the U.S.;

- establishing collaboration, distribution or other marketing arrangements with third parties to commercialize the EGP-437 Combination Product in markets outside the U.S.;

- achieving an adequate level of market acceptance of the EGP-437 Combination Product;

- protecting our rights to our intellectual property portfolio related to the EGP-437 Combination Product; and

- ensuring the manufacture of commercial quantities of the EGP-437 Combination Product.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect to devote substantial financial resources to our ongoing and planned activities, particularly preparing for and initiating our planned clinical trial evaluating the EGP-437 Combination Product for the treatment of macular edema. In the future, we expect to raise additional financial resources for the continued clinical development of the EGP-437 Combination Product. In addition, if we obtain regulatory approval for any of our product candidates, we would need to devote substantial financial resources to commercialization efforts, including product manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Our future capital requirements will depend on many factors, including:

- the progress, costs and outcome of our planned clinical trial for the EGP-437 Combination Product and of any clinical activities required for regulatory review of the EGP-437 Combination Product outside of the U.S.;

- the costs and timing of process development and manufacturing scale up and validation activities associated with the EGP-437 Combination Product;

- the costs, timing and outcome of regulatory review of the EGP-437 Combination Product in the U.S., and in other jurisdictions;

- the costs and timing of commercialization activities for the EGP-437 Combination Product if we receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and outsourced manufacturing capabilities;

- subject to receipt of marketing approval, the amount of revenue received from commercial sales of the EGP-437 Combination Product;

- the progress, costs and outcome of developing the EGP-437 Combination Product for the treatment of additional indications or for use in other patient populations;

- our ability to establish collaborations on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and

- the extent to which we in-license or acquire rights to other products, product candidates or technologies for the treatment of ophthalmic diseases.

As of December 31, 2014, we had cash and cash equivalents of $167,001. The net proceeds from the initial public offering of our common stock, or the IPO, together with our cash and cash equivalents as of December 31, 2014 will not enable us to fund our operating expenses and capital expenditure requirements for the next twelve months, thus we will need to raise additional funds.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. Our commercial revenues, if any, will be derived from sales of the EGP-437 Combination Product or any other products that we successfully develop, none of which we expect to be commercially available for several years, if at all. In addition, if approved, the EGP-437 Combination Product or any other product candidate that we develop or any product that we in-license may not achieve commercial success. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

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, government or other third-party funding, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. 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, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. 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. If we cannot raise funds on acceptable terms, we may not be able to grow our business or respond to competitive pressures.

If we raise additional funds through government or other third-party funding, collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, 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.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are an early-stage company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies and, beginning in 2008, conducting clinical trials of the EGP-437 Combination Product. All of our product candidates, other than the EGP-437 Combination Product, are still in preclinical development. We have not yet demonstrated our ability to successfully complete development of a product candidate, obtain marketing approvals, manufacture at commercial scale, or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Risks Related to the Discovery and Development of Our Product Candidates

We depend heavily on the success of the EGP-437 Combination Product, our most advanced product candidate, which we are developing for the treatment of non-infectious anterior uveitis and other disease indications. If we are unable to successfully raise additional funds to complete a confirmatory Phase 3 clinical trial and obtain marketing approval for the EGP-437 Combination Product for the treatment of non-infectious anterior uveitis, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize the EGP-437 Combination Product, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of the EGP-437 Combination Product for the treatment of patients with non-infectious anterior uveitis and for other ocular disease indications. There remains a significant risk that we will fail to successfully develop the EGP-437 Combination Product. In 2013, we completed a Phase 3 clinical trial to evaluate the safety, tolerability and efficacy of the EGP-437 Combination Product in patients with non-infectious anterior uveitis. Our development plan for the EGP-437 Combination Product consists of a confirmatory Phase 3 clinical trial evaluating the EGP-437 Combination Product for the treatment of non-infectious anterior uveitis and a separate clinical trial evaluating corneal endothelial cell counts six months post treatment of the EGP-437 Combination Product. We cannot accurately predict when or if the EGP-437 Combination Product will prove effective or safe in humans or whether it will receive marketing approval. Our ability to generate product revenues, which may never occur, will depend heavily on our obtaining marketing approval for and commercializing the EGP-437 Combination Product.

The success of the EGP-437 Combination Product will depend on several factors, including the following:

- raising additional funds to initiate and obtain favorable results from a confirmatory Phase 3 clinical trial for the EGP-437 Combination Product and for the endothelial cell count safety trial;
- applying for and receiving marketing approvals from applicable regulatory authorities for the EGP-437 Combination Product;
- making arrangements with third-party manufacturers for commercial quantities of both the EGP-437 and the EyeGate® II Delivery System and receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of the EGP-437 Combination Product, if and when approved, whether alone or in collaboration with others;
- acceptance of the EGP-437 Combination Product, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies, including the existing standard of care;
- maintaining a continued acceptable safety profile of the EGP-437 Combination Product following approval;
- obtaining and maintaining coverage and adequate reimbursement from third-party payors;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- protecting our rights in our intellectual property portfolio related to the EGP-437 Combination Product.

Successful development of the EGP-437 Combination Product for additional indications, if any, or for use in broader patient populations and our ability, if it is approved, to broaden the label for the EGP-437 Combination Product will depend on similar factors. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the EGP-437 Combination Product, which would materially harm our business.

If clinical trials of the EGP-437 Combination Product or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of the EGP-437 Combination Product or any other product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, including our EGP-437 Combination Product, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We will be required to demonstrate the safety of the EGP-437 Combination Product by assessing corneal endothelial cell counts at six months from treatment in order to support marketing approval of the EGP-437 Combination Product for the treatment of non-infectious anterior uveitis in the U.S. To meet this requirement in the future after raising additional funds, we plan to conduct a separate safety trial with no fewer than 100 patients who will be treated with the EGP-437 Combination Product and followed for six months post treatment. We cannot predict the results of this safety trial because we have no clinical data supporting the effect of our EGP-437 Combination Product on corneal endothelial cells six months post treatment.

In general, the FDA requires two adequate and well controlled pivotal clinical trials demonstrating effectiveness on a primary endpoint for marketing approval of a non-infectious anterior uveitis drug. The endpoint is based on total clearance of inflammatory cells in the anterior chamber of the eye. The trial must compare the EGP-437 Combination Product to standard of care. Our first Phase 3 trial evaluated the EGP-437 Combination Product for the treatment of non-infectious anterior uveitis against a positive control, the standard of care, prednisolone acetate ophthalmic suspension (1%), or PA. In our Phase 3 trial, the dose of the EGP-437 Combination Product tested was just outside the pre-set non-inferiority margin for intent-to-treat and per protocol populations and did not achieve statistical significance in the intent-to-treat population as compared to the positive control based on the primary efficacy endpoint.

We may fail to achieve success in a confirmatory Phase 3 clinical trial evaluating the EGP-437 Combination Product for the treatment of non-infectious anterior uveitis for a variety of potential reasons. Even if a confirmatory Phase 3 trial is successful in showing confirmatory data, the FDA may still require us to provide additional data to grant regulatory approval.

We would plan to conduct our confirmatory Phase 3 clinical trial at many clinical centers that were not included in our first Phase 3 trial. The introduction of new centers, and the resulting involvement of new treating physicians, can introduce additional variability into the conduct of the trials in accordance with their protocols and may result in greater variability of patient outcomes, which could adversely affect our ability to detect statistically significant differences between patients treated with the EGP-437 Combination Product and the standard of care control.

If, in our confirmatory Phase 3 clinical trial, we do not demonstrate non-inferiority as compared with the standard of care and if the FDA does not find this to be an acceptable means of meeting the requirements for marketing approval, we will not receive marketing approval for the EGP-437 Combination Product, and we will have to conduct another Phase 3 clinical trial if we wish to seek marketing approval for the EGP-437 Combination Product in the future.

The protocol for our planned confirmatory Phase 3 clinical trial and other supporting information are subject to review by the FDA and regulatory authorities outside the U.S. We do not plan on submitting the protocols for our second confirmatory Phase 3 clinical trial and our separate safety trial of the EGP-437 Combination Product to the FDA at any time prior to the raising of additional funds. We have not received guidance from other regulatory authorities outside the U.S. regarding the design of a confirmatory Phase 3 clinical trial.

Our confirmatory Phase 3 clinical trial will have a non-inferiority design. We may be unable to demonstrate non-inferiority against the standard of care, PA, which may cause us to undergo additional clinical trials or admit additional subjects to our trials delaying the time and increasing the expense it may take to commercialize our EGP-437 Combination Product.

Our confirmatory Phase 3 clinical trial will use a non-inferiority design rather than a superiority design. In order to meet our primary endpoint, we must show that patients treated with the EGP-437 Combination Product demonstrate non-inferiority according to pre-set non-inferiority margins as compared with the standard of care, PA. We may be unable to demonstrate non-inferiority against the standard of care. The design and conduct of non-inferiority trials, including selection of non-inferiority margins, account for many factors that can induce bias in the estimated effect of the standard of care in the non-inferiority trial and thus lead to bias in the estimated effect of the experimental treatment and perhaps lead to a trial design that does not ensure that the experimental treatment preserves a clinically acceptable fraction of the standard's effect, which may result in a vulnerability of the integrity of a non-inferiority trial to the irregularities in trial conduct. Our choice of an endpoint based on total clearance of inflammatory cells in the anterior chamber of the eye means that success will depend to a significant degree on the accuracy of our assumptions about the total clearance of inflammatory cells in the anterior chamber of the eye in the comparator arms of our Phase 3 trial. Although we believe we have been conservative in our assumptions, if, for example, patients in the comparator arm of our trial have significantly different clearance of inflammatory cells than we expect, we may find that our trial is unfeasible or we may have to enroll more patients at additional cost and delay.

If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the EGP-437 Combination Product or any other product candidates that we may develop, including:

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- any third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may decide, or regulators or institutional review boards may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not favorable or are only modestly favorable or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or

- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our pre-clinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for the EGP-437 Combination Product or our other product candidates that we may develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. In addition, some of our competitors may have ongoing clinical trials for product candidates that treat the same indications as the EGP-437 Combination Product, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse or unacceptable side effects are identified during the development of the EGP-437 Combination Product or any other product candidates that we may develop, we may need to abandon or limit our development of EGP-437 Combination Product or such other product candidates.

If the EGP-437 Combination Product or any of our other product candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Although the EGP-437 Combination Product appeared to be well tolerated in our Phase 1/2 and Phase 3 non-infectious anterior uveitis trials, our Phase 2 and Phase 3 dry eye trials and our Phase 2 cataract surgery trial, we have no clinical safety data on corneal endothelial cell counts or patient exposure to EGP-437 for more than two treatments given one week apart. Many compounds that initially showed promise in clinical or early stage testing for treating ophthalmic disease have later been found to cause side effects that prevented further development of the compound.

We may not be successful in our efforts to use our EyeGate® II Delivery System or platform to build a pipeline of product candidates.

A key element of our strategy is to use our proprietary EyeGate® II Delivery System or platform to rationally design, engineer and generate a pipeline of products and progress these therapies through clinical development for the treatment of a variety of ophthalmic diseases. Our research and development efforts to date have resulted in a pipeline of additional product candidates directed at the treatment of ophthalmic diseases. Other than EGP-437, our product candidates all are in early preclinical research and have not been tested in humans. These and any other potential product candidates that we identify may not be suitable for continued preclinical or clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize our product candidates that we develop based upon our technological approach, we will not be able to obtain product revenues in future periods.

We may expend our limited resources to pursue a particular product candidate or indication such as macular edema and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. To the extent our contemplated macular edema and dose curve trials are unsuccessful, we may not be able to raise additional funds for subsequent trials or pursuing other indications.

Risks Related to the Commercialization of Our Product Candidates

Even if the EGP-437 Combination Product or any other product candidate that we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for the EGP-437 Combination Product may be smaller than we estimate.

If the EGP-437 Combination Product or any other product candidate that we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Current treatments that are used for anterior uveitis include topical corticosteroids such as Durezol® (Novartis AG), Lotemax® (Valeant Pharmaceuticals International, Inc.), Pred Forte® (Allergan, Inc.) and prednisolone acetate ophthalmic suspension (1%) (Novartis AG). These treatments are well established in the medical community, and doctors may continue to rely on these treatments rather than our EGP-437 Combination Product, if and when it is approved for marketing by the FDA.

The degree of market acceptance of the EGP-437 Combination Product or any other product candidate that we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments, including the existing standard of care;
- our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement, particularly by Medicare in light of the prevalence of anterior uveitis in persons over age 65;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

Our assessment of the potential market opportunity for the EGP-437 Combination Product is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. If the actual market for the EGP-437 Combination Product is smaller than we expect, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing the EGP-437 Combination Product or any other product candidates that we may develop if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties.

In the future, we plan to build a focused sales and marketing infrastructure to market or co-promote the EGP-437 Combination Product and possibly other product candidates that we develop in the U.S., if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of the EGP-437 Combination Product or any other product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize the EGP-437 Combination Product or any other product candidates on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians 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 an independent sales and marketing organization.

We expect to enter into arrangements with third parties to perform consulting, sales, marketing and distribution services in markets outside the U.S. We may also enter into arrangements with third parties to perform these services in the U.S. if we do not establish our own sales, marketing and distribution capabilities in the U.S. or if we determine that such third-party arrangements are otherwise beneficial. Our product revenues and our profitability, if any, under any such third-party sales, marketing or distribution arrangements are likely to be lower than if we were to market, sell and distribute the EGP-437 Combination Product or any other product candidates that we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute the EGP-437 Combination Product or any other product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market the EGP-437 Combination Product or our other product candidates effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our EGP-437 Combination Product or any other product candidates that we may develop.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to the EGP-437 Combination Product and our other current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

The current standard of care for non-infectious anterior uveitis include topical corticosteroids such as Durezol® (Novartis AG), Lotemax® (Valeant Pharmaceuticals International, Inc.), Pred Forte® (Allergan, Inc.) and prednisolone acetate ophthalmic suspension (1%) (Novartis AG).

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than the EGP-437 Combination Product or other product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payors, particularly Medicare, seeking to encourage the use of generic products. Generic products are currently being used for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If the EGP-437 Combination Product or any other product candidate that we may develop achieves marketing approval, we expect that it will be priced at a significant premium over competitive generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize the EGP-437 Combination Product or any other product candidate that we may develop, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to commercialize the EGP-437 Combination Product or any other product candidates that we may develop successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for the EGP-437 Combination Product or any other product that we commercialize and, even if they are available, the level of reimbursement may not be satisfactory.

Inadequate reimbursement may adversely affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize the EGP-437 Combination Product or any other product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the U.S. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop would compromise our ability to generate revenues and become profitable.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

There can be no assurance that our product candidates or any products that we may in-license, if they are approved for sale in the U.S. or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost-effective by third-party payors, that coverage and an adequate level of reimbursement will be available, or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

Our strategy of obtaining rights to product candidates and approved products for the treatment of a range of ophthalmic diseases through in-licenses and acquisitions may not be successful.

We may expand our product pipeline through opportunistically in-licensing or acquiring the rights to other products, product candidates or technologies for the treatment of ophthalmic diseases. The future growth of our business may depend in part on our ability to in-license or acquire the rights to approved products, additional product candidates or technologies. However, we may be unable to in-license or acquire the rights to any such products, product candidates or technologies from third parties. The in-licensing and acquisition of pharmaceutical products is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire products, product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the rights to the relevant product, product candidate or technology on terms that would allow us to make an appropriate return on our investment. Furthermore, we may be unable to identify suitable products, product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable products, product candidates or technologies, our ability to pursue this element of our strategy could be impaired.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we develop.

We face an inherent risk of product liability exposure related to the use of the EGP-437 Combination Product and any other product candidates that we develop in human clinical trials and will face an even greater risk if we commercially sell any products that we develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced time and attention of our management to pursue our business strategy; and
- the inability to commercialize any products that we develop.

While we obtain insurance for each clinical trial we perform, we may not be adequately insured to cover all liabilities that we may incur. We will need to increase our insurance coverage as we expand our clinical trials. We will need to further increase our insurance coverage if we commence commercialization of the EGP-437 Combination Product or any other product candidate that receives marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Dependence on Third Parties

We may enter into collaborations with other third parties for the development or commercialization of our product candidates, including the EGP-437 Combination Product. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with third parties to commercialize the EGP-437 Combination Product in markets outside the U.S. We also may enter into arrangements with third parties to perform these services in the U.S. if we do not establish our own sales, marketing and distribution capabilities in the U.S. or if we determine that such third-party arrangements are otherwise beneficial. We also may seek third-party collaborators for development and commercialization of other product candidates. Our likely collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangement. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Any future collaborations that we enter into, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates that receive marketing approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If we do not receive the funding we expect under collaboration agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours were to be involved in a business combination, it might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be harmed.

If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected.

For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the U.S., the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform.

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We have relied on third parties, such as contract research organizations, or CROs, to conduct our completed trials of our EGP-437 Combination Product and do not plan to independently conduct clinical trials of the EGP-437 Combination Product or our other product candidates, including our planned Phase 3 clinical trial of our EGP-437 Combination Product. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials. These agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We contract with third parties for the manufacture of the EGP-437 Combination Product for clinical trials and expect to continue to do so in connection with the commercialization of the EGP-437 Combination Product and for clinical trials and commercialization of any other product candidates that we may develop. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of the EGP-437 Combination Product or any other of our product candidates. We rely, and expect to continue to rely, on third parties to manufacture clinical and commercial supplies of the EGP-437 Combination Product, preclinical and clinical supplies of our other product candidates that we may develop and commercial supplies of products if and when any of our product candidates receives marketing approval. Our current and anticipated future dependence upon others for the manufacture of the EGP-437 Combination Product and any other product candidate or product that we develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. In addition, any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

We currently rely exclusively on third-party manufacturers to assemble and prepare the EGP-437 Combination Product on a purchase order basis. We do not currently have any contractual commitments for commercial supply of bulk drug substance for EGP-437 or fill-finish services or for components of the EyeGate® II Delivery System. We also do not currently have arrangements in place for redundant supply or a second source for bulk drug substance for EGP-437 or for fill-finish services. The prices at which we are able to obtain supplies of EGP-437, fill-finish services and assemble the EyeGate® II Delivery System may vary substantially over time and adversely affect our financial results.

If our third-party manufacturers for the EGP-437 Combination Product fails to fulfill our purchase orders or should become unavailable to us for any reason, we believe that there are a limited number of potential replacement manufacturers, and we likely would incur added costs and delays in identifying or qualifying such replacements. We could also incur additional costs and delays in identifying or qualifying a replacement manufacturer for fill-finish services if our existing third-party manufacturer should become unavailable for any reason. We may be unable to establish any agreements with such replacement manufacturers or to do so on acceptable terms. Even if we could transfer manufacturing to a different third party, the shift would likely be expensive and time consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before using or selling any products manufactured at that facility.

In connection with our application for a license to market the EGP-437 Combination Product or other product candidates in the U.S., we may be required to conduct a comparability study if the product we intend to market is supplied by a manufacturer different from the one who supplied the product evaluated in our clinical studies. Delays in designing and completing this study to the satisfaction of the FDA could delay or preclude our development and commercialization plans and thereby limit our revenues and growth.

Reliance on third-party manufacturers entails additional risks, including:

- The EGP-437 Combination Product and any other product candidates that we may develop may compete with other product candidates and products for access to a limited number of suitable manufacturing facilities that operate under current good manufacturing practices, or cGMP, regulations;
- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the U.S. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our proprietary technology and products. We and our licensors have sought to protect our proprietary position by filing patent applications in the U.S. and abroad related to our novel technologies and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Maintaining patents in the U.S. is an expensive process and it is even more expensive to maintain patents and patent applications in foreign countries. As a result, it is possible that we and our licensors will fail to maintain such patents thereby reducing the rights of our portfolio.

The patent position of pharmaceutical, biotechnology and medical device companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned or licensed patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the medical device, biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office. The risks of being involved in such litigation and proceedings may increase as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses. Thus, we do not know with certainty that the EGP-437 Combination Product or any other product candidate, or our commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are party to a license agreement that imposes, and, for a variety of purposes, we will likely enter into additional licensing and funding arrangements with third parties that may impose, diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. Under certain of our existing licensing agreements, we are obligated to pay royalties or make specified milestone payments on net product sales of the EyeGate® II Delivery System or related technologies to the extent they are covered by the agreements. We also are obligated under certain of our existing license agreements to pay maintenance and other fees. We also have diligence and development obligations under certain of those agreements that we are required to satisfy. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Some of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain required regulatory approvals, we will not be able to commercialize the EGP-437 Combination Product or any other product candidate that we may develop, and our ability to generate revenue will be materially impaired. The marketing approval process is expensive, time-consuming and uncertain. As a result, we cannot predict when or if we, or any collaborators we may have in the future, will obtain marketing approval to commercialize the EGP-437 Combination Product or any other product candidate.

The activities associated with the development and commercialization of our product candidates, including the EGP-437 Combination Product, including design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and similar regulatory authorities outside the U.S. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market the EGP-437 Combination Product or any other product candidate from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs and consultants to assist us in this process.

The process of obtaining marketing approvals, both in the U.S. and abroad, is expensive and may take many years, especially if additional clinical trials are required, if approval is obtained at all. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety, purity and potency. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that the EGP-437 Combination Product or any other product candidate that we may develop is not safe, effective or pure, is only moderately effective or has undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

The regulatory process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell the EGP-437 Combination Product and any other product candidate that we may develop in other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., it is required that the product be approved for reimbursement before the product can be sold in that country. We or these third parties may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Even if we, or any collaborators we may have in the future, obtain marketing approvals for the EGP-437 Combination Product or our other product candidates, the terms of those approvals, ongoing regulations and post-marketing restrictions may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any collaborators we may have in the future, must therefore comply with requirements concerning advertising and promotion for any of our products for which we or they obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, if the EGP-437 Combination Product or any other product candidate that we may develop receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, our future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to physicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

We may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion or manufacturing of prescription products may lead to investigations by the FDA, Department of Justice and state Attorneys General alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Our relationships with customers and third-party payors may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the U.S. and elsewhere will play a primary role in the recommendation and prescription of any product candidates, including the EGP-437 Combination Product, for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which imposes obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

Recently enacted and future legislation may affect our ability to commercialize and the prices we obtain for any products that are approved in the U.S. or foreign jurisdictions.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could affect our ability to profitably sell or commercialize any product candidate, including the EGP-437 Combination Product, for which we obtain marketing approval or that we may in-license. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit coverage of and reduce the price that we receive for any approved products. While the MMA applies only to product benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA or other healthcare reform measures may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively PPACA. Among the provisions of PPACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new Medicare Part D coverage gap discount program, in which participating manufacturers must agree to offer 50% point-of-sale discounts off negotiated drug prices during the coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, and the addition of new government investigative powers, and enhanced penalties for noncompliance;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs; and
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the U.S. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the U.S. and require us to develop and implement costly compliance programs.

If we expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the U.S., it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we or our third-party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

We and our third-party manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical and business development expertise of Stephen From, our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team and a number of third party consultants. Although we have entered into an employment agreement with Mr. From, he may terminate his employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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 CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

We expect to expand our development capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to Our Common Stock

Because a small number of our existing stockholders own a majority of our voting stock, your ability to influence corporate matters will be limited

Our executive officers, directors and greater than 5% stockholders, in the aggregate, currently own 75.6% of our outstanding common stock. As a result, such persons, acting together, will have the ability to control our management and affairs and substantially all matters submitted to our stockholders for approval, including the election and removal of directors and approval of any significant transaction. These persons will also have the ability to control our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least the affirmative vote of all of our stockholders who would be entitled to cast to amend or repeal specified provisions of our restated certificate of incorporation or our amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

An active trading market for our common stock may not be sustained.

Prior to the IPO, there was no public market for our common stock. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares may never be sustained. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase without depressing the market price for the shares or at all.

Our common stock is quoted on the OTCQB Venture Marketplace, or the OTCQB, which limits the liquidity and price of our common stock more than if our common stock was listed on the NASDAQ Capital Market, the NYSE MKT or another national securities exchange and result in our stockholders not receiving the benefit of our being subject to the listing standards of a national securities exchange.

Our common stock is quoted over-the-counter on the OTCQB, which is a FINRA-sponsored entity and operated inter-dealer automated quotation system for equity securities not included in a national securities exchange. Quotation of our common stock on the OTCQB limits the liquidity and price of our common stock more than if our common stock were quoted or listed on the NASDAQ Capital Market or the NYSE MKT, which are national securities exchanges. In light of the size of the IPO, moreover, there are only a relatively small number of shareholders, which limits the liquidity of our common stock. Lack of liquidity limits the price at which you may be able to sell your shares or your ability to sell your shares at all.

Since our securities are quoted on the OTCQB, our securities holders may face significant restrictions on the resale of our securities due to state "Blue Sky" laws.

Each state has its own securities laws, often called "blue sky" laws, which (i) limit sales of securities to a state's residents unless the securities are registered in that state or qualify for an exemption from registration, and (ii) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or the transaction must be exempt from registration. The applicable broker must be registered in that state. We do not know whether our common stock will be registered or exempt from registration under the laws of any state. Since our common stock is quoted on the OTCQB, a determination regarding registration will be made by those broker-dealers, if any, who agree to serve as the market-makers for our common stock. There may be significant state blue sky law restrictions on the ability of investors to sell, and on purchasers to buy, our common stock. You should therefore consider the resale market for our common stock to be limited, as you may be unable to resell your common stock without the significant expense of state registration or qualification.

If our shares become subject to the penny stock rules, this may make it more difficult to sell our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTCQB does not meet such requirements and if the price of our common stock is less than $5.00, our common stock will be deemed penny stocks. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stock holders may have difficulty selling their shares.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price may be volatile. The stock market in general and the market for smaller specialty pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price you paid for such shares. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of the EGP-437 Combination Product or any other product candidate that we may develop;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional products, product candidates or technologies for the treatment of ophthalmic diseases, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation has often been instituted against that company. We also may face securities class-action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to commercialize EGP-437. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2014, we had federal net operating loss carryforwards of approximately $39.6 million, state net operating loss carryforwards of approximately $26.3 million and aggregate federal and state research and development tax credit carryforwards of approximately $895,000 available to reduce future taxable income. These federal and state net operating loss carryforwards and federal and state tax credit carryforwards which will expire at various dates through 2034, if not utilized. Utilization of these net operating loss and tax credit carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and comparable provisions of state, local and foreign tax laws due to changes in ownership of our company that have occurred previously or that could occur in the future. Under Section 382 of the Code and comparable provisions of state, local and foreign tax laws, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change by value in its equity ownership over a three year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research and development tax credits, to reduce its post-change income may be limited. We have not completed a study to determine whether the IPO, our most recent private placement and other transactions that have occurred over the past three years may have triggered an ownership change limitation. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we generate taxable income, our ability to use our pre-change net operating loss and tax credits carryforwards to reduce U.S. federal and state taxable income may be subject to limitations, which could result in increased future tax liability to us.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

We expect that the lock-up agreements pertaining to the IPO will expire 180 days from the date of effectiveness of our Registration Statement on Form S-1, or February 12, 2015. After the lock-up agreements expire, up to an additional 5,650,294 shares of common stock will be eligible for sale in the public market of which 4,788,175 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

We are an "emerging growth company," and a smaller reporting company and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of certain reduced reporting. In particular, in this Annual Report on Form 10-K, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to delay such adoption of new or revised accounting standards, and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public companies that are not emerging growth companies.

We are also a "smaller reporting company" as defined in Rule 12b-2 of the Exchange Act and have elected certain scaled disclosure available for smaller reporting companies.

We have identified material weaknesses in our internal controls over financial reporting that, if not properly remediated, could result in material misstatements in our financial statements in future periods.

The SEC, defines a material weakness as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. A deficiency in internal control exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis.

We have identified the following material weaknesses:

- Lack of experienced accounting and financial reporting personnel to manage the complexities of SEC financial reporting which resulted in significant changes to the financial statements as a result of our audit.

- Due to the limited number of people working in the office, many critical duties are combined and given to the available employees. Presently, a single individual prepares and signs checks, reconciles bank accounts, performs all payroll duties, and maintains the general ledger.

- Lack of adequate disclosure controls resulted in large audit adjustments related to a material contract.

If we are unable to correct deficiencies in internal controls in a timely manner, our ability to record, process, summarize and report financial information accurately and within the time periods specified in the rules and forms of the SEC will be adversely affected. This failure could negatively affect the market price and trading liquidity of our common stock, cause investors to lose confidence in our reported financial information, subject us to civil and criminal investigations and penalties, and generally materially and adversely impact our business and financial condition.

We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, FINRA rules and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often 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. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 and to build an internal control structure designed to meet the requirements of a public company. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, any future debt agreements that we may enter into, may preclude us from paying dividends without the lenders' consent or at all. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Item 1B. ***Unresolved Staff Comments.***

None.

Item 2. ***Properties.***

We currently have no facilities other than our principal executive office located at 271 Waverley Oaks Road, Suite 108, Waltham, MA 02452, and conduct our operations using third-party manufacturing facilities and trial sites. We believe our current facilities are adequate for our needs for the foreseeable future.

Item 3. ***Legal Proceedings.***

While we are not currently a party to any legal proceedings, from time to time we may be a party to a variety of legal proceedings that arise in the normal course of our business.

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.***

Price Range of Common Stock

Our common stock began trading on the OTCQB on February 13, 2015 in connection with out IPO, and currently trades under the symbol "EYEG." Prior to that time, there was no established public trading market for our common stock. As a result, we have not set forth quarterly information with respect to the high and low prices for our common stock for the two most recent fiscal years.

On March 25, 2015, the closing sale price of our common stock on the OTCQB Market was $3.14 per share. There were 62 holders of record of our common stock as of March 25, 2015. This number does not include beneficial owners whose shares were held in street name.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, and all currently available funds for use in the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in our current or future financing instruments.

Recent Sales of Unregistered Securities

Set forth below is information regarding shares of our common stock and the warrants and convertible promissory notes issued by us in the period covered by this report not registered under the Securities Act.

(1) In June, July and December 2014, we issued convertible promissory notes in the principal amount of approximately $1.83 million, convertible into shares of our common stock and warrants to purchase shares of our common stock at an exercise price equal to $6.00 per share. All of these convertible promissory notes converted into shares of our common stock upon the closing of the IPO. The warrants remain outstanding.

(2) In July 2014, we issued 15,036 shares of our common stock in connection with the amendment to our Amended and Restated License Agreement with the University of Miami.

The offer, sale, and issuance of the securities described in paragraphs (1) and (2) above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act in that the issuances of the securities to the accredited investors did not involve a public offering. The recipients of the securities in these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions.

Item 6. ***Selected Financial Data***

Not Applicable.

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations.***

Forward-Looking Statements

The following section of this Annual Report on Form 10-K entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains statements that are not statements of historical fact and are forward-looking statements within the meaning of federal securities laws. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Factors that may cause our actual results to differ materially from those in the forward-looking statements include those factors described in "Item 1A. Risk Factors" beginning on page 25 of this Annual Report on Form 10-K. You should carefully review all of these factors, as well as the comprehensive discussion of forward-looking statements on page 1 of this Annual Report on Form 10-K.

Overview

The Company formed as a Delaware corporation on December 26, 2004. We were originally incorporated in 1998 under the name of Optis France S.A. in Paris France. At that time, the name of the French corporation was changed to EyeGate Pharma S.A.S. and became a subsidiary of Eyegate Pharmaceuticals, Inc.

We are a clinical-stage specialty pharmaceutical company that is focused on developing and commercializing therapeutics and drug delivery systems for treating diseases of the eye. EGP-437, our first and only product in clinical trials, incorporates a reformulated topically active corticosteroid, dexamethasone phosphate, that is delivered into the ocular tissues through our proprietary innovative drug delivery system, the EyeGate II Delivery System. EGP-437 is being developed under the 505(b)(2) New Drug Application, or NDA, regulatory pathway for drugs submitted for approval to the U.S. Food and Drug Administration, or FDA, which enables an applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its NDA. The EyeGate II Delivery System and EGP-437, are designed to address two major issues in ophthalmic medicine: lack of patient compliance and safety. The EyeGate II Delivery System features a compact, elegant, and easy-to-use device that we believe has the potential to deliver drugs non-invasively and quickly into the ocular tissues through the use of iontophoresis, which can accelerate the onset of action, dramatically reduce treatment frequency versus eye drops and sustain therapeutic effect. The EyeGate® II Delivery System is easy-to-use, only takes a few minutes to employ and has been utilized to administer more than 1,700 experimental treatments. We hold worldwide commercialization rights to the EyeGate® II Delivery System.

As we are in our developmental stage, we have not generated any revenue. We have never been profitable and, from December 26, 2004 (inception) through December 31, 2014, our losses from operations have been $56.9 million. Our net loss was approximately $1.6 million and $3.7 million for the years ended December 31, 2014 and 2013, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, The EGP-437 Combination Product and any other product candidates we advance to clinical development. If we obtain regulatory approval for The EGP-437 Combination Product, we expect to incur significant expenses in order to create an infrastructure to support the commercialization of The EGP-437 Combination Product, including sales, marketing and distribution functions.

We will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

Financial Overview

Research and Development Expenses

We expense all research and development expenses as they are incurred. Research and development expenses primarily include:

- non-clinical development, preclinical research, and clinical trial and regulatory-related costs;
- expenses incurred under agreements with sites and consultants that conduct our clinical trials;
- expenses related to generating, filing, and maintaining intellectual property; and

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense.

Substantially all of our research and development expenses to date have been incurred in connection with EGP-437. We expect our research and development expenses to increase for the foreseeable future as we advance EGP-437 through clinical development, including the conduct of our planned clinical trials. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We are unable to estimate with any certainty the costs we will incur in the continued development of EGP-437. Clinical development timelines, the probability of success and development costs can differ materially from expectations.

We may never succeed in achieving marketing approval for our product candidate.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the cost of comparative agents used in trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

We do not expect EGP-437 to be commercially available, if at all, for the next several years.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation. Our general and administrative expenses consisted primarily of payroll expenses for our full-time employees. Other general and administrative expenses include professional fees for auditing, tax, patent costs and legal services.

We expect that general and administrative expenses will increase in the future as we expand our operating activities and incur additional costs associated with being a publicly-traded company and maintaining compliance with exchange listing and SEC requirements. These increases will likely include higher consulting costs, legal fees, accounting fees, directors' and officers' liability insurance premiums and fees associated with investor relations.

Total Other Income (Expense)

Total other income (expense) consists primarily of interest income we earn on interest-bearing accounts, and interest expense incurred on our outstanding debt including non-cash interest resulting from the accretion of original issue discount on certain of our outstanding notes. We also received the proceeds of certain research and development tax credits related to EyeGate Pharma S.A.S.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Accrued Research and Development Expenses

As part of the process of preparing financial statements, we are required to estimate and accrue research and development expenses. This process involves the following:

- communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in our financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and
- periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to contract research organizations and investigative sites in connection with clinical studies;
- fees paid to contract manufacturing organizations in connection with non-clinical development, preclinical research, and the production of clinical study materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to non-clinical development, preclinical studies, and clinical trials on our estimates of the services received and efforts expended pursuant to contracts with organizations/consultants that conduct and manage clinical studies on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts may depend on many factors, such as the successful enrollment of patients, site initiation and the completion of clinical study milestones. Our service providers invoice us as milestones are achieved and monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period.

However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies and other research activities.

Stock-Based Compensation

We have issued options to purchase our common stock. We account for stock based compensation in accordance with ASC 718, *Compensation — Stock Compensation*. ASC 718 establishes accounting for stock-based awards exchanged for employee services. Under the fair value recognition provisions of ASC 718, share based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service/vesting period. Determining the appropriate fair value model and calculating the fair value of stock-based payment awards require the use of highly subjective assumptions, including the expected life of the stock-based payment awards and stock price volatility.

We estimate the grant date fair value of stock options and the related compensation expense, using the Black-Scholes option valuation model. This option valuation model requires the input of subjective assumptions including: (1) expected life (estimated period of time outstanding) of the options granted, (2) volatility, (3) risk-free rate and (4) dividends. Because share-based compensation expense is based on awards ultimately expected to vest, it is reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeiture rates differ from those estimates. We have estimated expected forfeitures of stock options based on our historical turnover rate and used these rates in developing a future forfeiture rate. If our actual forfeiture rate varies from our estimates, additional adjustments to compensation expense may be required in future periods. In general, the assumptions used in calculating the fair value of stock-based payment awards represent management’s best estimates, but the estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future.

No options were granted in 2014 or 2013.

Significant Factors Used in Determining the Fair Value of Our Common Stock

The fair value of the shares of common stock that underlie the stock options we have granted under the plan has historically been determined by our board of directors based upon information available to it at the time of grant. Prior to December 31, 2011, our board of directors did not conduct any formal valuation procedure or commission any third party valuation or appraisal in connection with its determinations of the fair value of its common stock. Our board of directors considered the most persuasive evidence of fair value to be the prices at which our securities were sold in actual arms' length transactions. Our board of directors also considered numerous objective and subjective factors in the assessment of fair value, including reviews of our business and financial condition, the conditions of the industry in which we operate and the markets that we serve and general economic, market and United States and global capital market conditions, an analysis of publicly traded peer companies, the lack of marketability of our common stock, the likelihood of achieving a liquidity event for the shares of common stock underlying the stock options in question, such as an initial public offering or sale, the preferences and privileges of the preferred stock and common stock, the status of strategic initiatives being undertaken by our management and board of directors and, after December 31, 2011, independent third party valuations of our common stock. All options have been granted at exercise prices not less than the fair value of the underlying shares on the date of grant.

During the year ended December 31, 2014, we did not grant any options.

Other Information

Net Operating Loss Carryforwards

As of December 31, 2014, we have federal and state income tax net operating loss ("NOL") carryovers of approximately $39.6 million and $26.3 million, respectively, which will expire at various dates through 2034. As of December 31, 2014, we also has federal, state and foreign research and development tax credit carryforwards of approximately $895,000, $271,000, and $25,000, respectively, to offset future income taxes, which expire at various times through 2034.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not completed a study to determine the impact of this ownership change on our NOL carryforwards under Section 382 of the Code. If we experience a Section 382 ownership change in as a result of future changes in our stock ownership, some of which changes are outside our control, the tax benefits related to the NOL carryforwards may be further limited or lost.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board (PCAOB) regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more, (b) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering, (c) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Temporary Equity and Non-Controlling Interest

Certain of our convertible preferred stock issuances were directly sold by EyeGate S.A.S., resulting in a non-controlling interest. Such non-controlling interest and the related convertible preferred stock are classified as temporary equity on our consolidated balance sheet, and we record the interest in the earnings or loss of the subsidiary not attributable to us as net income (loss) attributable to non–controlling interests in the consolidated statements of operations and comprehensive loss.

Results of Operations

Comparison of Years Ended December 31, 2014 and 2013

The following table summarizes the results of our operations for the years ended December 31, 2014 and 2013:

	Year Ended December 31,		
	2014	2013	Change
Operating expenses:			
Research and development	$ 531,116	$ 1,010,268	$ (479,152)
General and administrative	1,936,967	2,087,637	(156,670)
Total operating expenses	2,462,083	3,097,905	(635,822)
Other (expense), net:	910,575	(584,680)	1,495,256
Net (loss)	(1,551,508)	(3,682,585)	2,131,077
Net income attributable to non-controlling interest	(222,484)	(192,862)	(25,622)
Net (loss) to the company	$ (1,773,992)	$ (3,879,497)	$ 2,105,455

Research and Development Expenses. Research and development expenses were $0.531 for the year ended December 31, 2014 compared to $1.0 million for the year ended December 31, 2013. The reduction of $0.479 million in costs was primarily due to a decrease in clinical trials of our EGP-437 Combination Product. There was a reduction of costs of $0.264 million from the completion of the Phase 3 non-infectious anterior uveitis trial in April 2013. There was a reduction in clinical operations staff and in Scientific Advisory Board fees of $0.147 million. We also reduced research and development consultants by $0.049 million. The remaining cost reduction is due to clinical product not being produced, which resulted in a reduction of $0.019 million.

General and Administrative Expenses. General and administrative expenses were approximately $1.9 million for the year ended December 31, 2014, compared to $2.1 million for the year ended December 31, 2013. The decrease of approximately $0.2 million was primarily comprised of a loss on Cancellation of Shareholders' note receivable (treated as a compensatory charge) of $0.201 million offset by decreases in payroll costs of $0.015 and in building operating, legal, accounting and consulting expenses of $0.386 million.

Other Income (Expense). Total other income (expense) was $0.911 million for the year ended December 31, 2014 and $(0.585) million for the year ended December 31, 2013. The change of $1.5 million is primarily due to the change in the warrant liability of $1.1 million and the extinguishment of a research liability of $0.240 million. These were offset by a reduction in non-cash interest related to the discount on certain notes issued in 2012 and recognized in 2013.

Liquidity and Capital Resources

In addition to proceeds from the IPO, we have funded our operations since inception through the issuance of convertible preferred stock and convertible promissory notes and, to a lesser extent, through research and development tax credits. Through December 31, 2014, we had raised a total of $54.1 million from such sales of our equity securities and debt instruments.

At December 31, 2014, we had cash and cash equivalents totaling $167,000.

The following table sets forth the primary sources and uses of cash for the years ended December 31, 2014 and 2013:

	Year ended December 31,	
	2014	2013
Cash used in operating activities	$ (950,617)	$ (2,957,615)
Cash used in investing activities	—	—
Cash provided by financing activities	613,273	1,461,009

Comparison of Years Ended December 31, 2014 and 2013

Operating Activities. Net cash used in operating activities was $0.951 million for the year ended December 31, 2014, compared to net cash used in operating activities of $2.958 million for the year ended December 31, 2013. The primary use of cash was to fund operating losses of $1.6 million in 2014 off-set in part by $26,815 million in stock based compensation charges and a loss on cancellation of shareholders' note receivable of $200,758 in 2014 and the fair value adjustment of common stock warrants of $1.1 million and for the year ended December 31, 2013 net losses of $3.683 million offset in part by non-cash compensation charges $184,030 and a decrease in restricted cash of $152,525, and non-cash interest expense of $533,269.

F*inancing Activities.* On February 28, 2014, we received proceeds of $446,151 from the issuance of unsecured convertible promissory notes under the 2013 Note Purchase Agreement. In April 2014, we received additional proceeds of $16,667 for additional 2013 Notes. In June, July and December 2014, we received additional proceeds of approximately $1,292,949 under the 2014 Notes. For the year ended December 31, 2013, we received proceeds of $490,803 and $968,970 from the issuance of unsecured convertible promissory notes under the 2012 and 2013 Note Purchase Agreement.

On June 6, 2014, we entered into a Convertible Promissory Note and Warrant Purchase Agreement ("2014 Note Purchase Agreement"), pursuant to which we could issue up to an aggregate principal amount of $2,000,000 of unsecured promissory notes (the "2014 Notes") to certain stockholders. The 2014 Notes converted into shares of our common stock upon the closing of the IPO. We also issued to each holder of a 2014 Note and for the 2014 Note Holders that had convertible promissory notes issued in 2012 and 2013, a warrant exercisable for our common stock upon the IPO. These warrants automatically converted into shares of our common stock upon the closing of the IPO.

The Company determined that the amended debt agreements were classified as troubled debt restructurings or modifications accounted for as extinguishments, however since the note holders were also preferred stockholders the gain or loss was reflected as a component of stockholders equity. The warrants issued by the Company in connection with the June 6, 2014 debt and amended debt issuance have been classified as a liability instrument, since there is a variable component to the number of shares, the class of shares and the strike price depending upon future financing transactions of the Company.

The Company determined the fair value of the warrants issued on June 6, 2014 and July 17, 2014 was approximately $1,364,000, based upon the following assumptions:

- The number of warrants to be issued and the exercise price will be determined based upon future events, including potential sale, liquidation or IPO transactions as described above. The Company utilized a probability weighting of potential outcomes to estimate the number of warrants issuable, the type of underlying security, and the exercise price and then a Black Scholes model to compute the estimated value of the warrant under each assumption.
- Volatility – 70%
- Term – 0.5 years for an IPO scenario; 5 years for an M&A or liquidation scenario
- Dividends – 0%
- Discount rate – 0.6 – 1.6%

The Company determined the fair value of the warrants issued on December 19, 2014 was approximately $34,000, based upon the following assumptions:

- The number of warrants to be issued and the strike price will be determined based upon future events, including potential sale, liquidation or IPO transactions as described above. The Company utilized a probability weighting of potential outcomes to estimate the number of warrants issuable, the type of underlying security, and the exercise price.
- Volatility — 55%
- Term — 0.25 years for an IPO scenario; 4.5 years for an M&A or liquidation scenario
- Dividends — 0%
- Discount rate — 0.6 – 1.74%

The Company recorded any changes in the fair value of the warrants in the statement of operations at each reporting period. At December 31, 2014, the 2014 Notes and the amended and restated notes (2013 and 2012 Notes) had a carrying value of $3.2 million and a face value of $3.4 million.

Funding Requirements and Other Liquidity Matters

Our EGP-437 Combination Product is still in clinical development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- seek marketing approval for our EGP-437 Combination Product;

- establish a sales and marketing infrastructure to commercialize our EGP-437 Combination Product in the United States, if approved;
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

The net proceeds from the IPO, together with our cash and cash equivalents as of December 31, 2014 will not enable us to fund our operating expenses and capital expenditure requirements for the next twelve months, thus we will need to raise additional funds. Because of the numerous risks and uncertainties associated with the development and commercialization of our EGP-437 Combination Product, if approved, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our EGP-437 Combination Product.

Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory review;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for our EGP-437 Combination Product, if approved;
- the revenue, if any, received from commercial sales of our EGP-437 Combination Product, if approved; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

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, collaborations, strategic alliances and licensing arrangements. 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, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt 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. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, including our EGP-437 Combination Product, 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 EGP-437 that we would otherwise prefer to develop and market ourselves.

Off-Balance Sheet Arrangements

We have no material off-balance sheet arrangements at December 31, 2014.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2014:

	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Convertible promissory notes due to stockholders[(1)]	$ 3,459,000	3,459,000	—	—	—
Royalty license commitment[(2)]	$ 100,000	12,500	37,500	37,500	12,500*

1 Amounts reported represent principal and interest as of December 31, 2014.

* The License agreement is a perpetual agreement. Only one year’s payment is presented in the more than five years column of this table.

2 Pursuant to the terms of the Amended and Restated License Agreement with the University of Miami and its School of Medicine, dated as of December 16, 2005. In addition, there are certain milestone payments, which are excluded from the table (in aggregate $150,000), whose payment obligation dates are unknown.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk.***

Not Applicable.

Item 8. ***Financial Statements and Supplementary Data.***

The information required by this item is contained in the consolidated financial statements filed as part of this Annual Report on Form 10-K are listed under Item 15 of Part IV below.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.***

None.

Item 9A. ***Controls and Procedures.***

This Report includes the certifications of our President and Chief Executive Officer (who is our principal executive officer and principal financial and accounting officer) required by Rule 13a-14 of the Exchange Act. See Exhibits 31.1 and 31.2. This Item 9A includes information concerning the controls and control evaluations referred to in those certifications.

(a) Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to management, including the President and Chief Executive Officer, to allow timely decisions regarding required disclosures.

In connection with the preparation of this Annual Report on the Form 10-K, our management, under the supervision and with the participation of our President and Chief Executive Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2014. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and our management necessarily was required to apply its judgment in evaluating and implementing our disclosure controls and procedures. Based upon the evaluation described above, our President and Chief Executive Officer has concluded that he believes that our disclosure controls and procedures have the following material weaknesses existing as of the end of the period covered by this report, in providing reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our President and Chief Executive Officer, to allow timely decisions regarding required disclosures, and is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms:

- Lack of experienced accounting and financial reporting personnel to manage the complexities of SEC financial reporting which resulted in significant changes to the financial statements as a result of our audit.

- Due to the limited number of people working in the office, many critical duties are combined and given to the available employees. Presently, a single individual prepares and signs checks, reconciles bank accounts, performs all payroll duties, and maintains the general ledger.

- Lack of adequate disclosure controls resulted in large audit adjustments related to a material contract.

If we are unable to correct deficiencies in internal controls in a timely manner, our ability to record, process, summarize and report financial information accurately and within the time periods specified in the rules and forms of the SEC may be adversely affected.

(b) Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) or an attestation report of our independent registered accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

(c) Changes in Internal Controls Over Financial Reporting

Our management, with the participation of the President and Chief Executive Officer, has evaluated whether any change in our internal control over financial reporting occurred during the fourth quarter ended December 31, 2014. Based on that evaluation, management concluded that there were no changes in our internal controls over financial reporting during the quarter ended December 31, 2014 that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

Item 9B. ***Other Information.***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance.***

Executive Officers and Directors

Our executive officers and directors, and their ages and positions as of March 27, 2015, are set forth below:

Name	Age	Position	Served as Officer or Director Since
Executive Officers			
Stephen From	51	President and Chief Executive Officer	October 2005
Michael Manzo	55	Vice President of Engineering	October 2006
Directors			
Paul Chaney	57	Chairman	September 2007
Morton Goldberg[(2)]	77	Director	October 2008
Praveen Tyle[(1)(2)]	55	Director	June 2008
Thomas Balland[(3)]	37	Director	September 2012
Thomas E. Hancock[(1)(3)]	51	Director	January 2007
Bernard Malfroy-Camine[(1)(2)]	62	Director	July 2012
Mounia Chaoui[(3)]	43	Director	October 2013
Stephen From	51	Director	October 2005

(1) Member of Compensation Committee.

(2) Member of Nominating and Corporate Governance Committee, or Governance Committee.

(3) Member of Audit Committee.

Executive Officers

Stephen From, President and Chief Executive Officer, has served as our President, Chief Executive Officer, and director since October 2005. Mr. From was formerly the Chief Financial Officer at Centelion SAS, an independent biotechnology subsidiary of Sanofi-Aventis. Prior to this, Mr. From spent several years as an investment banker specializing in the biotechnology and medical device sectors. He served as Director in the Global Healthcare Corporate and Investment Banking Group and Head of European Life Sciences for Bank of America Securities. Mr. From holds a BSc from the University of Western Ontario, an accounting diploma from Wilfred Laurier University and has qualified as a Chartered Accountant in Ontario, Canada.

We believe Mr. From's qualifications to sit on our board of directors include his executive leadership experience, financial expertise and the knowledge and understanding he has gained from serving as our President and Chief Executive Officer since 2005.

Michael Manzo, Vice President of Engineering, has been with us since October 2006 and has served as Vice President of Engineering for the last seven years. Mr. Manzo has over 30 years of experience in product development and manufacturing in the medical device industry. Prior to working at Eyegate, Mr. Manzo held positions of President and Chief Operating Officer (2002 – 2006) at Jenline Industries, Ltd., which is now part of Helix Medical, LLC. He has been part of multiple start-up companies over the years, ranging in medical specialties from cardiology, radiology, urology and laproscopic surgery. Mr. Manzo holds a Masters in Business Administration Degree from Suffolk University and a Bachelor of Science Degree in engineering from University of Massachusetts, Lowell.

Non-Employee Directors

Paul Chaney, Chairman of the Board, has served as a director since September 2007. He is co-founder, President & CEO of PanOptica, Inc, a private venture-backed biopharmaceutical company that licenses and develops drugs for the treatment of important ophthalmic conditions, and has held such positions since March 2009. Prior to founding PanOptica, Paul was Executive Vice President and President of Eyetech Pharmaceuticals Inc. or Eyetech. Prior to being acquired by OSI Pharmaceuticals Inc., Paul served as Eyetech's Chief Operating Officer, where he was responsible for the launch of Macugen, the first anti-VEGF treatment for neovascular age-related macular degeneration (wet-AMD), and was part of the executive team which led Eyetech's initial public offering in 2004. Paul has over 30 years of experience in the biopharmaceutical and ophthalmic medical device industry, including a variety of senior management positions at Pharmacia Corporation. He began his career as a sales representative for The Upjohn Company in 1980. Paul earned a double BA in English and Biological Sciences from the University of Delaware.

We believe Mr. Chaney's qualifications to sit on our board of directors include his executive leadership experience, including 19 years leading major ophthalmology businesses both in the U.S. and globally for both a large public pharmaceutical company and privately held start-ups. Mr. Chaney's responsibilities have spanned commercial operations, manufacturing, regulatory, business development, non-clinical and clinical development functions. He was responsible for building and leading the commercial organizations responsible for the launches of major glaucoma and retina therapeutics, and commercializing the ophthalmic device business for Pharmacia Corporation.

Morton F. Goldberg, MD, Director, has served as a director since June 2008. Since 2003 he has served as the Joseph E. Green Professor of Ophthalmology at the Wilmer Eye Institute, Johns Hopkins University School of Medicine, to which position he was appointed to in 2003. From 1989 to 2003 he served as the Director and William Holland Wilmer Professor of Ophthalmology at the Wilmer Eye Institute. Prior to this, he was a Professor and Chairman of the Department of Ophthalmology at the University of Illinois College of medicine in Chicago for nearly 20 years. Dr. Goldberg trained at Johns Hopkins as a resident and chief resident, and holds a joint appointment at the Johns Hopkins Applied Physics Laboratory. He is also a past President of the Association for Research in Vision and Ophthalmology, the Macula Society, and the Association of University Professors of Ophthalmology. Dr. Goldberg received his undergraduate degree with honors from Harvard College and his MD with honors from Harvard Medical School.

We believe Dr. Goldberg's qualifications to sit on our board of directors include his extensive expertise in eye care. He is a board certified in ophthalmology and highly experienced in both research and clinical ophthalmology. He has served as academic department chairman for almost 40 years, and also served as Chief Editor of the Archives of Ophthalmology, an important scientific and clinical journal. He has recently completed 50 years of personal eye research as well as personal care of innumerable eye patients having diseases amenable to treatment by iontophoresis.

Praveen Tyle, PhD, Director, has served as a director since June 2008. He is currently President, Chief Executive Officer and Member of the Board of Directors of Osmotica Pharmaceutical Corp., which positions he has held since January 2013. He is also a member of the board of Orient EuroPharma Co., Ltd. of Taiwan. Dr. Tyle has nearly 30 years of experience in the pharmaceutical industry with the majority of his tenure in senior executive leadership positions in areas of research and development, manufacturing, quality, business development and operations. He previously served as global Executive Vice President and Chief Scientific Officer and Managing Director of Osmotica Pharmaceutical Corp.'s Marietta, Georgia site, from August 2012 to December 2012. Prior to joining of Osmotica Pharmaceutical Corp. Dr. Tyle served as Executive Vice President (from January 2012 to August 2012) and Chief Scientific Officer (from October 2011 to August 2012) for the United States Pharmacopeia, or USP. Prior to joining USP, Dr. Tyle from 2008 to 2011, served as the Senior Vice President and Global Head of Business Development and Licensing at Novartis Consumer Health from March 2009 to September 2011. At Novartis Consumer Health, Dr. Tyle also served as Senior Vice President & Global Head of Research and Development from March 2009 to February 2010. Dr. Tyle holds a doctorate in pharmaceutics and pharmaceutical chemistry from the Ohio State University and a BS in Pharmacy (honors) from the Institute of Technology, Banaras Hindu University in India.

We believe Dr. Tyle's qualifications to sit on our board of directors include his executive research and development leadership experience and significant mergers and acquisitions and business development and licensing experience.

Thomas Balland, Director, has served as a director since September 2012. He is a Managing Director at IPSA, a venture capital firm, where he has been since 2002. He has over 10 years of venture capital investment experience. In addition to the company, Mr. Balland has invested in and serves on the boards of several biotech and medtech companies including CMC Biologics, Immutep S.A., SpineVision SA and SpineGuard S.A. He was also on the boards of several companies that were acquired by larger entities in the life sciences industry, including Technolas Perfect Vision GmbH. Prior to joining IPSA in 2002 Mr. Balland held various positions with firms such as Mars, Inc. and Up&Up. He has degrees in engineering and finance from INSA Lyon and ESCP-EAP respectively.

We believe Mr. Balland's qualifications to sit on our board of directors include his executive leadership experience and his business development, strategic planning and mergers and acquisitions experience with biotech and medtech companies.

Thomas E. Hancock, Director, has served as a director since January 2007. He has over fourteen years of experience in the biopharmaceutical industry and equity capital markets. Since September, 2004, he has been the a Principal of Nexus Medical Partners, where he has been responsible for several investments, including A&G Pharmaceuticals Inc., Magellan Biosciences, Inc., and Panacos Pharmaceuticals, Inc. and a principal of Nexus Investment Company, a FINRA member. Prior to joining Nexus Medical Partners, Thomas was a Senior Equity Analyst and Managing Director at US Bancorp Piper Jaffray, covering both the biopharmaceutical and drug discovery tools markets. He has also held numerous positions at Genentech, Inc. and COR Therapeutics, Inc. Mr. Hancock has a BS in Molecular Biology and a MBA from UC Berkeley.

We believe Mr. Hancock's qualifications to sit on our board of directors include his many years of biotech, investment banking and venture capital experience.

Bernard Malfroy-Camine, PhD, Director, has served as a director since July 2012. He is a scientist-turned-entrepreneur with nearly 30 years of experience in biotechnology and drug discovery. Since May 2013, he has been President and CEO of ViThera Pharmaceuticals, Inc. He has also served as Director, Business Development US Operations at Voisin Consulting, Inc. (also known as Voisin Consulting Life Sciences) since September 2012. Since October 2008, Dr. Malfroy-Camine has also been Founder, President and CEO of MindSet Rx, Inc., a virtual company which is a continuation of Eukarion, Inc., a Biotech company he had founded in 1991, and of which he was President and CEO. Dr. Malfroy-Camine has over 80 scientific publications and holds approximately 20 patents. He has a Master's degree in Mathematics and Physics from Ecole Polytechnique (Paris) and a Ph.D. in Neurobiology from University Paris VI.

We believe Dr. Malfroy-Camine's qualifications to sit on our board of directors include his executive leadership experience and his extensive experience in entrepreneurship, drug discovery and drug development.

Mounia Chaoui, **Director,** has served as a director since October 2013. Since May 2013, she has been a general partner at Turenne Capital, a healthcare growth and venture capital company. She has also served, since January 2013, as CEO of Finbiomed sarl, a financial consulting company. Prior to 2013, Ms. Chaoui served as Chief Executive Officer and Managing Partner at Inserm Transfert Initiative, a seed capital fund, from January 2012 to December 2012, and as principal, then general partner, of Ventech Venture Capital, from July 2001 to January 2012. She brings investor experience in life sciences and expertise in building international syndications. Ms. Chaoui has sat or is still sitting on the boards of BioVex Group, Inc., Cellerix, S.A., Covagen AG, Funxional Therapeutics Ltd., Inserm Transfert Initiative, Groupe Sebbin SAS, Scynexis, Inc., TiGenix NV and Xytis Pharmaceuticals Ltd. Ms. Chaoui graduated as an engineer from École Centrale de Paris and holds a Ph.D. in Molecular Biophysics.

We believe Ms. Chaoui's qualifications to sit on our board of directors include her executive leadership and 16 years of experience in fund raising, business, financial, clinical and technology development of biotechnology and medtechnology companies.

Board of Directors

In addition to the rights of our board of directors to elect directors under certain circumstances in accordance with our by-laws, members of our board of directors are elected at our annual meeting of stockholders

Independent Directors

Our board of directors is currently composed of eight members. Although our common stock is quoted on the OTCQB, in the future, we may attempt to be listed on the NASDAQ Capital Market. Under the published listing requirements of NASDAQ, independent directors must comprise a majority of a listed company's board of directors within twelve months of the completion of an initial public offering. Seven of the members of our board qualify as independent directors in accordance with the published listing requirements of NASDAQ. The independent members of our board of directors also will hold separate regularly scheduled executive session meetings at which only independent directors are present.

Classified Board

Our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- The Class I directors will be Paul Chaney and Bernard Malfroy-Camine, and their terms will expire at the annual meeting of stockholders to be held in 2016;

- The Class II directors will be Thomas E. Hancock, Praveen Tyle and Morton F. Goldberg, and their terms will expire at the annual meeting of stockholders to be held in 2017; and

- The Class III directors will be Stephen From, Thomas Balland and Mounia Chaoui, and their terms will expire at the annual meeting of stockholders to be held in 2018.

The authorized number of directors may be changed only by resolution of the board of directors. This classification of the board of directors into three classes with staggered three-year terms may have the effect of delaying or preventing changes in our control or management.

Board Leadership Structure

Our board of directors is currently led by its chairman, Paul Chaney. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the company continues to grow. We separate the roles of chief executive officer and chairman of the board in recognition of the differences between the two roles. The chief executive officer is responsible for setting the strategic direction for the company and the day-to-day leadership and performance of the company, while the chairman of the board of directors provides guidance to the chief executive officer and presides over meetings of the full board of directors. We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing the company.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of Board in Risk Oversight Process

Our board of directors has responsibility for the oversight of the company's risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board to understand the company's risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors, and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating/corporate governance committee manages risks associated with the independence of the board, corporate disclosure practices, and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board as a whole.

Corporate Governance

We believe our corporate governance initiatives comply with the Sarbanes-Oxley Act and the rules and regulations of the SEC adopted thereunder. In addition, as we may attempt to be listed on the NASDAQ Capital Market in the future, we believe our corporate initiatives comply with the rules of the NASDAQ Capital Market. Our board of directors continue to evaluate our corporate governance principles and policies.

Our board of directors have adopted a code of business conduct that applies to each of our directors, officers and employees. The code addresses various topics, including:

- compliance with applicable laws, rules and regulations;
- conflicts of interest;
- public disclosure of information;
- insider trading;
- corporate opportunities;
- competition and fair dealing;
- gifts;
- discrimination, harassment and retaliation;
- health and safety;
- record-keeping;
- confidentiality;
- protection and proper use of company assets;
- payments to government personnel; and
- reporting illegal and unethical behavior.

The code of business conduct is posted on our website. Any waiver of the code of business conduct for an executive officer or director may be granted only by our board of directors or a committee thereof and must be timely disclosed as required by applicable law. The code of business conduct will implement whistleblower procedures that establish format protocols for receiving and handling complaints from employees. Any concerns regarding accounting or auditing matters reported under these procedures will be communicated promptly to the audit committee.

Board Committees

Our board of directors has established an audit committee, a compensation committee and governance committee, each of which operate under a charter that has been approved by our board. The directors serving as members of these committees meet the criteria for independence under, and the functioning of these committees will comply with, the applicable requirements of the Sarbanes-Oxley Act and SEC rules and regulations. In addition, as we may attempt to be listed on the NASDAQ Capital Market in the future, we believe that the functioning of these committees will comply with the rules of the NASDAQ Capital Market. We intend to comply with future requirements as they become applicable to us. Each committee has the composition and responsibilities described below.

Audit Committee

Our board of directors has established an audit committee, which is comprised of Thomas E. Hancock, Thomas Balland and Mounia Chaoui, each of whom is a non-employee member of the board of directors. Thomas E. Hancock serves as the chair of the audit committee. The audit committee's main function is to oversee our accounting and financial reporting processes, internal systems of control, independent registered public accounting firm relationships and the audits of our financial statements. Pursuant to the audit committee charter, the functions of the committee include, among other things:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting and our disclosure controls and procedures;
- meeting independently with our registered public accounting firm and management;

- preparing the audit committee report required by SEC rules;
- reviewing and approving or ratifying any related person transactions; and
- overseeing our risk assessment and risk management policies.

All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC. Our board of directors has determined that Thomas E. Hancock is an "audit committee financial expert" as defined by applicable SEC rules. In addition, as we may attempt to be listed on the NASDAQ Capital Market in the future, our board of directors has also determined that Mr. Hancock has the requisite financial sophistication under applicable NASDAQ rules and regulations.

Compensation Committee

Our board of directors has established a compensation committee, which is comprised of Thomas E. Hancock, Praveen Tyle and Bernard Malfroy-Camine. Praveen Tyle serves as the chair of the compensation committee. Our compensation committee reviews and recommends policies relating to compensation and benefits of our officers and employees. Pursuant to the compensation committee charter, the functions of this committee include:

- evaluating the performance of our chief executive officer and determining the chief executive officer's salary and contingent compensation based on his or her performance and other relevant criteria;
- identifying the corporate and individual objectives governing the chief executive officer's compensation;
- in consultation with the chief executive officer, determining the compensation of our other officers;
- making recommendations to our board with respect to director compensation;
- reviewing and approving the terms of material agreements with our executive officers;
- overseeing and administering our equity incentive plans and employee benefit plans;
- reviewing and approving policies and procedures relating to the perquisites and expense accounts of our executive officers;
- if and as applicable, furnishing the annual compensation committee report required by SEC rules; and
- conducting a review of executive officer succession planning, as necessary, reporting its findings and recommendations to our board of directors, and working with the Board in evaluating potential successors to executive officer positions.

Our board of directors has determined that each of the members of the Compensation Committee is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act and is an "outside director" as that term is defined in Section 162(m) of the United States Internal Revenue Code of 1986, as amended, or Section 162(m).

Governance Committee

Our board of directors has established a governance committee, which is comprised of Bernard Malfroy-Camine, Morton F. Goldberg and Praveen Tyle. Bernard Malfroy-Camine serves as the chair of the governance committee. Pursuant to the governance committee charter, the functions of this committee include, among other things:

- identifying, evaluating, and making recommendations to our board of directors and our stockholders concerning nominees for election to our board, to each of the board's committees and as committee chairs;
- annually reviewing the performance and effectiveness of our board and developing and overseeing a performance evaluation process;
- annually evaluating the performance of management, the board and each board committee against their duties and responsibilities relating to corporate governance;
- annually evaluating adequacy of our corporate governance structure, policies, and procedures; and
- providing reports to our board regarding the committee's nominations for election to the board and its committees.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is or has in the past served as an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Report of the Audit Committee

Notwithstanding anything to the contrary set forth in any of the Company's previous or future filings under the Securities Act or the Securities Exchange Act that might incorporate this Annual Report on Form 10-K or any future filing with the SEC, in whole or in part, the following report shall not be deemed incorporated by reference into any such filing.

The undersigned members of the audit committee submit this report in connection with the committee's review of the financial reports of the Company for the fiscal year ended December 31, 2014 as follows:

1. The audit committee has reviewed and discussed with management the audited financial statements of the Company for the fiscal year ended December 31, 2014.

2. The audit committee has discussed with representatives of EisnerAmper LLP the matters required to be discussed with them by applicable requirements of Public Company Accounting Oversight Board Auditing Standard No. 16.

3. The audit committee has received the written disclosures and the letter from the independent accountant required by the Public Company Accounting Oversight Board regarding the independent accountant's communications with the audit committee concerning independence, and has discussed with the independent accountant the independent accountant's independence.

Based on the review and discussions referred to above, the audit committee recommended to the Company's board of directors that the audited financial statements be included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2014 for filing with the SEC.

Submitted by the Audit Committee:

Thomas E. Hancock, Chairman

Limitations on Liability and Indemnification Matters

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or controlling persons, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Non-Employee Director Compensation

We generally have not provided any cash compensation to our non-employee directors for their service on our board of directors or committees of our board of directors. We do not have an established policy with regard to equity-based compensation of members of our board of directors.

Upon the closing of the IPO, each of our non-employee directors were granted an option to purchase shares of our common stock with an exercise price per share equal to the initial public offering price of $6.00. Each of these options vest in three equal annual installments following the date of the grant, and each shall provide for full acceleration in the event of a change of control.

Each non-employee member of our board of directors that is initially elected to the our board of directors will receive an automatic grant of non-statutory stock options under our 2014 Equity Incentive Plan. Such option will be granted following his or her initial election to the board of directors and will be a non-statutory stock option to purchase shares of common stock with an exercise price equal to the fair market value of our common stock on the grant date. These initial option grants will vest ratably in annual installments over 3 years of service following the date of grant. For purposes of our automatic director grant program, a non-employee director is a director who is not employed by us and who does not receive compensation from us (excluding the non-employee director compensation described above) or have a business relationship with us that would require disclosure under certain SEC rules.

In addition, on the date of each annual meeting of our stockholders, each non-employee director will be granted a non-statutory stock option to purchase shares of our common stock with an exercise price equal to the fair market value of our common stock on the grant date. A non-employee director who receives an initial award will not receive the additional annual award in the same calendar year. Automatic annual grants vest in full on the one-year anniversary of the grant date.

All options granted to the non-employee directors as described above will have a maximum term of ten years.

We will also reimburse our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

Item 11. ***Executive Compensation.***

This section discusses the material components of the compensation paid to certain of our executive officers, which we refer to as our named executive officers. For our fiscal years ended December 31, 2013 and December 31, 2014, our named executive officers and their positions were:

- Stephen From, President and Chief Executive Officer
- Michael Manzo, Vice President of Engineering

Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers during our fiscal years ended December 31, 2013 and December 31, 2014.

Name and Principal Position	Year	Salary ($)	Bonus ($)[2]	Option Awards[1] ($)	Total ($)
Stephen From, President and Chief Executive Officer	2014	275,078	130,000	0	405,078
	2013	275,078	8,360	0	283,438
Michael Manzo, Vice President of Engineering	2014	175,049	0	0	175,049
	2013	175,049	0	0	175,049

1. The amounts in this column represent the aggregate grant date fair value of option awards or stock awards granted to the officer in the applicable fiscal year, computed in accordance with FASB ASC Topic 718. See Note 11 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a discussion of the assumptions made by us in determining the grant date fair value of our equity awards. In accordance with SEC rules, the grant date fair value of an award subject to performance conditions is based on the probable outcome of the conditions.

2. The amounts in this column represent discretionary bonus payments granted by the board in the applicable fiscal year.

Narrative Disclosure to Compensation Tables

Employment Agreements

We have an amended and restated employment agreement with our President and Chief Executive Officer, Stephen From, effective as of April 28, 2006. Pursuant to this agreement, Mr. From currently receives an annual base salary of $275,078 and he is entitled to receive a bonus of up to 50% of his annual base salary for the applicable fiscal year, and which was $130,000 and $8,360 for the years ended December 31, 2014 and 2013, respectively.

In July 2014, our board of directors approved a second amended and restated employment agreement with Mr. From, that will become effective when and if we become listed on the NASDAQ Capital Market. Pursuant to this agreement, Mr. From will receive an annual base salary of $400,000 and will be entitled to receive a bonus of up to 50% of his annual base salary for the applicable fiscal year. This agreement supersedes in its entirety any prior employment agreements we had with Mr. From.

We have an offer letter with our Vice President of Engineering, Michael Manzo, effective as of August 24, 2006. Pursuant to this agreement, Mr. Manzo currently receives an annual base salary of $200,000, which was increased from $175,049 by an amendment following the IPO, and he is entitled to receive a bonus of up to 15% of his annual base salary for the applicable fiscal year. Mr. Manzo did not receive a bonus for the year ended December 31, 2013 or for the year ended December 31, 2014.

In July 2014, our board of directors approved an amended and restated offer letter with Mr. Manzo, that will become effective when and if we become listed on the NASDAQ Capital Market. Pursuant to this letter, Mr. Manzo will receive an annual base salary of $250,000 and will be entitled to receive a bonus of up to 30% of his annual base salary for the applicable fiscal year. This agreement supersedes in its entirety any prior offer letters we had with Mr. Manzo.

Each of our named executive officers is eligible to receive certain benefits in the event of a change in control or if his employment is terminated under certain circumstances, as described under "Potential Payments Upon Termination or Change in Control" below.

Equity Compensation

We grant stock options and restricted shares to our named executive officers as the long-term incentive component of our compensation program. Stock options allow employees to purchase shares of our common stock at a price per share equal to the fair market value of our common stock on the date of grant and may or may not be intended to qualify as "incentive stock options" for United States federal income tax purposes. In the past, our board of directors has determined the fair market value of our common stock based upon inputs including valuation reports prepared by third-party valuation firms. Generally, one third of the equity awards we grant vest on the first year anniversary, with the remainder vesting in equal monthly installments over 24 months, subject to the employee's continued employment with us on the vesting date and our board of directors has discretion to provide that granted options will vest on an accelerated basis if a change of control of our company occurs, either at the time such award is granted or afterward.

Potential Payments Upon Termination or Change in Control

Stephen From

Pursuant to his employment agreement, if we terminate the employment of Stephen From without Cause or if he resigns for Good Reason, then he will be eligible to receive:

- continued payment of base salary for 1 year;
- a lump-sum cash payment equal to his target bonus payment for the year in which the termination occurs;
- reimbursement of up to $30,000 in relocation expenses; and
- payment by us of the monthly premiums under COBRA for such executive and his eligible dependents for up to 1 year following the termination.

"Cause" means the officer's unlawful or dishonest conduct, or a breach of any of his obligations made under his employment agreement, including, but to limited to, the confidentiality provisions.

"Good Reason" means a resignation after one of the following conditions has come into existence without the officer's consent: i) a material reduction in duties, authority or responsibility; ii) a material reduction in annual base salary; iii) a relocation of principal place of employment that increases his one-way commute by more than 50 miles; or iv) a material breach by us of his employment agreement.

Upon a Change in Control, all outstanding unvested options held by Mr. From accelerate and vest in full.

Michael Manzo

Pursuant to his offer letter, if we terminate the employment of Michael Manzo without Cause or if he resigns for Good Reason, then he will be eligible to receive continued payment of base salary for 6 months.

"Cause" means the officer's unlawful or dishonest conduct, or a breach of any of his obligations made under his offer letter, including, but to limited to, the restrictive covenants and agreements.

"Good Reason" means a resignation after one of the following conditions has come into existence without the officer's consent: i) a material reduction in duties, authority or responsibility; ii) a material reduction in annual base salary; iii) a relocation of principal place of employment that increases his one-way commute by more than 50 miles; or iv) a material breach by us of his offer letter.

Upon a Change in Control, all outstanding unvested options held by Mr. Manzo accelerate and vest in full.

Director Compensation

During our fiscal year ended December 31, 2014, we did not pay any cash fees, make any non-equity awards, pay any other non-equity compensation, or grant any option awards to the non-employee members of our board directors. Stephen From, our President and CEO, receives no compensation for his service as a director.

Employee Benefits and Perquisites

Our named executive officers will be eligible to participate in our health and welfare plans to the same extent as all full-time employees. We do not provide our named executive officers with perquisites or other personal benefits other than reimbursement of their healthcare premiums (prior to our offering health plans), as described in the Summary Compensation Table.

Outstanding Equity Awards at 2014 Fiscal Year-End

The following table shows certain information regarding outstanding equity awards held by our named executive officers as of December 31, 2014.

Generally, one-third of the options granted to our named executive officers vest on the one year anniversary of grant, with the remaining options vesting monthly for two years thereafter, subject to our repurchase right in the event that the executive's service terminates before vesting in such shares. For information regarding the vesting acceleration provisions applicable to the options held by our named executive officers, please see "Potential Payments Upon Termination or Change in Control" above.

Option Awards

Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Vested	Number of Securities Underlying Unexercised Options (#) Unvested	Option Exercise Price ($)	Option Expiration Date
Stephen From	25-Jul-06	52,990	0	0.65	25-Jul-16
	10-Jan-07	22,803	0	0.65	10-Jan-17
	15-Apr-08	27,803	0	0.65	15-Apr-18
	23-Jan-09	2,157	0	0.65	23-Jan-19
	23-Jan-09	278	0	0.65	23-Jan-19
	29-Jan-10	54,009	0	0.65	29-Jan-20
	25-Jun-10	34,672	0	0.65	25-Jun-20
	14-Jan-11	4,554	0	0.65	14-Jan-21
	14-Jan-11	47,439	0	0.65	14-Jan-21
	23-Dec-12	3,643	7,286(1)	0.65	23-Dec-22
	19-Feb-15	0	3,642(2)	6.00	19-Feb-25
	24-Feb-15	43,750	131,250(3)	5.75	24-Feb-25
Michael Manzo	16-Oct-06	7,286	0	0.65	16-Oct-16
	16-May-07	7,286	0	0.65	16-May-17
	15-Apr-08	3,436	0	0.65	15-Apr-18
	23-Jan-09	268	0	0.65	23-Jan-19
	23-Jan-09	1,366	0	0.65	23-Jan-19
	29-Jan-10	6,885	0	0.65	29-Jan-20
	25-Jun-10	4,567	0	0.65	25-Jun-20
	14-Jan-11	1,366	0	0.65	14-Jan-21
	14-Jan-11	6,400	0	0.65	14-Jan-21
	23-Dec-12	3,643	7,286(1)	0.65	23-Dec-22
	19-Feb-15	0	3,187(2)	6.00	19-Feb-25
	24-Feb-15	12,500	37,500(3)	5.75	24-Feb-25

(1) One-third of these options vest on the one year anniversary of the grant, with the remainder vesting in equal monthly installments over two years.

(2) One-third of these options vest on April 24, 2014, with the remainder vesting in equal monthly installments over two years.

(3) One-quarter of these options vest as of the grant date, one-quarter vest on the one year anniversary of the grant, with the remainder vesting in equal monthly installments over two years.

All option awards were granted under our 2005 Equity Incentive Plan, or the 2005 Plan, and our 2014 Employee Stock Purchase Plan, or the 2014 Plan.

Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that if Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that we shall have the power to indemnify our employees and agents to the fullest extent permitted by law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification. We have obtained directors' and officers' liability insurance.

We entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for certain expenses, judgments, fines and settlement amounts, among others, incurred by such person in any action or proceeding arising out of such person's services as a director or executive officer in any capacity with respect to any employee benefit plan or as a director, partner, trustee or agent of another entity at our request. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is incorporated by reference as an exhibit to this Annual Report on Form 10-K.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.***

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 27, 2015, by:

- each of our named executive officers;
- each of our directors;
- all of our directors and current executive officers as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership is based on 6,333,579 shares of common stock outstanding on March 27, 2015. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of March 27, 2015 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Eyegate Pharmaceuticals, Inc., 271 Waverley Oaks Road, Suite 108, Waltham, MA 02452. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Percentage**
5% or Greater Stockholders		
Entities affiliated with Ventech SA[(1)] 47, avenue de l'Opéra Paris, France 75002	2,839,178	43.2%
Entities affiliated with IPSA[(2)] 10 rue de la Paix, Paris, France 75002	1,549,650	24.1%
Natixis Private Equity[(3)] 5 – 7, rue de Monttessuy 75340 Paris cedex 07 France	737,647	11.5%
Executive Officers and Directors		
Stephen From[(4)]	341,909	5.2%
Michael Manzo[(5)]	60,293	*
Paul Chaney[(6)]	99,906	1.6%
Morton Goldberg[(7)]	39,065	*
Praveen Tyle[(8)]	39,065	*
Thomas Balland[(9)]	1,552,972	24.2%
Thomas E. Hancock[(10)]	3,322	*
Bernard Malfroy-Camine[(11)]	11,766	*
Mounia Chaoui[(12)]	3,322	*
All current executive officers and directors as a group (total 9 persons)	2,151,620	30.6%

* Represents beneficial ownership of less than one percent (1%) of the outstanding common stock.

(1) Consists of:

(a) 576,302 shares held by FCPR Ventech A;
(b) 610,371 shares held by FCPR Ventech B;
(c) 965 shares held by FCPR Ventech Coinvest; and
(d) 1,651,540 shares held by FCPR Ventech Capital II.

Alain Caffi and Jean Bourcereau, as directors of Ventech SA, have voting and investment power with respect to the shares held by all of the foregoing entities.

Includes 235,359 shares of common stock issuable upon exercise of warrants.

(2) Consists of:

(a) 5,791 shares of Eyegate S.A.S. held by Innoven 2002 FCPI N°6;
(b) 11,387 shares of Eyegate S.A.S. held by Innoven 2003 FCPI N°7;
(c) 39,437 shares of Eyegate S.A.S. held by FCPI Innoven Europe;
(d) 72,694 shares of Eyegate S.A.S. held by FCPI Innoven Europe 2;
(e) 39,160 shares of Eyegate S.A.S. held by FCPI Innoven Europe 3;
(f) 32,943 shares of Eyegate S.A.S. held by FCPI Innoven Capital;
(g) 20,102 shares of Eyegate S.A.S. held by FCPI Innoven Capital 2;
(h) 230,238 shares of Eyegate S.A.S. held by FCPI Poste Innovation;
(i) 149,680 shares of Eyegate S.A.S. held by FCPI Poste Innovation 2;
(j) 193,633 shares of Eyegate S.A.S. held by FCPI Poste Innovation 3;
(k) 325,945 shares of Eyegate S.A.S. held by FCPI Poste Innovation 5;
(l) 250,663 shares of Eyegate S.A.S. held by FCPI Poste Innovation 6;
(m) 80,706 shares of Eyegate S.A.S. held by FCPI Poste Innovation 9; and
(n) 97,271 shares of Eyegate S.A.S. held by FCPI La Banque Postale Innovation 1.

Jean-Michel Paulhac and Thomas Balland, as directors of Innoven Partenaires S.A., have voting and investment power with respect to the shares held by all of the foregoing entities.

Includes 89,172 shares of common stock issuable upon exercise of warrants.

(3) Dominique Sabassier, as general manager of Natixis Private Equity, has voting and investment power with respect to the shares held by Natixis Private Equity.

Includes 63,442 shares of common stock issuable upon exercise of warrants.

(4) Consists of 41,340 shares held and 300,569 shares issuable pursuant to stock options exercisable within 60 days of March 27, 2015.

(5) Consists of 60,293 shares issuable pursuant to stock options exercisable within 60 days of March 27, 2015.

(6) Consists of 8,333 shares held and 91,573 shares issuable pursuant to stock options exercisable within 60 days of March 27, 2015.

(7) Consists of 39,065 shares issuable pursuant to stock options exercisable within 60 days of March 27, 2015.

(8) Consists of 39,065 shares issuable pursuant to stock options exercisable within 60 days of March 27, 2015.

(9) Consists of 1,549,650 shares beneficially owned as a director of IPSA and 3,322 shares issuable pursuant to stock options exercisable within 60 days of March 27, 2015.

(10) Consists of 3,322 shares issuable pursuant to stock options exercisable within 60 days of March 27, 2015.

(11) Consists of 11,766 shares issuable pursuant to stock options exercisable within 60 days of March 27, 2015.

(12) Consists of 3,322 shares issuable pursuant to stock options exercisable within 60 days of March 27, 2015.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information as of December 31, 2014 concerning the number of shares of Common Stock issuable under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Restricted Stock Units, 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 (Excluding Securities Reflected in Column (a))
	(a)	(b)	(c)
Equity compensation plan approved by security holders[(1)]	752,372	$ 0.93	786,784
Equity compensation plan not approved by security holders	—	—	—
Total	752,372	$ 0.93	786,784

(1) Consists of our 2005 Plan and 2014 Plan.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence.***

The following is a description of transactions during the reporting period to which we have been a party, in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or beneficial owners of more than 5% of our common stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation, termination and change-in-control arrangements, which are described under "Executive Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

All of the transactions set forth below were approved by a majority of our board of directors, including a majority of the independent and disinterested members of our board of directors. We believe that we have executed all of the transactions set forth below on terms no less favorable to us than we could have obtained from unaffiliated third parties. It is our intention to ensure that all future transactions between us and our officers, directors and principal stockholders and their affiliates are approved by the audit committee and a majority of the members of our board of directors, including a majority of the independent and disinterested members of our board of directors, and are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

Some of our directors have previously been or are currently associated with our principal stockholders as indicated in the following table:

Director	**Principal Stockholder**
Thomas Balland	Entities affiliated with IPSA
Mounia Chaoui	Entities affiliated with Ventech SA
Bernard Malfroy-Camine	Entities affiliated with Ventech SA

Convertible Promissory Note Financings

On June 6, 2014 and July 17, 2014, we consummated two closings of a private placement, comprising the first tranche of a bridge financing, or the 2014 Private Placement, in which we issued convertible promissory notes in the aggregate principal amount of approximately $995,000 to certain investors, including Ventech, S.A. and IPSA; and in December 2014, we closed the second tranche of the 2014 Private Placement, in which we issued convertible promissory notes in the aggregate principle amount of approximately $288,000 to certain investors, including Ventech, S.A. and IPSA, all of such convertible promissory notes referred to as the 2014 Notes. We also issued warrants to purchase that number of shares of our common stock. The 2014 Notes converted into shares of our common stock in connection with our initial public offering.

Loans to Officers and Directors

On December 1, 2005, we made a loan to our President, CEO, and director, Stephen From in connection with his purchase of restricted stock, in the original principal amount of $132,341, which had an original maturity date of October 1, 2010. On September 3, 2010, our board extended the maturity date of this note to October 1, 2012 and on September 28, 2012, our board further extended the maturity date of this note to October 1, 2016. In January 2014, we and Mr. From entered into an agreement to terminate this note and forgive any obligation for payment thereof.

On September 23, 2006, we made an additional loan to Mr. From in connection with his purchase of restricted stock, in the original principal amount of $3,835, which had an original maturity date of May 23, 2011. On September 3, 2010, our board extended the maturity date of this note to September 23, 2013 and on September 28, 2012, our board further extended the maturity date of this note to May 23, 2017 and reduced the interest rate to 0.93% compounded semi-annually. In January 2014, we and Mr. From entered into an agreement to terminate this note and forgive any obligation for payment thereof.

Indemnification Agreements

We entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for certain expenses, judgments, fines and settlement amounts, among others, incurred by this person in any action or proceeding arising out of this person's services as a director or executive officer in any capacity with respect to any employee benefit plan or as a director, partner, trustee or agent of another entity at our request. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

Participation in our Initial Public Offering

Certain of our existing stockholders, as well as certain of our directors, purchased an aggregate of approximately $3.4 million of shares of our common stock in our initial public offering which closed on February 19, 2015 at the initial public offering price of $6.00 per share.

Item 14. ***Principal Accounting Fees and Services.***

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Fees for professional services provided by EisnerAmper LLP, our independent registered public accounting firm, in the only completed fiscal year of the Company in each of the following categories is as set forth in the table below. Our obligation to pay for professional services provided by EisnerAmper LLP commenced on April 1, 2014.

	2014	2013
Audit Fees[(1)]	$ 58,500	$ 410,000
Tax Fees[(2)]	$	$
All Other Fees	$	$
Total Fees	$ 58,500	$ 410,000

All of the services performed in the year ended December 31, 2014 were pre-approved by the Audit Committee. It is the Audit Committee's policy to pre-approve all audit and permitted non-audit services to be provided to us by the independent registered public accounting firm. The Audit Committee's authority to pre-approve non-audit services may be delegated to one or more members of the Audit Committee, who shall present all decisions to pre-approve an activity to the full Audit Committee at its first meeting following such decision. The Audit Committee has delegated this pre-approval authority to its Chairman for non-audit services with aggregate fees of $10,000 or less. In addition, the Audit Committee has considered whether the provision of the non-audit services above is compatible with maintaining he independent registered public accounting firm's independence.

Item 15. ***Exhibits, Financial Statement Schedules.***

(a) Documents Filed. The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements. The consolidated financial statements of Eyegate Pharmaceuticals, Inc. and its subsidiaries filed under this Item 15:

(2) Financial Statement Schedules: None. Financial statement schedules have been omitted since the required information is included in our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K.

(3) Exhibits. The exhibits listed in the accompanying Exhibit Index are filed as a part of this Annual Report on Form 10-K.

(b) Exhibits: The exhibits listed in the accompanying Exhibit Index are filed as a part of this Annual Report on Form 10-K.

(c) Separate Financial Statements and Schedules: None. Financial statement schedules have been omitted since the required information is included in our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
EYEGATE PHARMACEUTICALS, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

EyeGate Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of EyeGate Pharmaceuticals, Inc. (the “Company”) as of December 31, 2014 and 2013, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock, non-controlling interests and stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2014. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of EyeGate Pharmaceuticals, Inc. as of December 31, 2014 and 2013, and the consolidated results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred operating losses from operations and negative cash flows that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ EisnerAmper LLP

New York, New York
March 31, 2015

'EYEGATE PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2014	**2013**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 167,001	$ 501,172
Prepaid expenses and other current assets	26,443	22,351
Current portion of Refundable tax credit receivable	25,336	35,124
Total current assets	218,780	558,647
Property and equipment, net	1,257	2,981
Restricted cash	-	30,000
Deferred offering costs	1,148,994	
Other assets	37,439	100,566
Total assets	$ 1,406,470	$ 692,194
LIABILITIES, CONVERTIBLE PREFERRED STOCK, NON-CONTROLLING INTERESTS AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Grants payable	$ 36,401	$ 41,232
Accounts payable	565,947	13,691
Accrued expenses	913,063	488,989
Convertible notes due to stockholders, net (aggregate principal outstanding of $3,376,573 and $2,027,240, at December 31, 2014 and 2013, respectively	3,205,504	2,027,240
Warrant liability	303,102	—
Total current liabilities	5,024,017	2,571,152
Commitments and contingencies (Note 13)		
Convertible preferred stock and non-controlling interests: (classified as temporary equity)		
Series A convertible preferred stock, $0.01 par value, 2,483,692 shares authorized; 2,483,692 shares issued and outstanding at December 31, 2014 and 2013 (liquidation value of $5,960,863 at December 31, 2014)	254,525	254,525
Series B convertible preferred stock, $0.01 par value, 13,819,649 shares authorized; 8,073,508 shares issued and outstanding at December 31, 2014 and 2013 (liquidation value of $7,023,952 at December 31, 2014)	6,926,180	6,926,180
Series C convertible preferred stock, $0.01 par value, 5,161,241 shares authorized; 3,351,156 shares issued and outstanding at December 31, 2014 and 2013 (liquidation value of $5,857,140 at December 31, 2014)	5,745,127	5,745,127
Series D convertible preferred stock, $0.01 par value 29,020,554 shares authorized; 19,557,392 shares issued and outstanding at December 31, 2014 and 2013 (liquidation value of $23,762,876 at December 31, 2014)	23,482,834	23,482,834
Non-controlling interests	6,780,588	6,556,215
Total convertible preferred stock and non-controlling interests	43,189,254	42,964,881
Stockholders' deficit:		
Common stock, $0.01 par value: 70,000,000 shares authorized; 201,787 and 184,474 shares issued at December 31, 2014 and 2013	2,018	1,844
Additional paid-in capital	10,055,613	10,384,554
Accumulated deficit	(56,862,152)	(55,088,160)
Stockholders' notes receivable	(58,824)	(195,000)
Accumulated other comprehensive income	56,544	52,923
Total stockholders' deficit	(46,806,801)	(44,843,839)
Total liabilities, convertible preferred stock, non-controlling interests and stockholders' deficit	$ 1,406,470	$ 692,194

See accompanying notes to the consolidated financial statements.

EYEGATE PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2014	**2013**
Operating expenses:		
Research and development	$ 531,116	$ 1,010,268
General and administrative	1,930,967	2,087,637
Total operating expenses	2,462,083	3,097,905
Other income (expense), net:		
Research & development tax credit	15,911	24,520
Interest income	1,102	2,186
Extinguishment of research liability	240,000	—
Change in warrant liability	1,095,282	—
Interest expense	(441,720)	(611,386)
Total other income (expense), net	910,575	(584,680)
Net loss	(1,551,508)	(3,682,585)
Net income attributable to non-controlling interests	(222,484)	(196,862)
Net loss attributable to EyeGate Pharmaceuticals, Inc. stockholders	$ (1,773,992)	$ (3,879,447)
Net loss per common share – basic and diluted	$ (9.20)	$ (21.03)
Weighted average shares outstanding – basic and diluted	192,873	184,431

See accompanying notes to the consolidated financial statements.

EYEGATE PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,	
	2014	**2013**
Net loss	$ (1,551,508)	$ (3,682,585)
Other comprehensive income:		
Foreign currency translation adjustments	5,510	22,637
Total other comprehensive income	5,510	22,637
Less:		
Net income attributable to non-controlling interests	(222,484)	(196,862)
Other comprehensive income attributable to non-controlling interests	(1,889)	(8,827)
Comprehensive income attributable to non-controlling interests	(224,373)	(205,689)
Comprehensive loss attributable to EyeGate Pharmaceuticals, Inc. stockholders	$ (1,770,371)	$ (3,865,637)

See accompanying notes to the consolidated financial statements.

EYEGATE PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK NON-CONTROLLING INTERESTS AND STOCKHOLDERS' DEFICIT

	Convertible Preferred Stock								Non-Controlling Interest	Total Convertible Preferred Stock and Non-Controlling Interests
	Series A		Series B		Series C		Series D			
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount		
Balance at December 31, 2012	**2,483,692**	**$ 254,525**	**8,073,508**	**$ 6,926,180**	**3,351,156**	**$ 5,745,127**	**19,557,392**	**$ 23,482,834**	**$ 6,350,526**	**$ 42,759,192**
Exercise of common stock warrants										-
Receipt of stock subscription receivable related to the exercise of common stock options										-
Stock-based compensation										-
Net Loss										-
Net income (loss) attributable to non-controlling interest									196,862	196,862
Translation adjustment									8,827	8,827
Balance at December 31, 2013	**2,483,692**	**$ 254,525**	**8,073,508**	**$ 6,926,180**	**3,351,156**	**$ 5,745,127**	**19,557,392**	**$ 23,482,834**	**$ 6,556,215**	**$ 42,964,881**

	Common Stock		Additional Paid In Capital	Stockholders' Notes Receivable	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2012	**182,744**	**$ 1,827**	**$ 10,199,420**	**$ (195,197)**	**$ 39,113**	**$ (51,208,713)**	**$ (41,163,550)**
Exercise of common stock warrants	1,730	17	1,104				1,121
Receipt of stock subscription receivable related to the exercise of common stock options				197			197
Stock-based compensation			184,030				184,030
Net Loss						(3,879,447)	(3,879,447)
Net income (loss) attributable to non-controlling interest							-
Translation adjustment					13,810		13,810
Balance at December 31, 2013	**184,474**	**$ 1,844**	**$ 10,384,554**	**$ (195,000)**	**$ 52,923**	**$ (55,088,160)**	**$ (44,843,839)**

	Convertible Preferred Stock								Non- Controlling Interest	Total Convertible Preferred Stock and Non-Controlling Interests
	Series A		Series B		Series C		Series D			
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount		
Balance at December 31, 2013	**2,483,692**	**$ 254,525**	**8,073,508**	**$ 6,926,180**	**3,351,156**	**$ 5,745,127**	**19,557,392**	**$ 23,482,834**	**$ 6,556,215**	**$ 42,964,881**
Cancellation of shareholder note receivable										—
Stock-based compensation										—
Loss on modification and extinguishment of 2013 Notes payable due to related party treated as an equity transaction										—
Gain on troubled debt restructuring of 2012 Notes payable due from related parties treated as an equity transaction										—
Net loss									222,484	222,484
Translation adjustment									1,889	1,889
Balance at December 31, 2014	**2,483,692**	**$ 254,525**	**8,073,508**	**$ 6,926,180**	**3,351,156**	**$ 5,745,127**	**19,557,392**	**$ 23,482,834**	**$ 6,780,588**	**$ 43,189,254**

	Common Stock		Additional Paid In Capital	Stockholders' Notes Receivable	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2013	**184,474**	**$ 1,844**	**$ 10,384,554**	**$ (195,000)**	**$ 52,923**	**$ (55,088,160)**	**$ (44,843,839)**
Cancellation of shareholder note receivable				136,176			136,176
Stock-based compensation			26,815				26,815
Loss on modification and 2013 Notes payable to related parties treated as an equity transaction			(668,000)				(668,000)
Gain on troubled debt restructure of 2012 Notes payable due to related parties treated as an equity transaction			200,918				200,918
Issuance of shares as settlement of a liability	15,036	151	104,849				105,000
Exercise of common stock options	2,277	23	6,477				6,500
Net loss						(1,773,992)	(1,773,992)
Translation adjustment					3,621		3,621
Balance at December 31, 2014	**201,787**	**$ 2,018**	**$ 10,055,613**	**$ (58,824)**	**$ 56,544**	**$ (56,862,152)**	**$ (46,806,801)**

See accompanying notes to the consolidated financial statements.

EYEGATE PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2014	**2013**
Operating activities		
Net loss	$ (1,551,508)	$ (3,682,585)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,724	5,455
Non-cash interest expense	226,017	533,269
Stock-based compensation	26,815	184,030
Fair value adjustment of common stock warrants	(1,095,282)	
Write-off of stockholders notes receivable	200,758	—
Extinguishment of research liability	(240,000)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,092)	18,756
Refundable tax credit receivable	7,294	3,364
Other assets	(1,455)	(1,813)
Restricted cash	30,000	152,525
Accounts payable	552,256	(96,058)
Accrued expenses	896,856	(74,558)
Net cash used in operating activities	(950,617)	(2,957,615)
Financing activities		
Proceeds from convertible notes payable	1,755,767	1,459,691
Exercise of warrants	—	1,121
Receipt of stock subscription receivable related to the exercise of common stock options	-	197
Deferred offering costs	(1,148,994)	—
Exercise of stock options	6,500	—
Net cash provided by financing activities	613,273	1,461,009
Effect of exchange rate changes on cash	3,173	24,593
Net decrease in cash	(334,171)	(1,472,013)
Cash, beginning of period	501,172	1,973,185
Cash, end of period	$ 167,001	$ 501,172

See accompanying notes to the consolidated financial statements.

EYEGATE PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2014	**2013**
Supplemental disclosure of noncash investing and financing activities		
Warrants issued to related parties in conjunction with issuance of amended convertible notes	**$ 1,398,384**	$ —
Settlement of a liability with shares	$ 105,000	$ —
Accrued interest added to notes	$ 127,782	$ —

See accompanying notes to the consolidated financial statements.

EYEGATE PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business

EyeGate Pharmaceuticals, Inc. ("EyeGate" or the "Company"), a Delaware corporation, began operations in December 2004 and is a clinical-stage specialty pharmaceutical company that is focused on developing and commercializing therapeutics and drug delivery systems for treating diseases of the eye. EyeGate's first product in clinical trials incorporates a reformulated topically active corticosteroid, dexamethasone phosphate, that is delivered into the ocular tissues though our proprietary innovative drug delivery system, the EyeGate® II Delivery System.

On December 29, 2004, EyeGate acquired all the outstanding ordinary shares of Optis France S.A. ("Optis") in accordance with an Exchange Agreement. In exchange, EyeGate issued shares of common stock and Series A preferred stock of EyeGate to the shareholders of Optis. As a result, Optis became a wholly-owned subsidiary of EyeGate. Optis a company registered in France was founded for the purpose of developing safer, more effective and patient-friendly ocular treatments. The share contributions and exchange was considered an exchange of shares between entities under common control. As a result, EyeGate has recognized the assets and liabilities of Optis at their carrying amounts at the date of the share exchange. Subsequent to the share exchange, Optis changed its name to EyeGate Pharma S.A.S ("EyeGate Pharma.")

In 2006, EyeGate Pharma, raised $4,000,000 in capital, net of $54,853 of issuance and exchange rate costs, which resulted in a 30.336% non-controlling interest in EyeGate Pharma. In 2007, EyeGate Pharma raised $1,000,000 in capital, which resulted in a total 35.094% non-controlling interest in EyeGate Pharma. In 2008, EyeGate Pharma raised $3,142,853 in capital, which resulted in a total 40.668% non-controlling interest in EyeGate Pharma. In 2009, EyeGate Pharma raised $2,475,659 in capital, which resulted in a total 46.9% non-controlling interest in EyeGate Pharma. In 2011, EyeGate Pharma raised $1,441,641 in capital, which resulted in a total 49.6% non-controlling interest in EyeGate Pharma. In 2011, EyeGate Pharma raised $842,019 in capital from current investors and $633,215 in capital from its Parent, EyeGate, which resulted in a total 49.99% non-controlling interest in EyeGate Pharma (see Note 9). Such percentage remained unchanged through December 31, 2014.

On March 25, 2014, the Board approved a proposal to pursue an offering of its stock and to file an initial public offering ("IPO"). If the IPO is successful, all of the Company's preferred stock, and the non-controlling interests convertible into the Company's preferred stock, will be converted into common shares of the Company and EyeGate Pharma will once again become a wholly-owned subsidiary of the Company (see Note 15. Subsequent Events).

On June 17, 2014, the Company's Restated and Amended Certification of Incorporation, was further amended to authorize the Company to issue 120,485,136 shares consisting of 70,000,000 share of common stock $0.01 par value per share and 50,485,136 shares of preferred stock, $0.01 par value per share ("Preferred Stock"), of which 2,483,692 shares are designated as Series A Convertible Preferred Stock, $0.01 par value per share (the "Series A Preferred Stock") 13,819,649 shares are designated as Series B Convertible Preferred Stock, $0.01 par value per share (the "Series B Preferred Stock"), 5,161,241 shares are designated as Series C Convertible Preferred Stock, $0.01 par value per share (the "Series C Preferred Stock") and 29,020,554 shares are designated as Series D Convertible Preferred Stock, $0.01 par value per share (the "Series D Preferred Stock"). The term "Designated Preferred Stock" shall mean, as the context may require, individually or collectively, the Series A Preferred Stock, the Series B Preferred Stock, the Series C Preferred Stock and the Series D Preferred Stock."

Since its inception, EyeGate has devoted substantially all of its efforts to business planning, research and development, and raising capital.

The accompanying consolidated financial statements have been prepared assuming that EyeGate will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. At December 31, 2014, EyeGate has cash and cash equivalents of $167,001, and an accumulated deficit of $56,862,152. EyeGate has incurred operating losses and negative operating cash flows since inception, and future losses are anticipated. To continue development, EyeGate needs to raise additional capital through debt and/or equity financing, or access additional funding through grants. However, additional capital may not be available on terms favorable to EyeGate, if at all. Accordingly, no assurances can be given that management will be successful in these endeavors. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and EyeGate Pharma, a majority-owned subsidiary of EyeGate, collectively referred to as the Company. The interests in EyeGate Pharma not owned by the Company are reported in the consolidated balance sheets as non-controlling interests, a component of temporary equity, and the interest in the earnings or loss of the subsidiary not attributable to the Company is reported as net income (loss) attributable to non-controlling interests in the consolidated statements of operations and comprehensive loss. Non-controlling interests represents the cumulative portion of equity and operating results of subsidiaries not owned by the Company. The non-controlling interests are convertible into shares of the Company's convertible preferred stock (see Note 7) which are classified as temporary equity on the consolidated balance sheets, and accordingly, the non-controlling interests are also classified as temporary equity on the consolidated balance sheets. All inter-company balances and transactions have been eliminated in consolidation. These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States.

Reverse Stock Split

On September 25, 2014, the Company's Board of Directors approved a 1-for-10.98 reverse split of the Company's outstanding common stock. Accordingly, all shares and per share amounts were retroactively adjusted to reflect this reverse split.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make significant estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities, at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions are required in providing for losses on accounts receivable, fair value of warrants, establishing useful lives of intangible assets and conducting impairment reviews of long-lived assets. The Company bases its estimates on historical experience and various other assumptions that it believes to be reasonable under the circumstances. Although the Company regularly assesses these estimates, actual results could differ materially from these estimates. Changes in estimates are recorded in the period in which they become known.

Foreign Currency Translation

Operations of EyeGate Pharma are conducted in euros which represent its functional currency. Balance sheet accounts of such subsidiary were translated into U.S. dollars at the exchange rate in effect at the balance sheet date and income statement accounts were translated to the average rate of exchange prevailing during the period. Translation adjustments resulting from this process, were included in accumulated other comprehensive income on the consolidated balance sheet.

Cash and Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with maturity of 90 days or less when acquired, that are not restricted as to withdrawal, to be the equivalent of cash for the purpose of balance sheet and statement of cash flows presentation. Cash equivalents, which were nominal in amount, consisted of money market accounts that are readily convertible to cash. As of December 31, 2014 and 2013, the Company has classified $0 and $30,000 as restricted cash.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation. Depreciation is provided for on a straight-line basis over the estimated useful life of 3 to 7 years for all assets. Maintenance and repair costs are expensed as incurred. The Company reviews its property and equipment whenever events or changes in circumstances indicate that the carrying value of certain assets might not be recoverable, and recognizes an impairment loss when it is probable that the estimated cash flows are less than the carrying value of the asset.

Impairment of Long-Lived Assets

The Company evaluates potential impairment of long-lived assets and long-lived assets to be disposed of and considers whether long-lived assets held for use have been impaired whenever events or changes in circumstances indicate that the related carrying amount may not be recoverable. Management makes significant estimates and assumptions regarding future sales, cost trends, productivity and market maturity in order to test for impairment. Management reports those long-lived assets to be disposed of and assets held for sale at the lower of carrying amount or fair value less cost to sell. Based on current facts, estimates and assumptions, management believes that no assets are impaired at December 31, 2014. There is no assurance that management's estimates and assumptions will not change in future periods.

2. Summary of Significant Accounting Policies - (continued)

Research and Development Expenses

Research and development expenditures are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, benefits, facilities, research-related overhead, sponsored research costs, contracted services, license fees, and other external costs. Because the Company believes that, under its current process for developing its product, viability of the product is essentially concurrent with the establishment of technological feasibility, no costs have been capitalized to date.

Income Taxes

The Company provides deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. Deferred tax assets and liabilities are determined based on differences between the financial statement carrying amounts and the tax bases of the assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded 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 Company recognizes the impact of an uncertain tax position in the financial statements if that position is more likely than not of being sustained by the taxing authority. As of December 31, 2014, the Company had no unrecognized uncertain tax positions.

Refundable Tax Credits for Research and Development

EyeGate Pharma is entitled to receive refundable tax credits associated with its research and development expenses in France. These tax credits can be realized, upon request of the Company, in the form of a cash payment or credits against tax liabilities. The Company records the refundable tax credit as income in the year in which the research and development expenses are incurred.

Sale of Stock by the Subsidiary

The Company is largely dependent on obtaining financing to generate sufficient cash to cover operating costs. Through 2011, EyeGate Pharma, periodically issued preferred shares in exchange for U.S. dollar proceeds. At December 31, 2014, these shares represent a 49.99% non-controlling interest in the subsidiary, which reduced the Company's ownership interest in the subsidiary to 50.01%. The Company accounts for sale of stock by the subsidiary (of which there were no such sales in 2014 and 2013) as an equity transaction by recording the carrying value of the percentage of the equity sold as an increase in the non-controlling interest, with any excess proceeds representing a gain to the Company recorded to additional paid-in capital.

Concentration of Credit Risk and Off-Balance-Sheet Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash and cash equivalents. The Company invests cash in accredited financial institutions and cash equivalents in widely held money market funds. Consequently, such funds are subject to minimal credit risk.

The Company has no significant off-balance-sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in stockholders' equity during a period from transactions, and other events and circumstances from non-owner sources. The foreign currency translation adjustments (see above) are the Company's only component of other comprehensive income (loss).

2. Summary of Significant Accounting Policies - (continued)

Stock-Based Compensation

Stock-based compensation represents the cost related to stock-based awards granted to employees. The Company measures stock-based compensation cost at grant date, based on the estimated fair value of the award, and recognizes the cost as expense on a straight-line basis (net of estimated forfeitures) over the employee requisite service period. The Company estimates the fair value of stock options using a Black-Scholes valuation model. The Company recognizes compensation expense for non-employee stock option grants at the fair value of the goods or services received or the equity instruments issued, whichever is more reliably measurable. The Company recorded compensation expense for non-employee awards with graded vesting using the accelerated expense attribution method.

The Company records deferred tax assets for awards that result in deductions on the Company's income tax returns, based on the amount of compensation expenses recognized and the Company's statutory tax rate in the jurisdiction in which it will receive a deduction. Differences between the deferred tax assets recognized for financial reporting purposes and the actual tax benefit realized on the Company's income tax return are recorded in additional paid-in capital if the tax benefit exceeds the deferred tax asset, or in the consolidated statements of operations if the deferred tax asset exceeds the tax benefit and no additional paid-in capital exists from previous awards.

Net Loss per Share

Basic and diluted net loss per common share is based on the weighted average number of shares outstanding common stock.

In computing diluted loss per share, no effect has been given to the common shares issuable upon conversion or exercise of the following dilutive securities as the Company's net loss would make the effect anti-dilutive.

	Year Ended December 31,	
	2014	**2013**
Series A convertible preferred stock	625,895	625,895
Series B convertible preferred stock (including 525,004 shares from conversion of non-controlling interest)	1,262,651	1,262,651
Series C convertible preferred stock (including 187,183 shares from conversion of non-controlling interest)	537,233	537,233
Series D convertible preferred stock (including 358,146 shares from conversion of non-controlling interest)	2,145,810	2,145,810
Common stock warrants	18,176	18,176
Employee stock options	752,372	762,944
Total common shares issuable	5,342,137	5,352,709

The above table does not include shares issuable upon warrants issued to note holders or upon conversion of promissory notes (See Note 6) as the number of shares issuable under the warrants is not yet determinable.

Fair Value of Financial Instruments

The carrying amounts of receivables and payables approximate their fair values due to the short-term nature of these financial instruments. As of December 31, 2014 and 2013, the fair value of the Company's money market funds was $187 and $390,981, respectively.

Fair value of financial and non-financial assets and liabilities is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The three-tier hierarchy for inputs used in measuring fair value, which prioritizes the inputs used in the methodologies of measuring fair value for assets and liabilities, is as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities

Level 2 — Observable inputs other than quoted prices in active markets for identical assets and liabilities

Level 3 — No observable pricing inputs in the market

2. Summary of Significant Accounting Policies - (continued)

The following table represents the fair value of the warrant liability measured at fair value on a recurring basis:

	Level 1	Level 2	Level 3	Total
As of December 31, 2014				
Non-current liabilities:				
Warrant liability	$ —	$ —	$ 303,102	$ 303,102

The following are the changes in the level 3 warrant liability for the year ended December 31, 2014:

Beginning balance	$ 0
Issuance of warrants	1,398,384
Change in fair value	(1,095,282)
Ending balance	$ 303,102

As of December 31, 2013 — Not applicable

Deferred issuance costs

Deferred public offering costs, which primarily consist of direct, incremental legal and accounting fees relating to the Company's initial public offering, are capitalized within deferred issuance costs. The deferred issuance costs will be offset against IPO proceeds upon the consummation of the offering in February 2015. The Company has incurred approximately $1,149,000 in initial public offering costs as of December 31, 2014.

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income. ASU 2013-02 requires companies to provide information about the amounts reclassified out of accumulated other comprehensive income by component. Companies are also required to disclose these reclassifications by each respective line item on their statements of operations. ASU 2013-02 is effective prospectively for annual reporting periods beginning after December 15, 2012, and interim periods within those annual periods. The Company adopted ASU 2013-02 for the financial statements for the year ended December 31, 2013. This adoption did not have a material impact on the consolidated financial statements.

In July 2013, the FASB issued ASU No. 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. ASU 2013-11 clarifies guidance and eliminates diversity in practice on the presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists at the reporting date. The Company adopted this new guidance in the first quarter of fiscal year 2014. The adoption of ASU 2003-11 did not have a material impact on the consolidated financial statements.

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09 *Revenue from Contracts with Customers* .. This ASU provides a robust framework for addressing revenue issues. The core principle contained in ASU 2014-09 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration which the entity expects to be entitled in exchange for those goods and services. This amendment will be effective for public entities for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company will evaluate the impact of this ASU after it begins to earn revenue.

In June 2014, the FASB issued ASU 2014-10 *Development Stage Entities*. The amendments to the authoritative literature in this ASU remove the definition of a development stage entity, thereby removing the distinction between the development stage entities and the other reporting entities. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. These amendments are effective for annual reporting period beginning after December 15, 2014, and interim periods beginning after December 15, 2015, however early adoption is permitted. The Company has elected to early adopt ASU 2014-10 effective with its interim financial information for the three and six months ended June 30, 2014. Upon adoption of this ASU, the Company eliminated the inception-to-date information in the statements of operations, comprehensive loss, cash flows and convertible preferred stock, non-controlling interests and stockholders' deficit and no longer labels its financial statements as those of a company in the development stage.

2. Summary of Significant Accounting Policies - (continued)

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15"). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Specifically, ASU 2014-15 provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new standard will be effective for reporting periods beginning after December 15, 2016, with early adoption permitted. Management is currently evaluating the impact of the adoption of ASU 2014-15 on our financial statements and disclosures.

3. Property and Equipment

Property and equipment at December 31, 2014 and 2013 consists of the following:

	Estimated Useful Life (Years)	2014	2013
Laboratory equipment	7	$ 14,661	$ 14,661
Computer equipment	3	182,914	182,914
Computer software	3	46,038	46,038
Furniture, fixtures and office equipment	5	24,480	24,480
		268,093	268,093
Less accumulated depreciation		266,836	265,112
		$ 1,257	$ 2,981

Depreciation expense was $1,724 and $5,455 for the years ended December 31, 2014 and 2013, respectively.

4. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2014	2013
Payroll and benefits	$ 168,269	$ 30,920
Clinical trials	57,629	216,350
Consulting	8,917	12,988
Professional fees	534,984	157,953
Accrued interest	143,264	70,778
Total accrued expenses	$ 913,063	$ 488,989

5. Grants Payable

On October 27, 1998, the EyeGate Pharma was awarded a non-interest bearing grant from OSEO/Anvar of France. The balance of the grant was repaid in 2012. No annuity payments (specified percentage of the proceeds from the sale or license of products funded by such research grant) were payable as of December 31, 2014 or December 31, 2013.

In February 2007, the Company was awarded a second non-interest bearing grant from OSEO/Anvar of France. The balance of the grant payable was $36,401 and $41,232 at December 31, 2014 and December 31, 2013, respectively. There are no incremental annuity payments provided for through this grant. The balance of the grant payable is currently due. The Company, as of the issuance of this report, has paid the grant.

6. Debt

On December 21, 2012, the Company issued unsecured promissory notes (the "2012 Notes") to certain stockholders in the aggregate principal amount of $525,000. The notes accrued interest at a rate of 8% per annum on the outstanding principal amount. The 2012 Notes were scheduled to mature December 10, 2013 at an aggregate repayment principal amount of $1,058,270 (the "premium" of $533,000 was recognized as additional interest through December 10, 2013) resulting in an effective interest rate of approximately 88%. On December 2, 2013, the 2012 Notes, the Company and the Requisite Holders agreed to extend the maturity of the notes until June 10, 2014. All other terms of the 2012 Notes remained the same. As discussed below, the 2012 Notes were amended and restated on June 6, 2014.

On July 20, 2013, the Company entered into a Convertible Promissory Note Purchase Agreement ("Note Purchase Agreement"), pursuant to which the Company could issue up to an aggregate principal amount of $1,500,000 of unsecured promissory notes (the "2013 Notes") to certain stockholders. The 2013 Notes were scheduled to mature on July 29, 2014, and accrued interest at a rate of 8% per annum. In the event that the Company issued equity securities resulting in gross proceeds to the Company of at least $3 million prior to maturity, the Company was to pay the note holders the repayment principal and all accrued and unpaid interest, at such time. In the event that the Company consummated a sale of the Company, as defined, the Company was to, while the 2012 Notes remain outstanding and at the election of the holders of two-thirds of the aggregate principal outstanding either (i) pay the holders the repayment principal amount plus accrued interest or (ii) immediately prior to the closing, convert all outstanding principal and interest into the Company's Series D convertible preferred stock at 87.5% of the Series D convertible preferred stock conversion price.

On July 29, 2013, the Company issued 2013 Notes in an aggregate principal amount of $968,970 pursuant to the Note Purchase Agreement. On February 28, 2014, the Company issued an additional aggregate principal amount of $446,151 in convertible promissory notes (the "2013 Notes") and on April 15, 2014, the Company issued $16,667 of additional 2013 Notes. As discussed below, on June 6, 2014, the 2013 Notes were amended and restated along with the 2012 Notes.

On June 6, 2014, the Company entered into a Convertible Promissory Note and Warrant Purchase Agreement ("Note and Warrant Purchase Agreement"), pursuant to which the Company could issue up to an aggregate principal amount of $2,000,000 of unsecured promissory notes (the "2014 Notes") to certain stockholders. The 2014 Notes mature on June 6, 2015, and accrue interest at a rate of 12% per annum. In the event that the Company issues equity securities, resulting in gross proceeds to the Company of at least $5 million prior to maturity, all outstanding principal and accrued and unpaid interest under the 2014 Notes will automatically convert into the newly issued equity securities at 70% of the offering price, as applicable, in connection with the closing of the first sale of the equity securities of the Company. In the event that the Company consummates a sale of the Company, as defined, the Company shall, while the 2014 Notes remain outstanding and at the election of the holders of two-thirds of the aggregate principal outstanding shall immediately prior to the closing, convert all outstanding principal and interest into the Company's Series D convertible preferred stock (or other Subsequent Qualified Financing Instruments) at 70.0% of the Series D convertible preferred stock original issuance price.

The Company and each holder of 2012 and 2013 Notes executed an amended and restated promissory note ("Amended and Restated Notes") in the principal amount of the sum of all outstanding principal and accrued and unpaid interest as at June 6, 2014, which aggregated approximately $2.1 million as of June 6, 2014. The Amended and Restated Notes have the same terms as the 2014 Notes.

As part of the Amended and Restated Notes, the requirement to pay the above mentioned premium of $533,000 on the 2012 Notes was rescinded. The Company determined that the restructuring and amendment of 2012 debt agreement resulted in a troubled debt restructuring, primarily due to concession in the form of the rescission of the premium and resulted in a gain of approximately $200,000. Since such note holders are also shareholders in the Company, such gain was recognized as a capital contribution by the note holders. The fair value of the warrants of approximately $260,000 (see discussion below) issued to such note holders was recorded as a warrant liability. The carrying amount of the Amended and Restated debt is approximately $660,000 at December 31, 2014, representing the expected, undiscounted cash flows over the term of the notes and the face amount is approximately $586,000.

6. Debt - (continued)

The restructuring of the 2013 notes resulted in a recognition of an extinguishment of debt as the terms of the new debt and of the original instrument are substantially different. The Company recorded a loss of $668,000, (the difference between the reacquisition price, consisting of the warrant issued and the fair value of the 'new' debt, and the net carrying amount of the debt before modification) and recorded the fair value of the warrant liability of approximately $668,000 separately. The loss has been recorded as a capital transaction as the Note holders are also Preferred Stockholders. Accordingly, the carrying value of the Amended and Restated debt was approximately $1.5 million at December 31, 2014.

On June 6, 2014, July 17, 2014 and December 19, 2014, the Company issued 2014 Notes in an aggregate principal amount of approximately $1,283,000 pursuant to the Note and Warrant Purchase Agreement, of which approximately $495,000 was received on June 6, 2014 and $288,000 was received on December 19, 2014 by the Company. The fair value of the warrants issued in July 17, 2014 with such debt of approximately $219,000 was recognized as a debt discount and accreted to interest expense over the one year maturity term of the debt. On December 19, 2014, the Company issued 2014 Notes in an aggregate principal amount of approximately $288,000 pursuant to the Note and Warrant Purchase Agreement. The fair value of the warrants issued on December 19, 2014 with such debt was approximately $34,000 was recognized as a debt discount and accreted to interest expense over the remaining maturity term of the debt. At December 31, 2014, the carrying amount of the 2014 Notes was approximately $1,039,000.

The Company evaluated the features of the Amended and Restated Notes, and the 2014 Notes, to ascertain if the embedded conversion feature was required to be bifurcated and accounted for as a derivative. The Company evaluated whether the embedded feature met the definition of a derivative and determined that the conversion option does not as it does not meet the "net settlement" requirement. The underlying shares of the Company are those of a private company and are not considered readily convertible to cash, and therefore bifurcation is not required. The Company next considered whether the discount upon conversion required recognition of a beneficial conversion feature. Since the debt is only convertible in the instance of specific transactions, it is considered contingently convertible, and any beneficial conversion would only be recognized upon the occurrence of one of the contingent events.

The Company issued to each holder of a 2014 Note or the Amended and Restated Notes, a warrant exercisable for common stock of the Company if the Company consummates an initial public offering ("IPO") on or prior to December 31, 2014 or Series D convertible preferred stock at the original issuance price of such equity issuance if the IPO is not consummated on or prior to December 31, 2014 or if the Company is sold in 2014 in an M&A transaction consummated prior to the closing of the IPO. Under such scenario the number of warrants exercisable into Series D convertible stock would be approximately 2.1 million shares at an exercise price of $1.22 per share. The number of shares subject to such Warrant shall be equal to the sum of (a) the principal amount of any Amended and Restated Notes of any holder or affiliates, as defined, and (b) the principal amount of any 2014 Notes of such holder issued by the Company, divided by (2) the original issue price of the Series D Preferred Stock or common stock at the IPO price.

Since the warrants are convertible into Series D Preferred Stock, which is a redeemable security and presented as temporary equity these warrants are classified as liabilities.

The Company determined the fair value of the warrants issued on June 6, 2014 and July 17, 2014 was approximately $1,364,000, based upon the following assumptions:

- The number of warrants to be issued and the strike price will be determined based upon future events, including potential sale, liquidation or IPO transactions as described above. The Company utilized a probability weighting of potential outcomes to estimate the number of warrants issuable, the type of underlying security, and the exercise price.
- Volatility — 70%
- Term — 0.5 years for an IPO scenario; 5 years for an M&A or liquidation scenario
- Dividends — 0%
- Discount rate — 0.6 – 1.6%

The Company determined the fair value of the warrants issued on December 19, 2014 was approximately $34,000, based upon the following assumptions:

- The number of warrants to be issued and the strike price will be determined based upon future events, including potential sale, liquidation or IPO transactions as described above. The Company utilized a probability weighting of potential outcomes to estimate the number of warrants issuable, the type of underlying security, and the exercise price.
- Volatility — 55%
- Term — 0.25 years for an IPO scenario; 4.5 years for an M&A or liquidation scenario
- Dividends — 0%
- Discount rate — 0.6 – 1.74%

The Company utilized a probability weighting of the calculated values of the warrant utilizing a Black Scholes methodology to compute the estimated fair value. The Company will record changes in the fair value of the warrants in the statement of operations at each reporting period. The change in the fair value of the warrants for the twelve months ended December 31, 2014 was a decrease of approximately $1,096,000. The remaining warrant liability at December 31, 2014 is approximately $303,000.

7. Preferred Stock

At December 31, 2014, the Company had 50,485,136 authorized shares of convertible preferred stock, of which 2,483,692 shares were designated as Series A convertible preferred stock ("Series A preferred stock"), 13,819,649 shares were designated as Series B convertible preferred stock ("Series B preferred stock"), 5,161,241 shares were designated as Series C convertible preferred stock ("Series C preferred stock"), and 29,020,554 shares were designated as Series D convertible preferred stock ("Series D preferred stock").

As of December 31, 2014 and 2013, the number of convertible preferred shares outstanding is as follows:

	Year Ended December 31,	
	2014	**2013**
Series A convertible preferred stock	2,483,692	2,483,692
Series B convertible preferred stock	8,073,508	8,073,508
Series C convertible preferred stock	3,351,156	3,351,156
Series D convertible preferred stock	19,557,392	19,557,392
Total preferred shares	33,465,748	33,465,748

7. Preferred Stock - (continued)

The rights, preferences and privileges of the Series A, B, C and D preferred stock are as follows:

Voting

The holders of the Series A, B, C and D preferred stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote other than matters that must by law be voted by class or series vote. Each preferred stockholder is entitled to the number of votes equal to the number of shares of common stock into which each preferred share is convertible at the time of such vote.

Dividends

Series A, B, C and D preferred stockholders are entitled to receive dividends with respect to any shares of Series A, B, C and D shares held by them, only if, when and as such dividends are declared by the Company's Board of Directors (the "Board") out of funds legally available for that purpose. As of December 31, 2014, the Company has not declared dividends related to the Series A, B, C and D preferred stock.

Liquidation Preference

In the event of any liquidation, dissolution or winding-up of the affairs of the Company, including a change of control, the holders of the then outstanding shares of Series D preferred stock, including the holders of the corresponding EyeGate Pharma shares per the exchange agreements, shall receive an amount equal to the original issuance price of Series D preferred stock ($1.22) plus all accumulated but unpaid dividends, payable in preference and priority to any payments made to the holders of the then outstanding Series A, B and C preferred stock and common stock. The holders of the then outstanding shares of Series C preferred stock shall receive an amount equal to the original issuance price of Series C preferred stock ($1.75) plus all accumulated but unpaid dividends, payable in preference and priority to any payments made to the holders of the then outstanding Series B and A preferred stock and common stock. The holders of the then outstanding shares of Series B preferred stock shall receive an amount equal to the original issuance price of Series B preferred stock ($0.87) plus all accumulated but unpaid dividends, payable in preference and priority to any payments made to the holders of the then outstanding Series A preferred stock and common stock. The holders of the then outstanding Series A preferred stock shall receive an amount equal to the original issuance price per share of Series A preferred stock ($2.40) plus all accumulated but unpaid dividends. The remaining assets available for distribution, if any, shall be distributed among the holders of shares of common stock, such distribution to be made ratably based on the number of common shares held by each.

7. Preferred Stock - (continued)

Conversion

Each share of Series A, B, C and D preferred stock is convertible at the option of the holder, into a number of fully paid shares of common stock as determined by dividing the respective preferred stock issue price by the conversion price in effect at the time. The initial conversion price of the Series D preferred stock is $1.22, Series C preferred stock is $1.75, and Series A and B preferred stock is $0.87 and are subject to adjustment in accordance with antidilution provisions. All outstanding shares of Series A, B, C and D preferred stock automatically converted to common stock immediately upon the closing of the Company's initial public offering in February 2015 at the conversion rates of 1:0.251, 1:0.091, 1:0.091, and 1:0.091, respectively.

All series of preferred stock have classified as temporary equity as the preferred stock is redeemable at the option of the holder in the event of a change in control.

8. Warrants

At December 31, 2014, the following warrants were outstanding:

Class of Stock	Number of Shares		Exercise Price	Common Shares upon conversion
Series C Preferred	11,901	$	1.75	1,239
Series D Preferred	27,932	$	1.22	2,549
Common Stock	10,929	$	0.65	10,929
Common Stock	7,247	$	5.16	7,247
Total common stock	58,009			21,964

The above table does not include shares issuable upon exercise of warrants issued to note holders as the number of warrants issuable is not yet determinable (see Note 6).

All of the warrant agreements contain a provision providing for a cashless exercise whereby, the number of warrants to be issued will be reduced by the number shares which could be purchased from the proceeds of the exercise of the respective warrant. The warrants to purchase the Series C preferred stock and the Series D preferred stock and to purchase 10,928 shares of common stock must be exercised prior to the closing of an IPO or such warrants will expire. The remaining warrants expire from 2015 through 2018.

9. Non-controlling interests

Shares issuable from the conversion of non-controlling interests are as follows:

	Year Ended December 31,	
	2014	**2013**
Series B convertible preferred stock	525,004	525,004
Series C convertible preferred stock	187,183	187,183
Series D convertible preferred stock	358,146	358,146
	1,070,333	1,070,033

The subsidiary shares are convertible to Series B, Series C or Series D preferred shares of the Company, respectively, or to common stock of the Company, at the option of the holder (voluntary exchange) or mandatorily upon the occurrence of a Mandatory Exchange Event, as defined in the Exchange Agreement and accordingly the non-controlling interests are classified as temporary equity.

10. Stockholders' Notes Receivable

In 2005 and 2006, certain of the Company's stockholders and officers issued various promissory notes totaling $195,000 for the sale of common stock. The notes were full recourse and were collateralized by the shares of stock sold. The notes bore interest at 6.75% and were due in one payment on the fifth anniversary of the note. The Board resolved to change the interest rate on these notes from 6.75% to 0.93%, effective October 1, 2012. The holders of these notes were granted an extension of maturity to October 1, 2016.

On January 15, 2014, the Company's Board of Directors authorized loan forgiveness on the promissory note with the President of Eyegate. The note principal totaled $136,176, plus accrued interest of $64,582, which is included as a component of general and administrative expenses. As of December 31, 2014, $58,824 is outstanding.

11. Equity Incentive Plan

In 2005, the Company approved the 2005 Equity Incentive Plan (the "2005 Plan"). The 2005 Plan provides for the granting of options, restricted stock or other stock-based awards to employees, officers, directors, consultants and advisors. During 2010, the maximum number of common shares that may be issued pursuant to the 2005 Plan was increased to 891,222 shares. The Board is responsible for administration of the 2005 Plan. The Board determines the term of each option, the option exercise price, the number of shares for which each option is granted and the rate at which each option is exercisable. Incentive stock options may be granted to any officer or employee at an exercise price per share of not less than the fair value per common share on the date of the grant (not less than 110% of fair value in the case of holders of more than 10% of the Company's voting stock) and with a term not to exceed ten years from the date of the grant (five years for incentive stock options granted to holders of more than 10% of the Company's voting stock). Nonqualified stock options may be granted to any officer, employee, consultant or director at an exercise price per share of not less than the par value per share.

11. Equity Incentive Plan - (continued)

The Company's Board adopted the 2014 Equity Incentive Plan, or the ("2014 Plan"), and the Company's stockholders approved the 2014 Plan in February 2015.

The following is a summary of stock option activity for the year ended December 31, 2014:

	Number of Options	Weighted- Average Exercise Price	Weighted-Average Contractual Life (In Years)
Outstanding at beginning of year	762,944	$ 0.91	
Granted	—		
Exercised	(2,277)	$ 2.85	
Expired	(8,295)	$ 3.60	
Outstanding at end of year	752,372	$ 0.93	4.55
Exercisable at end of year	733,049	$ 0.93	6.87
Vested and expected to vest at end of year	733,049	$ 0.93	6.87

No options were granted in 2014 and 2013. In September 2014, the Company entered into two consulting arrangements that provided for 60,358 shares of common stock options issuable in connection with the Company's IPO in February 2015.

The total stock-based compensation expense for employees and non-employees is included in the accompanying consolidated statements of operations as follows:

	Year Ended December 31,	
	2014	2013
Research & development	$ 11,413	$ 57,901
General and administrative	15,402	126,129
	$ 26,815	$ 184,030

As of December 31, 2014, there is approximately $5,095 of total unrecognized compensation expense related to unvested stock-based compensation arrangements granted. That cost is expected to be recognized over a weighted average period of 1.00 years. The intrinsic value of stock options outstanding and exercisable at December 31, 2014 is de minimus.

11. Equity Incentive Plan - (continued)

Stock Option Repricing

On March 12, 2012, the Company modified the terms of stock options held by three officers and six other employees to purchase 613,817 shares of the Company's common stock. The options were originally granted between 2006 and 2011 with exercise prices ranging from $2.85 to $4.06 and had a weighted average remaining term of 7.1 years when modified. The Company reduced the exercise price of the options to $0.66 per share reflecting the Company's most recent valuation of its common stock. In connection with the repricing, the Company recorded additional stock-based compensation expense of $31,290 for the year ended December 31, 2013.

12. Income Taxes

The components of income (loss) before income taxes are as follows:

	Year Ended December 31,	
	2014	**2013**
Domestic	$ (1,996,387)	$ (3,879,447)
Foreign	444,879	196,862
Total	$ (1,551,508)	$ (3,682,585)

The difference between the effective rate reflected in the provision for income taxes on loss before taxes and the amounts determined by applying the applicable statutory U.S. tax rate are analyzed below:

	Year Ended December 31,	
	2014	**2013**
United States federal income tax rate	34.00%	34.00%
State taxes, net of federal benefit	6.27%	5.28%
Permanent differences	50.55%	(4.58)%
Change in valuation allowance	(84.54)%	(31.36)%
Expiration of state net operating loss carryforward	(16.20)%	(7.20)%
Research and development credits	0%	5.05%
Change in State Rate	12.52%	0%
Other	(2.60)%	(1.19)%
Effective tax rate	0.00%	0.00%

The Company's deferred tax assets consist of the following:

	2014	**2013**
Net operating loss carryforwards	$ 15,491,353	$ 14,174,494
Research and development credit carryforwards	1,190,024	1,190,023
Capitalized research and development	4,823,160	5,590,524
Nonqualified stock option	100,712	98,236
Warrants issued for services	587	383
Depreciation and amortization	0	594
Start-up costs/organization costs	26,938	26,276
Cash versus accrual adjustments	1,979,847	1,220,390
Total deferred tax assets	23,612,621	22,300,920
Valuation allowance	(23,612,621)	(22,300,920)
Net deferred tax asset	$ —	$ —

12. Income Taxes - (continued)

As of December 31, 2014, the Company has federal, and state net operating loss carryforwards of approximately $39,642,444 and $26,260,965, respectively, to offset future federal and state taxable income, which expire at various times through 2034. The Company has foreign net operating loss carryforwards of $4,623,428 as of December 31, 2014, which can be carried forward indefinitely. As of December 31, 2014, the Company also has federal, state and foreign research and development tax credit carryforwards of approximately $894,872, $270,647, and $24,505, respectively, to offset future income taxes, which expire at various times through 2034. The federal and state net operating loss and research tax credit carryforwards may be subject to the limitations provided in the Internal Revenue Code ("IRC") Sections 382 and 383.

The Company files United States federal income tax returns and income tax returns in the Commonwealth of Massachusetts as well as foreign tax returns for its subsidiary in France. The Company is not under examination by any jurisdiction for any tax year.

The Company has recorded a valuation allowance against its United States deferred tax assets in each of the years ended December 31, 2014 and 2013 because the Company's management believes that it is more likely than not that these assets will not be realized. The valuation allowance increased by $1,311,700 and $1,156,590 during the year ended December 31, 2014 and 2013, respectively, primarily as a result of net operating losses.

As of December 31, 2014, the Company had no unrecognized tax benefits or related interest and penalties accrued. The Company will recognize interest and penalties related to tax positions in income tax expense. The Company has not, as yet, conducted a study of R&D credit carryforwards. This study may result in an adjustment to the Company's R&D credit carryforwards, however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position.

The net operating loss and tax credit carryforwards are subject to review by the Internal Revenue Service in accordance with the provisions of Section 382 of the Internal Revenue Code. Under this Internal Revenue Code section, substantial changes in the Company's ownership may limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset the Company's taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of the Company of more than 50% within a three-year period. Any such annual limitation may significantly reduce the utilization of the Company's net operating loss carryforwards before they expire. The closing of the Company's initial public offering, alone or together with transactions that have occurred or that may occur in the future, may trigger an ownership change pursuant to Section 382, which could limit the amount of research and development and net operating loss carryforwards that could be utilized annually in the future to offset the Company's taxable income, if any. Any such limitation, whether as the result of the Company's initial public offering, sales of common stock by the Company's existing stockholders or additional sales of common stock by the Company after its initial public offering, could have a material adverse effect on the Company's results of operations in future years.

13. Commitments and Contingencies

Operating Leases

The Company has a lease for the rental of office space for its corporate headquarters. The lease covers the rental of up to 2,390 square feet.

The Company executed a lease agreement in January 2013 which expired in June 2013. The Company exercised its option to continue the lease on a month to month basis. The agreement is cancellable by either party with one month notice.

License Agreements

The Company is a licensee under two license agreements that grant the Company the exclusive right to commercialize the technology related to its proprietary drug delivery system. Both license agreements require the Company to pay royalties to the licensor based on revenues related to the licensed technology.

One of the license agreements requires the Company to pay an annual license fee of $12,500 and, beginning January 1, 2012, requires the Company to pay an annual minimum royalty of $100,000 until the Company has a product using the technology approved and available for commercial sale in the United States. This license also requires payments upon the Company's achievement of certain milestones. Unless terminated pursuant to the license agreement, this license will expire 12 years after the date of the first commercial sale of a product containing the licensed technology. On July 7, 2014, the Company and the Licensor entered into an amendment of the license agreement, whereby the parties agreed to eliminate the past and future minimum royalty provisions and related obligations in exchange for the increase of certain future milestone payments, as well as the issuance of 15,036 shares of our common stock to the licensor. The Company extinguished $240,000, net of the fair value of the stock consideration received, in the year ended December 31, 2014.

Future minimum payments under the license as of December 31, 2014 are $12,500 per year.

Contingencies

The Company neglected to file its Reports of Foreign Bank and Financial Accounts ("FBAR") for 2011 and 2012 as required by the Bank Secrecy Act. The Company's failure to file an FBAR when required may result in civil penalties, criminal penalties or both. The Company could be subject to penalties up to the greater of $100,000 per year or 50% of the amount in the account at the time of the violation. On July 24, 2014, the Company filed the delinquent returns. As of December 31, 2014, the Company has not recorded an accrual related to this contingency as it has not been assessed a penalty and because management believes that the Company did not willfully fail to file FBAR and it has retained records of account, therefore, the Company may not be subject to a significant penalty.

14. Employee Benefit Plans

The Company has an employee benefit plan for its United States-based employees under Section 401(k) of the Internal Revenue Code. The Plan allows all eligible employees to make contributions up to a specified percentage of their compensation. Under the Plan, the Company may, but is not obligated to, match a portion of the employee contribution up to a defined maximum. The Company made no matching contribution for the years ended December 31, 2014 and 2013.

15. Subsequent Events

On February 13, 2015, the Company completed an initial public offering for 683,250 shares of common stock. The common stock was offered at an initial price to the public of $6.00 per share. The gross proceeds to the Company from this offering was approximately $4,100,000 before deducting underwriting discounts and other estimated offering expenses. The Company granted the representative of the underwriters a 45-day option to purchase up to 102,487 additional shares of its common stock to cover over-allotments, if any. The shares began trading on the OTCQB Venture Marketplace under the symbol "EYEG" on February 13, 2015 and the initial offering was closed on February 19, 2015.

SIGNATURES

Pursuant to the requirements of Section 13 and 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.

Date: March 31, 2015 By: /s/ Stephen From
Chief Executive Officer and President

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:

Signature	Title	Date
/s/ Stephen From Stephen From	President, Chief Executive Officer and Director (principal executive officer and principal financial and accounting officer)	March 31, 2015
/s/ Paul Chaney Paul Chaney	Director	March 31, 2015
/s/ Morton Goldberg Morton Goldberg	Director	March 31, 2015
/s/ Praveen Tyle Praveen Tyle	Director	March 31, 2015
/s/ Thomas Balland Thomas Balland	Director	March 31, 2015
/s/ Thomas E. Hancock Thomas E. Hancock	Director	March 31, 2015
/s/ Bernard Malfroy-Camine Bernard Malfroy-Camine	Director	March 31, 2015
/s/ Mounia Chaoui Mounia Chaoui	Director	March 31, 2015

EXHIBIT INDEX

The following exhibits are filed as part of this Annual Report on Form 10-K. Where such filing is made by incorporation by reference to a previously filed document, such document is identified.

Exhibit Number	Description of Exhibit
3.1[3]	Restated Certificate of Incorporation of the Registrant.
3.2[1]	Amended and Restated By-laws of the Registrant
4.1[2]	Specimen Stock Certificate evidencing the shares of common stock
10.1[1]	2005 Equity Incentive Plan, as amended
10.2[4]	2014 Equity Incentive Plan
10.3[3]	Employee Stock Purchase Plan
10.4[1]	Transaction Protocol (License Agreement), by and between Optis B.V., Optis France SA, and Mrs. Francine Behar-Cohen, dated as of July 23, 1999
10.5[1]	Amended and Restated License Agreement, by and between University of Miami and EyeGate Pharma SA (f/k/a Optis France SA), dated as of December 16, 2005
10.6[1]	First Amendment to First Amended and Restated License Agreement of and between EyeGate Pharma SA and University of Miami, dated as of July 7, 2014
10.7[1]	Form of Indemnification Agreement
10.8[1]	Form of Notice of Stock Option Grant pertaining to the 2014 Equity Incentive Plan
10.9[1]	Form of Notice of Stock Unit Award pertaining to the 2014 Equity Incentive Plan
21.1*	Subsidiaries of the Registrant
23.1*	Consent of Independent Registered Accounting Firm
31.1**	Certification pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

1 Previously filed as an exhibit to the Company's Registration Statement on Form S-1 (filed July 30, 2014) and incorporated by reference thereto.

2 Previously filed as an exhibit to Amendment No. 2 to the Company's Registration Statement on Form S-1 (filed August 29, 2014) and incorporated by reference thereto.

3 Previously filed as an exhibit to Amendment No. 3 to the Company's Registration Statement on Form S-1 (filed September 12, 2014) and incorporated by reference thereto.

4 Previously filed as an exhibit to Amendment No. 7 to the Company's Registration Statement on Form S-1 (filed December 24, 2014) and incorporated by reference thereto.

* Filed herewith.

** This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

Exhibit 21.1

Subsidiaries of the Registrant

EyeGate Pharma S.A.S.	**(France)**

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement of EyeGate Pharmaceuticals, Inc. on Form S-8 (No. 333-202207) of our report dated March 31, 2015, on our audits of the consolidated financial statements as of December 31, 2014 and 2013 and for each of the years in the two-year period ended December 31, 2014, which report is included in this Annual Report on Form 10-K, to be filed on or about March 31, 2015. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ EISNERAMPER LLP

New York, New York
March 31, 2015

EXHIBIT 31.1

Certification

I, Stephen From, certify that:

1. I have reviewed this Annual Report on Form 10-K of Eyegate Pharmaceuticals, 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 15d-15(e)) 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. 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

c. 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.

Date: March 31, 2015

/s/ Stephen From

Stephen From
President and Chief Executive Officer
(Principal executive officer and principal financial and accounting officer)

EXHIBIT 32.1

CERTIFICATION OF PERIODIC FINANCIAL REPORT
PURSUANT TO 18 U.S.C. SECTION 1350

The undersigned officer of Eyegate Pharmaceuticals, Inc. (the "Company") hereby certifies to his knowledge that the Company's Annual Report on Form 10-K for the year ended December 31, 2013 (the "Report") to which this certification is being furnished as an exhibit, as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company. This certification is provided solely pursuant to 18 U.S.C. Section 1350 and Item 601(b)(32) of Regulation S-K ("Item 601(b)(32)") promulgated under the Securities Act of 1933, as amended (the "Securities Act"), and the Exchange Act. In accordance with clause (ii) of Item 601(b)(32), this certification (A) shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and (B) shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Date: March 31, 2015

/s/ Stephen From
Stephen From
President and Chief Executive Officer
(Principal executive officer and principal financial
and accounting officer)