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

FORM 10-K

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the fiscal year ended December 31, 2019

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 001-36672

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) 788-8869
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	EYEG	The Nasdaq Capital Market
Warrants to Purchase Common Stock	EYEGW	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None.

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 every Interactive Data File required to be submitted 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 such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of June 30, 2019 was approximately $7,794,576. Shares of the registrant's common stock held by each officer and director and each person known to the registrant to own 10% or more of the outstanding voting power of the registrant have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not a determination for other purposes.

At March 2, 2020, there were 4,626,755 shares of the registrant's common stock issued and outstanding.

EYEGATE PHARMACEUTICALS, INC.
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For the Year Ended December 31, 2019
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FORWARD-LOOKING STATEMENTS

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 21 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 pharmaceutical company focused on developing products for treating disorders of the eye. Our lead product in clinical development is the EyeGate Ocular Bandage Gel ("OBG"), a topically applied eye drop formulation of modified hyaluronic acid ("HA"). HA is a naturally occurring polymer that is important in many physiological processes, including wound healing, hydration, tissue homeostasis, and joint lubrication. We uniquely modify the HA through chemical cross-linking, which allows it to adhere longer to the ocular surface providing protection and lubrication for the treatment of corneal wounds, defects, and epitheliopathies. As EyeGate OBG will be the first prescription HA eye drop in the United States, it is being developed under the *de novo* pathway for devices.

EyeGate OBG is currently being developed for two different indications: wound healing for patients who have undergone photorefractive keratectomy ("PRK") surgery and patients with punctate epitheliopathies ("PE"), specifically in patients with a history of dry eye. We have completed four clinical trials, three for PRK and one for PE. We recently announced positive topline data from the pivotal study for PRK surgery, thus anticipate completion of development for this indication. We plan to file the *de novo* application for commercialization with the Food and Drug Administration ("FDA") in the first half of 2020. In the third quarter of 2019, we initiated a follow-on trial for the indication of PE, evaluating several different exploratory endpoints, with topline data expected in the first half of 2020.

In addition, we previously worked to develop our legacy platform, EGP-437, which incorporated a reformulated topically active corticosteroid, Dexamethasone Phosphate, that was delivered into the ocular tissues through our iontophoresis drug delivery system, the EyeGate® II Delivery System ("EGP-437 Combination Product"). Our development work on EGP-437 focused on the treatment of various inflammatory conditions of the eye, including the treatment of ocular inflammation and pain in post-surgical cataract patients and anterior uveitis. Further development related to this platform is currently on hold.

We entered into two exclusive global license agreements with a subsidiary of Bausch Health Companies ("BHC") for our EGP-437 Combination Product in the fields of anterior uveitis and for the treatment of post-operative ocular inflammation and pain in ocular surgery patients. Effective March 14, 2019, BHC voluntarily terminated these license agreements reinstating to us all of the rights and privileges of the EGP-437 platform.

Our Strategy

Our goal is to focus on developing products for treating disorders of the eye. The key elements of this strategy are to:

- *File the de novo application with the FDA to commercialize our EyeGate OBG eye drop for the first indication* We recently completed clinical development for our first indication, wound healing in patients who have undergone PRK surgery. We plan to file the *de novo* application for commercialization in the first half of 2020.

- *Continue clinical development of our EyeGate OBG eye drop for the treatment of PE, specifically in patients with dry eye.*In the third quarter of 2019, we initiated a follow-on trial for the indication of PE, evaluating several different exploratory endpoints, with topline data expected in the first half of 2020. Post data, we anticipate discussing the results with the FDA to determine an acceptable endpoint for the pivotal study. Assuming a positive outcome, we plan to initiate the pivotal study in the second half of 2020.

- *Expand OBG franchise by combining our EyeGate OBG eye drop with an active pharmaceutical ingredient.*We are completing preliminary research to determine which drug will be combined with OBG for our first Investigational New Drug ("IND") filing. We are assessing off patent drugs, including antibiotics and anti-inflammatories, which we believe will allow for a 505(b)(2) pathway with the FDA. Assuming a positive outcome, we plan to initiate a phase 2 study by year end 2020.

- *Pursue strategic collaborations.* We plan to evaluate opportunities to enter into collaborations that may contribute to our ability to advance our 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.

EyeGate OBG

EyeGate OBG is a synthetic biocompatible modified HA capable of coating the ocular surface and designed to resist degradation under conditions present in the eye. This prolongs residence time of the bandage on the ocular surface, thereby addressing the limitations of current non-cross-linked hyaluronic acid formulations. Additionally, cross-linking allows the product's viscosity to be modified to meet optimum ocular needs. The increased viscosity and non-covalent muco-adhesive interfacial forces improve residence time in the tear film, thus providing a coating that aids and promotes re-epithelization of the ocular surface via physical protection.

EyeGate OBG exhibits significant shear thinning properties. This feature allows the modified HA to act as a more concentrated, viscous barrier at low shear rates in a resting tear film, but also as a lower resistance fluid (therefore thinned) during high shear events such as blinking. This property enables better residence time and a more favorable ocular surface coating with less optical blur. This should enhance ocular surface protection and patient comfort.

EyeGate OBG has been shown to provide a mechanical barrier that aids in the management of corneal epithelial defects and re-epithelization in both preclinical studies and in clinical ophthalmic veterinary use. As such, PRK surgery was chosen as the subject population which is best suited to demonstrate this effect. PRK is an efficacious alternative to patients seeking surgical correction of refractive errors who are not suitable candidates for laser in situ keratomileusis ("LASIK") due to inadequate corneal thickness, larger pupil size, history of keratoconjunctivitis sicca ("KCS"), or anterior basement membrane disease.

We believe that EyeGate OBG can be used for the management of a variety of large and small corneal epithelial defects including PE, which also includes dry eye. PE is an early sign of epithelial compromise and is associated with a variety of pathologic ocular inflammatory conditions including ocular causes, as well as systemic diseases. This ocular surface condition is common and may represent areas of epithelial cell damage and loss and therefore stain positively with fluorescein. Causes can include dry eye, acute and chronic bacterial and viral conjunctivitis, trauma, contact lens wear (tight lens syndrome), chemical irritation and burns, diabetic and infectious neuropathies, chemotherapy and corneal abrasion.

Current Targeted Indications

EyeGate OBG: Corneal Wound Repair

EyeGate OBG has been shown to provide a mechanical barrier that aids in the management of corneal epithelial defects and re-epithelization in both preclinical studies and in clinical ophthalmic veterinary use. PRK surgery was chosen as the subject population that is best suited to demonstrate this effect. PRK is an efficacious alternative to patients seeking surgical correction of refractive errors who are not suitable candidates for LASIK due to inadequate corneal thickness, larger pupil size, history of KCS, or anterior basement membrane disease. PRK involves controlled mechanical removal of corneal epithelium with subsequent excimer laser photoablation of the underlying Bowman's layer and anterior stroma, including the subepithelial nerve plexus.

The military prefers PRK as a refractive surgery due to the stability of the PRK incision and the absence of risk for flap dislocation during military active duty. Although this procedure yields desirable visual acuity results, common complications of the procedure include post-operative pain secondary to the epithelial defects, risk of corneal infection prior to re-epithelization of the large epithelial defect, corneal haze formation, decreased contrast sensitivity, and slower visual recovery.

EyeGate OBG provides a thin coating to the surface of the eye, serving as a protectant and lubricant to facilitate and manage corneal re-epithelization.

EyeGate OBG: Punctate Epitheliopathies with a Focus on Dry Eye

PE is an early sign of epithelial compromise and is associated with a variety of pathologic ocular inflammatory conditions including ocular causes, as well as systemic diseases. This ocular surface condition is common and may represent areas of epithelial cell damage and loss and therefore stain positively with fluorescein. PE is characterized by a breakdown or damage of the epithelium of the cornea in a pinpoint pattern, which can be seen with examination with a slit lamp. Patients may present with non-specific symptoms such as red eye, tearing, foreign body sensation, photophobia and burning. Causes can include dry eye, acute and chronic bacterial and viral conjunctivitis, trauma, contact lens wear (tight lens syndrome), chemical irritation and burns, diabetic and infectious neuropathies, chemotherapy and corneal abrasion.

Standard of care treatments are aimed at attempting to heal these punctate micro defects and/or epitheliopathies and can include increasing humidity, artificial tears, lubricants and ointments and in severe cases can even utilize bandage contact lens, antibiotics and amniotic membrane graphs, as well as treating the underlying cause with topical anti-inflammatory and T cell modulators. Often these current treatments fall short, as they are ineffective in protecting and enabling corneal re-epithelization. The artificial tears have limited residence time and often do nothing to mechanically protect the cornea and create an environment that can manage corneal re-epithelization. Furthermore, many of the ointments and gels, although offering better residence time, are thicker and blur vision, thus making them less attractive for day time use.

EyeGate OBG, once applied to the eye, forms a thin layer that protects and lubricates the eye to promote re-epithelization in the management of a variety of large and small corneal epithelial defects including PE.

Clinical Trial Results

EyeGate OBG: Corneal Wound Repair

Initial Pilot Study:

In the first quarter of 2017, we reported topline results from the first in-human trial of EyeGate OBG for the re-epithelialization of large corneal epithelial defects in patients having undergone PRK surgery. The prospective, randomized, controlled study enrolled 39 patients undergoing bilateral PRK surgery and aimed to assess the safety and performance of EyeGate OBG on its own or combined with a Bandage Contact Lens ("BCL") compared to the current standard of care, artificial tears and BCL. The primary endpoint of the study was complete wound closure by Day 3.

The enrolled patients were randomized into one of three study groups, with patients receiving the same treatment in both eyes:

· Patients in arm 1 (n=12) received EyeGate OBG four times daily ("QID") for two weeks after surgery.

· Arm 2 (n=14) was comprised of EyeGate OBG QID for 2 weeks after surgery in combination with a BCL.

· Arm 3 (n=13) was comprised of artificial tears administered four times daily and BCL.

The study demonstrated safety and tolerability of EyeGate OBG, with encouraging potential efficacy. 83.3% of the subjects in Arm 1 (EyeGate OBG alone) achieved complete wound closure by Day 3, compared to 53.8% of patients that received the standard of care. Thus, the OBG arm had approximately 55% more patients achieve full wound closure on Day 3 than the standard of care arm. Also, on Day 3, the average wound length, measured horizontally and vertically was 83.3% and 66.7% smaller, respectively, for the OBG arm compared to the standard of care arm. Additionally, on Day 1 (24 hours post-surgery), the average wound length, measured horizontally and vertically, was 35.9% and 27.4% smaller, respectively, for the OBG arm compared to the standard of care arm. Based on these positive results, we continued development with a reading center masked, controlled trial evaluating EyeGate OBG monotherapy against BCL in 2018.

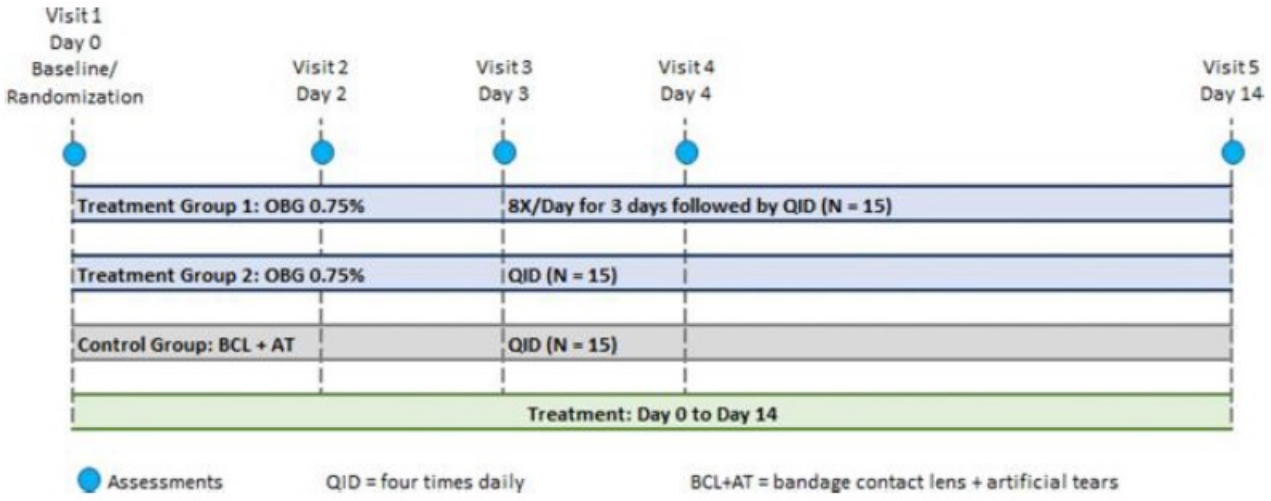
				Length in mm			
	# Subjects per arm	Closed Wound: Day 3		Day 1		Day 3	
		#	%	Horizontal	Vertical	Horizontal	Vertical
Arm 1: OBG	12	10	83.3%	4.1	4.5	0.10	0.20
Arm 2: OBG + BCL	14	9	64.3%	6.3	6.50	0.30	0.30
Arm 3: BCL + AT[1]	13	7	53.8%	6.4	6.20	0.60	0.60
Total Subjects Enrolled	**39**						
OBG: % better than BCL			**54.8%**	**35.9%**	**27.4%**	**83.3%**	**66.7%**

Follow-On Pilot Study:

In the fourth quarter of 2018, we reported positive topline results from the follow-on clinical trial of EyeGate OBG for the management of re-epithelialization of large corneal epithelial defects in patients having undergone PRK surgery. The prospective, randomized, controlled study enrolled 45 patients undergoing bilateral PRK surgery and was designed to assess safety and efficacy by comparing two dosing regimens of EyeGate's OBG to the current standard of care, a BCL plus artificial tears. The efficacy assessments included the percentage of patients achieving complete wound healing on Day 3 and Day 4 and wound size on Day 2. These assessments were evaluated by an independent masked reading center, using digital slit-lamp photographs of fluorescein staining in all treated eyes, and a protocol-driven method in order to quantify the outcomes.

The enrolled patients were randomized into one of three study groups, with patients receiving the same treatment in both eyes:

- Patients in arm 1 (n=15) received EyeGate OBG eight times daily for three days followed by four times daily ("QID") for an additional 11 days after surgery.
- Arm 2 (n=15) was comprised of EyeGate OBG QID for two weeks after surgery.
- Arm 3 (n=15) was comprised of BCL and artificial tears administered four times daily.



Both of the OBG dosing regimens outperformed the standard of care in the number of eyes healed at Day 3 and Day 4 post-surgery. At Day 3, 73% and 87% of eyes receiving the two OBG treatment regimens were completely healed compared to 67% for standard of care. At Day 4 post-surgery, 100% in both OBG treatment groups were completely healed compared to 87% in the standard of care comparator group. Additionally, the maximum wound size was 67% and 49% smaller at Day 2 post-surgery for the two OBG groups compared to the standard of care. There were no safety concerns observed in any group.

Pivotal Study:

In the fourth quarter of 2019, we reported positive topline results from our corneal wound repair pivotal clinical trial of EyeGate OBG for the corneal re-epithelialization in patients having undergone PRK surgery. The prospective, controlled study randomized 234 patients undergoing bilateral PRK surgery and was designed to assess safety and efficacy by comparing EyeGate's OBG to the current standard of care, a BCL. The primary endpoint was the proportion of study eyes achieving complete wound closure on Day 3 (and remaining closed). This assessment was evaluated by an independent masked reading center, using digital slit-lamp photographs of fluorescein staining in all treated eyes, and a protocol-driven method in order to quantify the outcomes.

The enrolled patients were randomized into one of two study groups, with patients receiving the same treatment in both eyes:

- Arm 1 (n=117) was comprised of EyeGate OBG QID for two weeks after surgery.
- Arm 2 (n=117) was comprised of BCL administered four times daily.

EyeGate OBG demonstrated superiority for the primary endpoint with a p-value of 0.0203. The statistical significance measurement was based on the number of patients in each arm that achieved complete corneal defect closure three days post refractive surgery. At Day 3, 80.2% of eyes receiving the OBG treatment regimen were completely healed, compared with 67.0% for BCL. Additionally, at Day 2, the average wound size for all eyes treated with OBG was 3.61 mm^2, compared to 6.66 mm^2 for eyes treated with BCL, which is 46% smaller than the standard of care.

PRIMARY ENDPOINT: Proportion closed at Day 3												
Study Eye												
Per Protocol Population	OBG		BCL			ITT Population	OBG		BCL	
Number of subjects	115		114			Number of subjects	116		115	
Primary endpoint	92		76			Primary endpoint	93		77	
	80.0%		66.7%				80.2%		67.0%	
p-Value	0.0201					p-Value	0.0203			
Both Eyes										
Per Protocol Population	OBG		BCL			ITT Population	OBG		BCL	
Number of subjects	115		114			Number of subjects	117		117	
No. subjects both eyes	84	73%	65	57%		No. subjects both eyes	85	73%	65	56%
No. subjects one eye	15	13%	22	19%		No. subjects one eye	15	13%	25	21%
No. subjects no eyes	16	14%	27	24%		No. subjects no eyes	17	15%	27	23%
Number of eyes	230		228			Number of eyes	234		234	
Primary endpoint	183		152			Primary endpoint	185		155	
	79.6%		66.7%				79.1%		66.2%	
p-Value	0.0123					p-Value	0.0119			

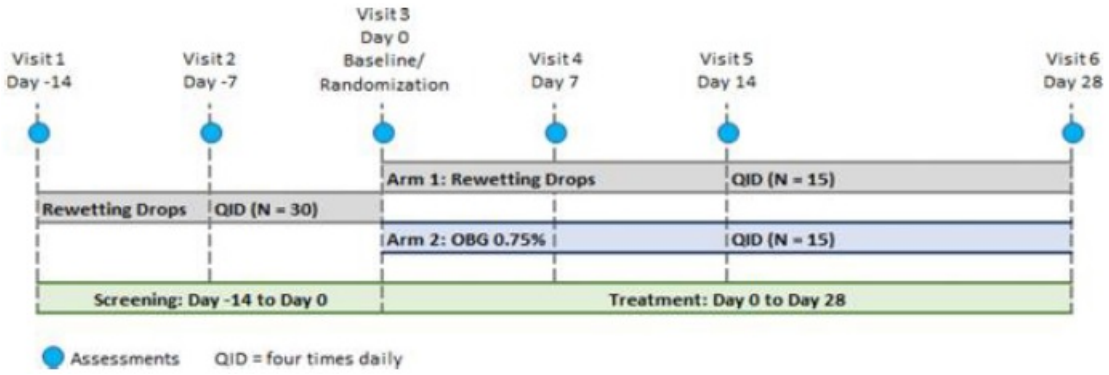
EyeGate OBG: Punctate Epitheliopathies with a Focus on Dry Eye

Initial Pilot Study:

In the fourth quarter of 2018, we reported positive topline results from the clinical trial of EyeGate OBG evaluating the potential to help clinicians better manage PE due to pathologies such as dry eye. This controlled, investigator masked study enrolled 30 patients with PE due to pathologies such as dry eye. The trial was designed to assess safety and efficacy by comparing EyeGate's OBG to the comparator group, a commercially available rewetting eye drop. The assessments included corneal fluorescein staining and symptomology at Day 7, Day 14 and Day 28. Randomization occurred after a two-week run in period where all patients were taking the rewetting eye drops only. Patients with a corneal staining score on the NEI scale of ≥4 entered the treatment phase and either continued to receive rewetting eye drops or were switched to OBG eye drops.

The enrolled patients were randomized into one of two study groups, with patients receiving the same treatment in both eyes:

- Arm 1 (n=15) received rewetting drops four times daily for four weeks.
- Arm 2 (n=15) received EyeGate OBG four times daily for four weeks.



EyeGate OBG eye drops achieved a statistically significant improvement (p-value < 0.05) in symptoms as quickly as Day 7 and also at Day 28. Additionally, at Day 28 OBG realized a 30% decrease in symptoms from baseline compared to only 4% for the comparator group. Symptomology was assessed using a patient reported outcome questionnaire based on comfort in both eyes. Staining measurements of the central cornea, a region dense in nerve endings, showed a reduction of up to 40% for OBG compared to up to 23% for the rewetting eye drop arm when combining the results from both eyes, which we believe better correlates clinically with the symptomology results. Staining measurements of the total cornea did not show a significant difference in reduction between the two arms with 26% for OBG compared to 23% for the rewetting eye drop at Day 7. There were no safety concerns observed in any group.

Clinical Development Plan

EyeGate OBG

Wound Healing:

We recently completed clinical development for our first indication, wound healing in patients who have undergone PRK surgery. We plan to file the *de novo* application for commercialization in the first half of 2020.

PE:

In the third quarter of 2019, we initiated a follow-on trial for the indication of PE, evaluating several different exploratory endpoints, with topline data expected in the first half of 2020. Once we receive that data, we anticipate discussing the results with the FDA to determine an acceptable endpoint for the pivotal study. Assuming a positive outcome, we plan to initiate the pivotal study in the second half of 2020.

Combination Product:

We are completing preliminary research to determine which drug will be combined with OBG for our first IND filing. We are assessing off patent drugs, including antibiotics and anti-inflammatories, which we believe will allow for a 505(b)(2) pathway with the FDA. Assuming a positive outcome, we plan to initiate a phase 2 study by year end 2020.

Intellectual Property and Proprietary Rights

Overview

We are building an intellectual property portfolio for our CMHA-S platform and any other product candidates that we may develop, 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, drug composition patents directed to EGP-437 and other compositions and devices related to the EyeGate® II Delivery System. In addition, further patent applications are directed to the CMHA-S platform in combination with active therapeutics to treat ocular diseases. These issued patents will expire between 2020 and 2036. 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. 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 new drug application ("NDA"). See "Government Regulation—Patent Term Restoration and Marketing Exclusivity" below.

We have been developing drug compositions and drug delivery systems for non-invasive treatment on the eye for several years. These delivery systems include various patented and patent pending drug delivery devices, active therapeutics and combination device/therapeutic to treat components of the eye, such as the cornea, sclera, and combinations thereof. These devices and therapeutics have been further improved to provide better patient comfort levels, patient compliance and recovery times. We hold eight U.S. patents and 24 corresponding international patents. Additionally, we hold 149 patents by way of our subsidiary, EyeGate Pharma S.A.S., a French corporation, or EyeGate S.A.S.

License Agreements

We are a party to four license agreements as described below. These license agreements require us to pay royalties or fees to the licensor based on revenue or milestones related to the licensed technology.

On February 15, 1999, we entered into an exclusive worldwide license agreement with the University of Miami School of Medicine to license technology relating to our EyeGate® II Delivery System, which grants us the right to use certain French, European, Canadian, Japanese, American, Mexican, Korean, Brazilian and Israeli patents in our EGP-437 Combination Product. This agreement, which was amended in December 2005, requires us to pay to the University of Miami an annual license fee of $12,500. This license also requires payments to the University of Miami upon our achievement of certain milestones. 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 upon certain milestones being met. 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.

On July 23, 1999, we entered into a perpetual Transaction Protocol agreement with Francine Behar-Cohen to acknowledge 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 of the pre-tax turnover generated from sales of our EGP-437 Combination Product relating to our inclusion of the EyeGate® II Delivery System. The fees due under the agreement expired in January 2018, but the Company continues to maintain its rights under the agreement.

On September 12, 2013, Jade Therapeutics, Inc. (“Jade”) entered into an agreement with BioTime, Inc. granting to it the exclusive worldwide right to commercialize CMHA-S for ophthalmic treatments in humans. The agreement calls for a license issue fee paid to BioTime of $50,000 and requires us (through our Jade subsidiary) to pay an annual fee of $30,000 and royalties to BioTime based on revenue relating to any product incorporating the CMHA-S technology. The agreement expires when patent protection for the CMHA-S technology lapses.

On September 26, 2018, we entered into an intellectual property licensing agreement (the “SentrX Agreement”) with SentrX, a veterinary medical device company that develops and manufactures veterinary wound care products. Under the SentrX Agreement, we will in-license the rights to trade secrets and know-how related to the manufacturing of EyeGate OBG. The SentrX Agreement will enable us to pursue a different vendor with a larger capacity for manufacturing and an FDA-inspected facility for commercialization of a product for human use. Under the SentrX Agreement, we paid SentrX an upfront payment of $250,000. SentrX is eligible to receive milestone payments totaling up to $4.75 million, upon and subject to the achievement of certain specified developmental and commercial milestones.

We were previously a party to an exclusive worldwide license agreement with the University of Utah Research Foundation to further the commercial development of the NASH technology, together with alkylated HA. The agreement called for payments due to the University of Utah, consisting of a license grant fee of $15,000 due within 30 days of signing, and minimum royalty payments, initially $5,000, and escalating ratably up to $20,000 in 2021. On October 8, 2019, we provided written notice to terminate this agreement effective 120 days from this written notice, or February 5, 2020.

On July 9, 2015, we entered into an exclusive worldwide licensing agreement with a subsidiary of Bausch Health Companies, Inc. (“BHC”), through which we granted BHC exclusive, worldwide commercial and manufacturing rights to our EGP-437 Combination Product in the field of anterior uveitis, as well as a right of last negotiation to license the EGP-437 Combination Product for other indications. Under the agreement, BHC paid us an upfront payment of $1.0 million. We were eligible to receive milestone payments totaling up to $32.5 million, upon and subject to the achievement of certain specified developmental and commercial milestones. In addition, we were eligible to receive royalties based on a specified percent of net sales of the EGP-437 Combination Product throughout the world, subject to adjustment in certain circumstances. BHC voluntarily terminated this license agreement effective March 14, 2019.

On February 21, 2017, we entered into an exclusive, worldwide licensing agreement with a subsidiary of BHC (the “New BHC Agreement”), through which we granted BHC exclusive, worldwide commercial and manufacturing rights to our EGP-437 Combination Product in the field of ocular iontophoretic treatment for post-operative ocular inflammation and pain in ocular surgery patients (the “New Field”). Under the New BHC Agreement, BHC paid us an initial upfront payment of $4.0 million, and we were eligible to receive milestone payments totaling up to approximately $99.0 million, upon and subject to the achievement of certain specified developmental and commercial progress of the EGP-437 Combination Product for the New Field. In addition, we were eligible under the New BHC Agreement to receive royalties based on a specified percent of net sales of the EGP-437 Combination Product for the New Field throughout the world, subject to adjustment in certain circumstances. BHC voluntarily terminated this license agreement effective March 14, 2019.

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

If EyeGate OBG is approved by the FDA for commercial sale, we may enter into agreements with third parties to sell EyeGate OBG or we may choose to market EyeGate OBG directly to physicians in the United States through our own sales and marketing force and related internal commercialization infrastructure. If we market EyeGate OBG directly, we will need to incur significant additional expenses and commit significant additional management resources to establish and train an internal sales and marketing force to market and sell EyeGate OBG.

Manufacturing

We currently do not have 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 EyeGate OBG 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.

We are not aware of any FDA approved eye drops for the management of re-epithelization of corneal epithelial defects following PRK surgery or for the management of PE. However, a large percentage of patients with PE have dry eye for which Restasis® (Allergan, Inc.) and Xiidra® (Novartis) are competitors for the treatment of dry eye.

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 ("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)).

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 our products. 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® OBG, 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 FDA has confirmed that EyeGate® OBG would be submitted under the 510(k) *de novo* clearance process when used as a standalone 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 patients 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. The commercial success of our EyeGate OBG, if and when commercialized, and 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 that 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 EyeGate OBG or any other product candidate that we may develop 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.

Employees

As of December 31, 2019, we had ten full time employees.

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. We view our operations and manage our business in one operating segment. We operate in one geographic segment.

Our Corporate Information

EyeGate Pharmaceuticals, Inc. 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 the time of our incorporation in Delaware, 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 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, which have caused management to determine there is substantial doubt regarding our ability to continue as a going concern. 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 $7.1 million for the year ended December 31, 2019, $10.8 million for the year ended December 31, 2018 and $100.2 million from the period of inception (December 26, 2004) through December 31, 2019. To date, we have financed our operations primarily through private placements and public offerings of our securities, and payments from our license agreements. 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 development stage 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 caused management to determine there is 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, 2019 with respect to this uncertainty.

We anticipate that our expenses will continue to be significant with the clinical trials for the ongoing development of our EyeGate OBG product.

Our expenses will also increase if and as we:

- seek marketing approval for EyeGate OBG, whether alone or in collaboration with third parties;
- continue the research and development of any 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 EyeGate OBG.

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. FDA or foreign equivalents to perform studies or clinical trials in addition to those currently expected; and
- there are any delays in enrollment of patients in or completing our clinical trials or the development of EyeGate OBG 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 EyeGate OBG or other product candidates that we may develop, which may never occur. This will require us to be successful in a range of challenging activities, including:

- establishing collaboration, distribution or other marketing arrangements with third parties to commercialize EyeGate OBG in markets outside the U.S.;
- achieving an adequate level of market acceptance of our product candidates;
- protecting our rights to our intellectual property portfolio related to our product candidates; and
- ensuring the manufacture of commercial quantities of EyeGate OBG.

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 continuing the clinical development of our EyeGate OBG product. In the future, we expect to raise additional financial resources for the continued clinical development of EyeGate OBG, and other product candidates we may develop. 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 clinical trials for our product candidates and of any clinical activities required for regulatory review of our product candidates outside of the U.S.;
- the costs and timing of process development and manufacturing scale up and validation activities associated with our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates in the U.S., and in other jurisdictions;
- the costs and timing of commercialization activities for our product candidates 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 our product candidates;

- 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, 2019, we had cash and cash equivalents of $3.8 million. With the net proceeds received from closing a registered direct offering on January 3, 2020, we believe we will have sufficient cash to fund planned operations through December 31, 2020, however, the acceleration or reduction of cash outflows by management can significantly impact the timing for raising additional capital to complete development of its products. To continue development, we will need to raise additional capital through debt and/or equity financing, or access additional funding through grants. Although we completed our initial public offering and subsequent public offerings, registered direct offerings and private placements, additional capital may not be available on terms favorable to us, if at all. Accordingly, no assurances can be given that management will be successful in these endeavors. These conditions raise substantial doubt about our 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 we be unable to continue as a going concern.

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 EyeGate OBG 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, EyeGate OBG 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 a clinical-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 conducting clinical trials of EyeGate OBG and the EGP-437 Combination Product. 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 pre-revenue 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 EyeGate OBG. If we are unable to successfully obtain marketing approval for EyeGate OBG, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize EyeGate OBG, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of EyeGate OBG. There remains a significant risk that we will fail to successfully develop EyeGate OBG.

In 2017, we completed the first in-human trial of EyeGate OBG evaluating the ability of EyeGate OBG to manage ocular surface re-epithelialization following PRK surgery. In 2018, we completed the second clinical trial for PRK surgery, as well as the first clinical trial focused on treating patients with PE. In 2019, we completed the pivotal clinical trial for PRK surgery and based on positive results, we plan to file the *de novo* application for the OBG product in the first half of 2020.

We cannot accurately predict when or if EyeGate OBG 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 EyeGate OBG .

The success of EyeGate OBG will depend on several factors, including the following:

- obtaining favorable results from any subsequent pivotal trial of EyeGate OBG;
- applying for and receiving marketing approvals from applicable regulatory authorities for EyeGate OBG;
- making arrangements with third-party manufacturers for commercial quantities of EyeGate OBG 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 EyeGate OBG, if and when approved, whether alone or in collaboration with others;
- acceptance of EyeGate OBG, 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 EyeGate OBG 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 EyeGate OBG.

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 EyeGate OBG, which would materially harm our business.

If clinical trials of EyeGate OBG 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 EyeGate OBG or any other product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, including EyeGate OBG, 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.

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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

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 our product candidates, we may need to abandon or limit our development of such product candidates.

If EyeGate OBG 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. 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 expend our limited resources to pursue a particular product candidate or indication 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 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 EyeGate OBG 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 EyeGate OBG may be smaller than we estimate.

If EyeGate OBG 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 treatment or standard of care post PRK surgery is a BCL, such as the Acuvue Oasys® (Johnson & Johnson Vision Care, Inc.), along with a variety of topical antibiotics and anti-inflammatories, which are available from several suppliers. BCL as treatments post PRK surgery are well established in the medical community, and doctors may continue to rely on these treatments rather than the EyeGate OBG Product, if and when it is cleared for marketing by the FDA.

Our assessment of the potential market opportunity for EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG or any other product candidates that we may develop if and when they are approved.

We do not have a sales or marketing infrastructure. To achieve commercial success for any product for which we have obtained marketing approval and have not licensed the commercialization rights, 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 an ophthalmic focused sales and marketing infrastructure to market or co-promote EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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.

Current treatment or standard of care post PRK surgery is a BCL, such as the Acuvue Oasys® (Johnson & Johnson Vision Care, Inc.) along with a variety of topical antibiotics and anti-inflammatories, which are available from several suppliers.

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 EyeGate OBG 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 EyeGate OBG or any other product candidate that we may develop achieves marketing approval, we expect that it will be priced at a premium over competitive 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG. 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 EyeGate OBG 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. To date, the only agreements we entered into were our Licensing Agreements with BHC, which were terminated effective March 14, 2019. 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.

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 ("CROs") to conduct our completed trials of EyeGate OBG and our other product candidates, and do not plan to independently conduct clinical trials of EyeGate OBG or other product candidates that we may develop. 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 EyeGate OBG for clinical trials and expect to continue to do so in connection with the commercialization of EyeGate OBG, 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 EyeGate OBG 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 EyeGate OBG, 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 EyeGate OBG 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 EyeGate OBG on a purchase order basis. We do not currently have any contractual commitments for commercial supply of bulk drug substance for EyeGate OBG, or fill-finish services. We also do not currently have arrangements in place for redundant supply or a second source for bulk drug substance for EyeGate OBG, or for fill-finish services. The prices at which we are able to obtain supplies of EyeGate OBG and fill-finish services may vary substantially over time and adversely affect our financial results.

If our third-party manufacturers for EyeGate OBG fail 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 EyeGate OBG 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:

- EyeGate OBG 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 ("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. We currently have 13 pending patents. 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.

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 EyeGate OBG, 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 licensing agreements that impose, 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 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 EyeGate OBG 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 EyeGate OBG or any other product candidate.

The activities associated with the development and commercialization of our product candidates, including EyeGate OBG, 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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 EyeGate OBG 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 adverse 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 EyeGate OBG, 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 EyeGate OBG, 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 ("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, former President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (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, former 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. In addition, it is possible that changes in administration and policy, including the potential repeal of all or parts of the PPACA, could result in additional proposals and/or changes to health care system legislation.

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 ("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, the financial expertise of Sarah Romano, our Chief Financial 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 and an offer letter with Ms. Romano, either of them may terminate his or her 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.

We may fail to realize any benefits and incur losses related to any acquisition.

The success of our strategic acquisitions will depend, in part, on our ability to successfully integrate the acquired businesses with our existing business. It is possible that the integration process could result in the loss of key employees, the disruption of ongoing business or inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with clients, customers and employees or to achieve the anticipated benefits of the acquisition. Successful integration may also be hampered by any differences between the operations and corporate culture of the two organizations. If we experience difficulties with the integration process, the anticipated benefits of the acquisition may not be realized fully, or at all, or may take longer to realize than expected.

Risks Related to Our Common Stock

Our principal stockholder holds a significant percentage of voting power and will be able to exert significant control over us.

Armistice Capital Master Fund Ltd. (the "Master Fund"), an entity affiliated with Steve J. Boyd and Keith Maher, each of whom are members of our board of directors and over which Mr. Boyd holds voting and investment power, holds shares of common stock that represent approximately 39% of all outstanding voting power, and as such may significantly influence the results of matters voted on by the Company's shareholders. The Master Fund additionally holds 4,092 shares of Series C Preferred Stock that are convertible into 852,500 shares of common stock and warrants to purchase 2,202,085 shares of common stock. The warrants are subject to a blocker provision that prevents the Master Fund from exercising such warrants to the extent it would result in the Master Fund beneficially owning more than 4.99% of shares of our common stock. The interests of the Master Fund, Mr. Boyd and Mr. Maher may conflict with your interests. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors may perceive disadvantages in owning stock in companies with controlling 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 affirmative vote of stockholders holding at least two-thirds of shares entitled to be 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.

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 EyeGate OBG 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 EyeGate OBG. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources.

We have previously received notices from NASDAQ of non-compliance with its minimum bid price rules.

On March 20, 2018, we received a written notification (the "Notice Letter") from Nasdaq indicating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), as the closing bid price for our Common Stock was below the $1.00 per share requirement for the last 30 consecutive business days. The Notice Letter stated that we have 180 calendar days, or until September 17, 2018 (the "Initial Compliance Period"), to regain compliance with the minimum bid price requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we can regain compliance if the closing bid price of our Common Stock is at least $1.00 for a minimum of 10 consecutive business days. We did not achieve compliance with the minimum bid price requirement by the end of the Initial Compliance Period, however, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), on the last day of the Initial Compliance Period we filed for extension and were granted a second 180-day compliance period, or until March 18, 2019, to regain compliance.

On March 19, 2019, we received written notification from Nasdaq indicating that based upon our continued non-compliance with the bid price rule as of March 18, 2019, our common stock would be subject to delisting from The Nasdaq Capital Market on March 28, 2019, unless we timely request a hearing before the Nasdaq Hearings Panel (the "Panel"). We timely requested a hearing and presented our plan to evidence future compliance with the bid price rule before the Panel on May 2, 2019. The Panel granted our request for continued listing of our common stock on The Nasdaq Capital Market pursuant to an extension through September 16, 2019, subject to the condition that we regain compliance with the Bid Price Rule by such date. We completed a 1-for-15 reverse stock split effective August 30, 2019, thus regaining compliance with the Bid Price Rule and resulting in full compliance with all applicable Nasdaq listing rules. A delisting of our common stock would have an adverse effect on the market liquidity of our common stock and, as a result, the market price for our common stock could become more volatile. Further, a delisting also could make it more difficult for us to raise additional capital.

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

As of December 31, 2019, we had federal net operating loss carryforwards of approximately $59.0 million, state net operating loss carryforwards of approximately $41.1 million and aggregate federal and state research and development tax credit carryforwards of approximately $2.2 million and $0.5 million, respectively, available to reduce future taxable income. Certain of these federal and state net operating loss carryforwards and federal and state tax credit carryforwards will expire at various dates through 2039, if not utilized. Federal net operating losses generated as of December 31, 2017 will carry-forward until 2037 and net operating losses generated during the year ended December 31, 2018 and later will be carried forward indefinitely until utilized, but their utilization will be limited to 80% of taxable income. 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 our initial public offering, our registered direct offering, our follow-on public offerings, and other transactions that have occurred 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. In addition, the Tax Cuts and Jobs Act ("TCJA") enacted on December 22, 2017 limits the amount of net operating losses that we are permitted to deduct in any taxable year to 80% of our taxable income in such year. The TCJA also eliminates the ability to carry back net operating losses to prior years, but allows net operating losses generated after 2017 to be carried forward indefinitely. As such, there is a risk that due to such items, our existing net operating losses could expire or be unavailable to offset future income.

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 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 ("JOBS Act") and may remain an emerging growth company for up to five years following the end of the fiscal year during which we first sold common equity securities under an effective registration statement, which period for us would end on December 31, 2020. 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 under the smaller reporting company requirements 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.

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

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 continue to evaluate 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 are required to furnish a report by our management on our internal control over financial reporting. However, while we remain either a non-accelerated filer and/or 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 have engaged in a process to document and evaluate our internal control over financial reporting. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to continue 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. 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 two facilities including our principal executive office located at 271 Waverley Oaks Road, Suite 108, Waltham, MA 02452, and our office located at 391 Chipeta Way, Suite H, Salt Lake City UT, 84108. We 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.***

Market Information

Our common stock began trading on the OTCQB Venture Marketplace on February 13, 2015 in connection with our initial public offering and currently trades under the symbol "EYEG." Prior to that time, there was no established public trading market for our common stock. On July 31, 2015, our Common Stock and Warrants issued in our follow-on offering, which closed on August 5, 2015, began trading on The NASDAQ Capital Market under the symbols "EYEG" and "EYEGW," respectively. In connection with this listing, the Common Stock ceased being quoted on the OTCQB Venture Marketplace.

There were 55 holders of record of our common stock as of March 2, 2020. This number does not include beneficial owners whose shares were held in street name.

Reverse Stock Split

On August 30, 2019, we effected a reverse stock split of its shares of common stock at a ratio of 1-for-15. The reverse stock split was previously authorized at the annual meeting of our stockholders on June 20, 2019, and our Board of Directors subsequently approved the ratio and timing of the reverse stock split. All references to numbers of common shares and per-share information in this Annual Report have been adjusted retroactively to reflect the 1-for-15 reverse stock split.

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

None.

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 21 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.

Business Overview

We are a clinical-stage pharmaceutical company focused on developing products for treating disorders of the eye. Our lead product in clinical development is the EyeGate Ocular Bandage Gel ("OBG"), a topically applied eye drop formulation of modified hyaluronic acid ("HA"). HA is a naturally occurring polymer that is important in many physiological processes, including wound healing, hydration, tissue homeostasis, and joint lubrication. We uniquely modify the HA through chemical cross-linking, which allows it to adhere longer to the ocular surface providing protection and lubrication for the treatment of corneal wounds, defects, and epitheliopathies. As EyeGate OBG will be the first prescription HA eye drop in the United States, it is being developed under the *de novo* pathway for devices.

EyeGate OBG is currently being developed for two different indications: wound healing for patients who have undergone photorefractive keratectomy ("PRK") surgery and patients with punctate epitheliopathies ("PE"), specifically in patients with a history of dry eye. We have completed four clinical trials, three for PRK and one for PE. We recently announced positive topline data from the pivotal study for PRK surgery, thus completing development for this indication. We plan to file the *de novo* application for commercialization with the Food and Drug Administration ("FDA") in the first half of 2020. In the third quarter of 2019, we initiated a follow-on trial for the indication of PE, evaluating several different exploratory endpoints, with topline data expected in the first half of 2020.

In addition, we were developing our legacy platform, EGP-437, which incorporated a reformulated topically active corticosteroid, Dexamethasone Phosphate, that was delivered into the ocular tissues through our iontophoresis drug delivery system, the EyeGate® II Delivery System ("EGP-437 Combination Product"). Further development related to this platform is currently on hold.

We entered into two exclusive global license agreements with a subsidiary of BHC for our EGP-437 Combination Product in the fields of anterior uveitis and for the treatment of post-operative ocular inflammation and pain in ocular surgery patients. Effective March 14, 2019, BHC voluntarily terminated these license agreements reinstating to us all of the rights and privileges of the EGP-437 platform.

On March 20, 2018, we received a written notification (the "Notice Letter") from Nasdaq indicating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), as the closing bid price for our Common Stock was below the $1.00 per share requirement for the last 30 consecutive business days. The Notice Letter stated that we have 180 calendar days, or until September 17, 2018 (the "Initial Compliance Period"), to regain compliance with the minimum bid price requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we can regain compliance if the closing bid price of our Common Stock is at least $1.00 for a minimum of 10 consecutive business days. We did not achieve compliance with the minimum bid price requirement by the end of the Initial Compliance Period, however, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), on the last day of the Initial Compliance Period we filed for extension and were granted a second 180-day compliance period, or until March 18, 2019, to regain compliance.

On March 19, 2019, we received written notification from Nasdaq indicating that based upon our continued non-compliance with the bid price rule as of March 18, 2019, our common stock would be subject to delisting from The Nasdaq Capital Market on March 28, 2019, unless we timely request a hearing before the Nasdaq Hearings Panel (the "Panel"). We timely requested a hearing and presented our plan to evidence future compliance with the bid price rule before the Panel on May 2, 2019. The Panel granted our request for continued listing of our common stock on The Nasdaq Capital Market pursuant to an extension through September 16, 2019, subject to the condition that we regain compliance with the Bid Price Rule by such date. We completed a 1-for-15 reverse stock split effective August 30, 2019, thus regaining compliance with the Bid Price Rule and resulting in full compliance with all applicable Nasdaq listing rules.

Throughout our history, we have not generated significant revenue. We have never been profitable, and from inception through December 31, 2019, our losses from operations have aggregated $100.2 million. Our Net Loss was approximately $7.1 million and $10.8 million for the twelve months ended December 31, 2019 and 2018, 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 our EyeGate OBG, our lead product candidate for corneal epithelial defects, and any other product candidates we advance to clinical development. If we obtain regulatory approval for EyeGate OBG, we expect to incur significant expenses in order to create an infrastructure to support the commercialization of EyeGate OBG 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, debt financings, license and development agreements, 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. These conditions raise substantial doubt about our ability to continue as a going concern. We will need to generate significant revenue to achieve profitability, and we may never do so.

EyeGate Pharmaceuticals, Inc. was formed in Delaware 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. Jade was formed in Delaware on December 31, 2012. EyeGate Pharma S.A.S. and Jade are wholly-owned subsidiaries of EyeGate Pharmaceuticals, Inc.

Financial Overview

Revenues

To date, we have recognized collaboration revenue from several U.S. government grants made to Jade for ocular therapeutic research (collectively, the "U.S. Government Grants"), as well as from BHC as performance obligations toward milestones were met. *See* Note 2 to our financial statements, "Summary of Significant Accounting Policies". We expect to continue to incur significant operating losses as we fund research and clinical trial activities relating to our ocular therapeutic assets, consisting of our CMHA-S-based products, or any other product candidate that we may develop. There can be no guarantee that the losses incurred to fund these activities will succeed in generating revenue.

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, bonuses, benefits, travel and stock-based compensation expense.

Substantially all of our research and development expenses to date have been incurred in connection with our EyeGate OBG and EGP-437 Combination Product. We expect our research and development expenses to increase for the near future as we advance EyeGate OBG and any other product candidate 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 our EyeGate OBG and any other product candidate that we may develop. 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 our product candidates 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 remain consistent for the near future until commercialization of our CMHA-S based products, which could lead to an increase in these expenses.

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 financing arrangements.

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 and restricted stock. Stock-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. 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.

Revenue Recognition

Our revenues are generated primarily through arrangements which generally contain multiple elements, or deliverables, including licenses and R&D activities to be performed by us on behalf of the licensor or grantor. Payments to us under these arrangements typically include one or more of the following: (1) nonrefundable, upfront license fees, (2) funding of discovery research efforts on a full-time equivalent basis, (3) reimbursement of research, development and intellectual property costs, (4) milestone payments, and (5) royalties on future product sales.

In May 2014, the FASB issued ASU No. 2014-09, *Revenues from Contracts with Customers* ("Topic 606"), as subsequently amended, that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most recent revenue recognition guidance, including industry-specific guidance. The core principle of the revenue model is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This standard was effective for public companies for years ending after December 15, 2017, with early adoption permitted.

We adopted the new standard on January 1, 2018, using the modified retrospective method, which resulted in a cumulative effect adjustment in the amount of $9.5 million to beginning 2018 accumulated deficit and to deferred and unbilled revenue for the BHC contracts impacted by the adoption of the new standard. The changes to the method and/or timing of our revenue recognition associated with the adoption of the new standard primarily relate to the determination that there is one performance obligation in each contract with BHC and that the license combined with the R&D services is the performance obligation. As a result of termination of the BHC contracts in the first quarter of 2019, we recognized the deferred revenue balance of $2.686 million for the year ended December 31, 2019 and no further revenue will be recognized related to these contracts.

Under this new guidance, we recognize revenue when our customer obtains control of promised services, in an amount that reflects the consideration which we expect to receive in exchange for those services. To determine whether arrangements are within the scope of this new guidance, we perform the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy our performance obligation. We apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. Upon adoption of ASU No. 2014-09, we recognize revenue from the transaction price applied to each single performance obligation over time as milestones are reached for each performance obligation. We only recognize revenue on those milestones that are within our control and any constrained variable consideration that requires regulatory approval will only be included in the transaction price when performance is complete.

In addition, we may receive government grant funds for specified ocular therapeutic research activities. Revenue under these grants will be recorded when we perform the activities specified by the terms of each grant and are entitled to the funds.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted. Under ASU No. 2016-02, lessees are required to recognize for all leases at the commencement date a lease liability, which is a lessee's obligation to make lease payments arising from a lease measured on a discounted basis, and the right-to-use assets, which are asset that represents the lessee's right to use or control the use of a specified asset for the lease term. We did not early adopt this standard and had leases (*see* Note 10 to our financial statements) in place at the effective date. We evaluated the effect of the new guidance and adopted the new standard effective January 1, 2019 using the modified retrospective method. As a result, we recorded right-of-use leased assets and corresponding liabilities of approximately $0.137 million on January 1, 2019.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles—Goodwill and Other*, which simplifies the accounting for goodwill impairment. The guidance removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. All other goodwill impairment guidance will remain largely unchanged. Entities will continue to have the option to perform a qualitative assessment to determine if a quantitative impairment test is necessary. The same one-step impairment test will be applied to goodwill at all reporting units, even those with zero or negative carrying amounts. Entities will be required to disclose the amount of goodwill at reporting units with zero or negative carrying amounts. The new standard was effective for us on January 1, 2020 and is required to be applied prospectively. We evaluated the effect of the new guidance and adopted ASU No. 2017-04 effective January 1, 2020. The adoption of this standard will not have a material impact on our Consolidated Financial Statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. ASU No. 2016-13 replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The new guidance is effective for smaller reporting companies in fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. We do not expect the adoption of this standard to have a material effect on our financial statements.

Other Information

Net Operating Loss Carryforwards

As of December 31, 2019, we have federal and state income tax net operating loss ("NOL") carryovers of approximately $59.0 million and $41.1 million, respectively. Federal NOL carryovers as of December 31, 2017 totaling $46.0 million and state NOL carryovers as of December 31, 2019 totaling $41.1 million will expire at various dates through 2039. Federal NOL carryovers generated during the years ended December 31, 2019 and 2018 totaling $13.0 million will be carried forward indefinitely, but their utilization will be limited to 80% of taxable income. As of December 31, 2019 we also have federal, state and foreign research and development tax credit carryforwards of approximately $2.2 million, $0.5 million, and $25,000, respectively, to offset future income taxes, which expire at various times through 2039.

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 our initial public offering, our registered direct offering, our follow-on public offerings, 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. In addition, the TCJA enacted on December 22, 2017 limits the amount of NOLs that we are permitted to deduct in any taxable year to 80% of our taxable income in such year. The TCJA also eliminates the ability to carry back NOLs to prior years but allows NOLs generated after 2017 to be carried forward indefinitely. As such, there is a risk that due to such items, our existing NOLs could expire or be unavailable to offset future income.

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 have evaluated 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 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, or December 31, 2020, (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.

Results of Operations

Comparison of Years Ended December 31, 2019 and 2018

The following table summarizes the results of our operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		
	2019	2018	Change
Collaboration Revenue	$ 2,686,000	$ 1,652,520	$ 1,033,480
Operating Expenses:			
Research and Development	(5,389,357)	(8,055,763)	2,666,406
General and Administrative	(4,405,684)	(4,441,458)	35,774
Total Operating Expenses	(9,795,041)	(12,497,221)	2,702,180
Other Income, Net	107,741	119,323	(11,582)
Loss Before Income Tax Expense	(7,001,300)	(10,725,378)	3,724,078
Income Tax Expense	(95,396)	(86,045)	(9,351)
Net Loss	$ (7,096,696)	$ (10,811,423)	$ 3,714,727

Collaboration Revenue. Collaboration Revenue was $2.686 million for the year ended December 31, 2019, compared to $1.653 million for the year ended December 31, 2018. The revenue recognized for the year ended December 31, 2019 was a result of the termination of the license agreements with BHC and no further revenue will be recognized related to these agreements. The revenue recognized for the year ended December 31, 2018 was related to milestone payments earned from BHC under the new standard for revenue recognition. As a result of adopting the new standard, $1.653 million of additional revenue was recognized during the year ended December 31, 2018.

Research and Development Expenses. Research and Development Expenses were $5.389 million for the year ended December 31, 2019 compared to $8.056 million for the year ended December 31, 2018. The decrease of $2.666 million was primarily due to decreases in clinical activity related to EGP-437; decreased personnel related costs; as well as costs associated with OBG's follow-on wound healing clinical trial and initial PE clinical trial, each of which were completed in 2018. These decreases were partially offset by increases in OBG's pivotal wound healing clinical trial, which was completed in 2019, as well as OBG's follow-on PE clinical trial, which was fully enrolled in 2019 with data expected in the first half of 2020. Additionally, an increase of $0.500 million was recorded to the present value of the earn-out payment due upon FDA approval of the EyeGate OBG as a result of the 2019 fourth quarter assessment of present value, which took into consideration discount factors and probability of FDA approval. This increase of $0.500 million was recorded to contingent consideration on the Consolidated Balance Sheets and research and development expense on the Consolidated Statement of Operations and Comprehensive Loss.

General and Administrative Expenses. General and Administrative Expenses were $4.406 million for the year ended December 31, 2019, compared to $4.441 million for the year ended December 31, 2018. The decrease of $0.036 million was mainly due to decreases in professional fees and office costs, partially offset by an increase in personnel-related costs and other corporate expenses.

Other Income, Net. Other Income, Net was $0.108 million for the year ended December 31, 2019, compared to $0.119 million for the year ended December 31, 2018 due to less interest earned on our cash balances.

Income Tax Expense. Income Tax Expense was $0.095 million for the year ended December 31, 2019, compared to $0.086 million for the year ended December 31, 2018. The 2019 tax expense was a result of an increase in the state blended tax rate, which was applied to the deferred tax liability balance. The 2018 tax expense was a result of the 2017 partial release of valuation allowance against our previously recorded deferred tax assets as a result of the impact of legislation commonly known as TCJA where future reversals of deductible temporary differences, such as those from our indefinite-lived in-process research and development, can offset taxable temporary differences from future net operating loss carryforwards due to their indefinite carryforward period under the new tax law.

Liquidity and Capital Resources

Since becoming a public company in 2015, we have financed our operations from several registered offerings and private placements of our securities and payments from our BHC License Agreements and the U.S. Government Grants. From inception through March 4, 2020, we have raised a total of approximately $100.9 million from such sales of our equity and debt securities, both as a public company and prior to our IPO, as well as approximately $14.9 million in payments received under our license agreements and U.S. Government Grants.

Through December 31, 2019, we have received cash payments of $13.8 million under the BHC Agreements, which are presented as Collaboration Revenue on our Consolidated Statement of Operations and Comprehensive Loss, or Deferred or Unbilled Revenue on our Consolidated Balance Sheets. Additionally, on January 1, 2018, $9.5 million was recorded as a reduction to our opening accumulated deficit balance on our Consolidated Balance Sheets after adopting the new revenue recognition guidance.

On May 24, 2016, we entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC (the "Sales Agent"), to create an at the market equity program under which we could from time to time offer and sell up to 87,952 shares of our Common Stock through the Sales Agent. The ATM Agreement terminated automatically pursuant to its terms on May 24, 2019.

On June 14, 2017, we completed a public offering of 355,777 shares of Common Stock and 1,995 shares of Series B Preferred Stock (convertible into 88,666 shares of Common Stock), along with warrants to purchase 444,443 shares of Common Stock. Following the 1-for-15 reverse stock split effected on August 30, 2019, the shares underlying these warrants were adjusted to reflect the reverse stock split and rounded up to the nearest whole share in accordance with their terms. The offering was priced at $22.50 per share of Common Stock (or share of Common Stock issuable upon conversion of a share of Series B Convertible Preferred Stock) and warrant. The total net proceeds to us from this offering, after deducting the placement agent fees and offering expenses, were approximately $8.8 million. Additionally, the investors received, for each share of Common Stock, or for each share of Common Stock issuable upon conversion of a share of Series B Preferred Stock purchased in the public offering, warrants to purchase one share of Common Stock at an exercise price of $22.50 per share, which in the aggregate represented warrants to purchase an aggregate of 444,443 shares of Common Stock. The warrants issued to investors became initially exercisable immediately upon issuance and terminate on June 14, 2022, five years following the date of issuance. All 1,995 shares of Series B Preferred Stock have been converted into an aggregate of 88,666 shares of Common Stock.

On April 17, 2018, we completed a public offering of 982,000 shares of Common Stock and 6,536.4 shares of Series C Convertible Preferred Stock (convertible into 1,361,750 shares of Common Stock), along with warrants to purchase 2,343,750 shares of Common Stock. Following the 1-for-15 reverse stock split effected on August 30, 2019, the shares underlying these warrants were adjusted to reflect the reverse stock split and rounded up to the nearest whole share in accordance with their terms. The offering was priced at $4.80 per share of Common Stock (or share of Common Stock issuable upon conversion of a share of Series C Convertible Preferred Stock) and warrant. The total net proceeds to us from the offering, after deducting the placement agent fees and offering expenses, were approximately $10.1 million. Additionally, the investors received, for each share of Common Stock, or for each share of Common Stock issuable upon conversion of a share of Series C Convertible Preferred Stock purchased in the public offering, warrants to purchase one share of Common Stock at an exercise price of $4.80 per share, which in the aggregate represented warrants to purchase an aggregate 2,343,750 shares of Common Stock. The warrants issued to investors became initially exercisable immediately upon issuance and terminate on April 17, 2023, five years following the date of issuance. Concurrently with the closing of the public offering, a holder elected to convert 1,400 shares of Series C Convertible Preferred Stock into 291,667 shares of Common Stock. Subsequently, on April 18, 2018, April 23, 2018, and April 30, 2018, holders converted 1,044.4 shares of Series C Convertible Preferred stock into 217,583 shares of Common Stock.

On October 2, 2019, we completed a private placement of 600,000 shares of Common Stock and warrants to purchase up to 600,000 shares of Common Stock to an affiliate of Armistice Capital, LLC, with a combined purchase price per share and warrant of $3.125. The total gross proceeds from the private placement were approximately $1.9 million. The warrants have an exercise price of $3.125 per share, subject to adjustments as provided under the terms of the warrants, and will be exercisable on the six month anniversary of their issuance date. The warrants are exercisable for five years from the issuance date.

On January 3, 2020, we completed a registered direct offering for 500,000 shares of Common Stock with a purchase price of $10.00 per share. The total net proceeds to the Company from the offering were approximately $4.5 million.

At December 31, 2019, we had unrestricted cash and cash equivalents totaling $3,776,712.

The following table sets forth the primary sources and uses of cash for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
Net Cash Used in Operating Activities	$ (8,153,833)	$ (10,844,512)
Net Cash Used in Investing Activities	-	(270,000)
Net Cash Provided by Financing Activities	$ 3,920,805	$ 11,304,805

Comparison of Years Ended December 31, 2019 and 2018

Operating Activities. Net cash used in operating activities was $8.154 million for the year ended December 31, 2019, compared to $10.845 million for the year ended December 31, 2018. During the year ended December 31, 2019, we recorded a net loss of $7.097 million and a decrease in deferred revenue of $2.686 million, partially offset by non-cash expenses for stock-based compensation and contingent consideration in the amounts of $0.852 million and $0.500 million, respectively, as well as an increase in accounts payable and accrued expense of $0.157 million. During the year ended December 31, 2018, we recorded a net loss of $10.811 million and a decrease in accounts payable and accrued expenses of $1.337 million, partially offset by a non-cash expense for stock-based compensation of $0.875 million and an increase in prepaid expenses and other current assets of $0.380 million.

Investing Activities. Net cash used in investing activities was $0 million for the year ended December 31, 2019, compared to $0.270 million for the year ended December 31, 2018. During the year ended December 31, 2018, we made the upfront payment of $0.250 million under the SentrX agreement and purchased $0.020 million in laboratory equipment.

Financing Activities. We received $3.921 million in cash from financing activities for the year ended December 31, 2019, compared to $11.305 million for the year ended December 31, 2018. During the year ended December 31, 2019, we received net proceeds of $1.8 million from the private placement with an affiliate of Armistice Capital, LLC and $2.150 million from the exercise of warrants. During the year ended December 31, 2018, we received net proceeds of $10.109 million from a stock offering and $1.206 million from the exercise of warrants.

Funding Requirements and Other Liquidity Matters

Our CMHA-S-based product pipeline is still in various stages of 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 CMHA-S-based products or any other products that we successfully develop;
- establish a sales and marketing infrastructure to commercialize our CMHA-S-based products in the United States, if approved; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and future commercialization efforts.

Until such time, if ever, as we can generate substantial product revenue, 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 the rights of 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 CMHA-S-based products, 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 the CMHA-S-based products or any other products that we would otherwise prefer to develop and market ourselves.

Based on our cash on hand at December 31, 2019 and the approximately $4.5 million in net proceeds received from a registered direct offering that closed on January 3, 2020, we believe we will have sufficient cash to fund planned operations through December 31, 2020. However, the acceleration or reduction of cash outflows by management can significantly impact the timing for raising additional capital to complete development of its products. To continue development, we will need to raise additional capital through debt and/or equity financing, or access additional funding through grants. Although we successfully completed our IPO and several subsequent registered offerings and private placements of our securities, additional capital may not be available on terms favorable to us, if at all. On May 13, 2019, the SEC declared effective our registration statement on Form S-3, registering a total of $50,000,000 of our securities for sale to the public from time to time in what is known as a “shelf offering”. We do not know if our future offerings, including offerings pursuant to our shelf registration statement, will succeed. Accordingly, no assurances can be given that management will be successful in these endeavors. Our recurring losses from operations have caused management to determine there is substantial doubt about our ability to continue as a going concern. Our Consolidated 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 we be unable to continue as a going concern.

Off-Balance Sheet Arrangements

We had no material off-balance sheet arrangements at December 31, 2019.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2019:

	Total	Less Than 1 Year	1-3 Years	3 Years & Thereafter
Leases (1)	$ 86,390	$ 86,390	$ -	$ -
Licensing Agreement (2)	325,000	47,500	85,000	192,500
Total (3)	$ 411,390	$ 133,890	$ 85,000	$ 192,500

(1) Lease obligations reflect our obligation to make payments in connection with operating leases for our office space.
(2) Licensing Agreement obligations represent our commitments under license agreements, including those made by us under our license agreements with the University of Miami School of Medicine, the University of Utah Research Foundation, and BioTime.
(3) This table does not include (a) anticipated expenditures under supply agreements for periods for which we are not yet bound under binding purchase orders, and (b) contracts that are entered into in the ordinary course of business that are not material in the aggregate in any period presented above.

In addition, in the course of normal business operations, we have agreements with contract service providers to assist in the performance of our research and development and manufacturing activities. Expenditures to contract research organizations vary based on the study and phases during the clinical development stages. Subject to required notice periods and our obligations under binding purchase orders, we can elect to discontinue the work under these agreements at any time. We could also enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require upfront payments and even long-term commitments of cash.

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 our Chief Financial Officer (who is our 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, the Company's Management, under the supervision of, and with the participation of, our President and Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2019. 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 and our Chief Financial Officer have concluded that they believe that our disclosure controls and procedures were effective as of the end of the period covered by this report.

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

Our management, under the supervision of our President and Chief Executive Officer and our Chief Financial Officer, is responsible for establishing and maintaining an adequate system of internal control over financial reporting. Internal control over financial reporting (as defined in Rules 13a-15(f) and 15d(f) under the Exchange Act) is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

A company's internal control over financial reporting includes those policies and procedures that: (a) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (b) provide reasonable assurance that transactions are recorded as necessary to permit preparation of Consolidated Financial Statements in accordance with U.S. GAAP; (c) provide reasonable assurance that receipts and expenditures are being made only in accordance with appropriate authorization of management and the board of directors; and (d) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the Consolidated Financial Statements.

In connection with the preparation of this report, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019 based on the criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). As a result of that evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2019.

As a smaller reporting company and an "emerging growth company" under the Jumpstart Our Business Startups Act, we are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. As a result, EisnerAmper LLP, our independent registered public accounting firm, has not audited or issued an attestation report with respect to the effectiveness of our internal control over financial reporting as of December 31, 2019.

(c) Changes in Internal Controls Over Financial Reporting

Our management, with the participation of the Chief Executive Officer and the Chief Financial Officer, has evaluated whether any change in our internal control over financial reporting occurred during the quarter ended December 31, 2019. Based on that evaluation, management concluded that there were no changes to our internal control over financial accounting and reporting that occurred during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial accounting and reporting.

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

None.

PART III

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

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2020 Annual Meeting of Stockholders.

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

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2020 Annual Meeting of Stockholders.

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

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2020 Annual Meeting of Stockholders.

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

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2020 Annual Meeting of Stockholders.

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

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2020 Annual Meeting of Stockholders.

PART IV

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 of
EyeGate Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of EyeGate Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2019 and 2018, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred 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.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2014.

EISNERAMPER LLP
New York, New York
March 4, 2020

EYEGATE PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 3,776,712	$ 8,004,237
Prepaid Expenses and Other Current Assets	458,810	455,760
Right-of-Use Assets	83,926	-
Current Portion of Refundable Tax Credit Receivable	4,857	18,436
Total Current Assets	4,324,305	8,478,433
Property and Equipment, Net	16,846	43,518
Restricted Cash	45,000	45,000
Goodwill	1,525,896	1,525,896
Intangible Assets and In-Process R&D, Net	4,131,064	4,156,064
Other Assets	69,403	31,706
Total Assets	$ 10,112,514	$ 14,280,617
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 210,289	$ 63,654
Accrued Expenses	1,120,480	1,114,728
Lease Liabilities	83,926	-
Deferred Revenue	-	2,686,000
Total Current Liabilities	1,414,695	3,864,382
Non-Current Liabilities:		
Contingent Consideration	1,710,000	1,210,000
Deferred Tax Liability	365,364	269,968
Total Non-Current Liabilities	2,075,364	1,479,968
Total Liabilities	3,490,059	5,344,350
Commitments and Contingencies (Note 11)		
Stockholders' Equity:		
Preferred Stock, $0.01 Par Value: 9,994,184 shares authorized; 3,750 designated Series A, 0 shares issued and outstanding at December 31, 2019 and December 31, 2018, 10,000 designated Series B, 0 shares issued and outstanding at December 31, 2019 and December 31, 2018; 10,000 shares designated Series C, 4,092 shares issued and outstanding at December 31, 2019 and December 31, 2018	41	41
Common Stock, $0.01 Par Value: 120,000,000 shares authorized; 4,077,755 shares issued and outstanding at December 31, 2019 and 3,038,592 shares issued and outstanding at December 31, 2018	40,778	30,386
Additional Paid-In Capital	106,689,065	101,921,707
Accumulated Deficit	(100,246,894)	(93,150,198)
Accumulated Other Comprehensive Income	139,465	134,331
Total Stockholders' Equity	6,622,455	8,936,267
Total Liabilities and Stockholders' Equity	$ 10,112,514	$ 14,280,617

See Accompanying Notes to the Consolidated Financial Statements.

EYEGATE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,	
	2019	**2018**
Collaboration Revenue	$ 2,686,000	$ 1,652,520
Operating Expenses:		
Research and Development	5,389,357	8,055,763
General and Administrative	4,405,684	4,441,458
Total Operating Expenses	9,795,041	12,497,221
Other Income, Net:		
Interest Income	108,066	120,363
Interest Expense	(325)	(1,040)
Total Other Income, Net	107,741	119,323
Loss Before Income Tax Expense	(7,001,300)	(10,725,378)
Income Tax Expense	(95,396)	(86,045)
Net Loss	$ (7,096,696)	$ (10,811,423)
Net Loss per Common Share - Basic and Diluted	$ (2.23)	$ (4.57)
Weighted Average Shares Outstanding - Basic and Diluted	3,181,019	2,365,583
Net Loss	$ (7,096,696)	$ (10,811,423)
Other Comprehensive Loss:		
Foreign Currency Translation Adjustments	5,134	6,858
Comprehensive Loss	$ (7,091,562)	$ (10,804,565)

See Accompanying Notes to the Consolidated Financial Statements.

EYEGATE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
Years Ended December 31, 2019 and 2018

	Series C Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Equity
Balance at December 31, 2018	**4,092**	**$ 41**	**3,038,592**	**$ 30,386**	**$ 101,921,707**	**$ 134,331**	**$ (93,150,198)**	**$ 8,936,267**
Stock-Based Compensation					852,230			852,230
Issuance of Common Stock in Offerings, Net of Offering Costs of $97,082			600,000	6,000	1,771,918			1,777,918
Issuance of Shares of Common Stock from Warrant Exercises			447,961	4,480	2,145,736			2,150,216
Cancellation of Fractional Shares due to Reverse Stock Split			(23)	-	-			-
Settlement of Fractional Shares due to Reverse Stock Split			(907)	(9)	(2,605)			(2,614)
Cancellation of Restricted Stock			(7,868)	(79)	79			-
Foreign Currency Translation Adjustment						5,134		5,134
Net Loss							(7,096,696)	(7,096,696)
Balance December 31, 2019	**4,092**	**$ 41**	**4,077,755**	**$ 40,778**	**$ 106,689,065**	**$ 139,465**	**$ (100,246,894)**	**$ 6,622,455**

See Accompanying Notes to the Condensed Consolidated Financial Statements.

EYEGATE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
Years Ended December 31, 2018 and 2017

	Series B		Series C	
	Shares	Amount	Shares	Amount
Balance at December 31, 2017	**600**	**$ 6**	**-**	**$ -**
Cumulative Effect of Change in Accounting Principle (Note 2)				
Balance at January 1, 2018	**600**	**6**	**-**	**-**
Stock-Based Compensation				
Cancellation and Correction of Restricted Stock Par Value				
Issuance of Common Stock in Offerings, Net of Offering Costs of $1,141,238			6,536	65
Conversion of Series B Preferred Stock into Common Stock	(600)	(6)		
Conversion of Series C Preferred Stock into Common Stock			(2,444)	(24)
Issuance of Common Shares from Warrant Exercises				
Cancellation of Restricted Stock				
Foreign Currency Translation Adjustment				
Net Loss				
Balance at December 31, 2018	**-**	**$ -**	**4,092**	**$ 41**

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity (Deficit)
Balance at December 31, 2017	**1,150,484**	**$ 11,505**	**$ 89,750,749**	**$ 127,473**	**$ (91,816,655)**	**$ (1,926,922)**
Cumulative Effect of Change in Accounting Principle (Note 2)					9,477,880	9,477,880
Balance at January 1, 2018	**1,150,484**	**11,505**	**89,750,749**	**127,473**	**(82,338,775)**	**7,550,958**
Stock-Based Compensation			875,287			875,287
Cancellation and Correction of Restricted Stock Par Value	119,000	1,190	(1,190)			-
Issuance of Common Stock in Offerings, Net of Offering Costs of $1,141,238	982,000	9,820	10,098,877			10,108,762
Conversion of Series B Preferred Stock into Common Stock	26,667	267	(261)			-
Conversion of Series C Preferred Stock into Common Stock	509,250	5,092	(5,068)			-
Issuance of Common Shares from Warrant Exercises	251,208	2,512	1,203,313			1,205,825
Cancellation of Restricted Stock	(17)	-	-			-
Foreign Currency Translation Adjustment				6,858		6,858
Net Loss					(10,811,423)	(10,811,423)
Balance at December 31, 2018	**3,038,592**	**$ 30,386**	**$ 101,921,707**	**$ 134,331**	**$ (93,150,198)**	**$ 8,936,267**

See Accompanying Notes to the Consolidated Financial Statements.

EYEGATE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2019	**2018**
Operating Activities		
Net Loss	$ (7,096,696)	$ (10,811,423)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization of Intangible Assets	51,672	38,483
Reduction of Right-of-Use Assets	162,261	-
Stock-Based Compensation	852,230	875,287
Contingent Consideration	500,000	-
Deferred Taxes	95,396	86,045
Changes in Operating Assets and Liabilities:		
Prepaid Expenses and Other Current Assets	(3,051)	379,609
Refundable Tax Credit Receivable	13,210	4,191
Other Assets	(37,697)	69,643
Accounts Payable	146,636	(642,435)
Lease Liabilities	(162,261)	-
Deferred Revenue	(2,686,000)	540,208
Unbilled Revenue	-	(689,928)
Accrued Expenses	10,467	(694,192)
Net Cash Used in Operating Activities	(8,153,833)	(10,844,512)
Investing Activities:		
Purchase of Property and Equipment	-	(20,000)
Payment Under License Agreement	-	(250,000)
Net Cash Used in Investing Activities	-	(270,000)
Financing Activities:		
Proceeds from Stock Offerings, Net of Offering Costs	1,777,918	10,108,762
Exercise of Warrants	2,150,216	1,205,825
Settlement of Fractional Shares	(2,614)	-
Equipment Financing Payments	(4,715)	(9,782)
Net Cash Provided by Financing Activities	3,920,805	11,304,805
Effect of Exchange Rate Changes on Cash	5,503	7,915
Net (Decrease) Increase in Cash	(4,227,525)	198,208
Cash, Including Restricted Cash, Beginning of Year	8,049,237	7,851,029
Cash, Including Restricted Cash, End of Year	$ 3,821,712	$ 8,049,237
Supplemental Disclosures of Noncash Operating and Financing Activities:		
Creation of Right-of-Use Assets and Related Lease Liabilities Upon Adoption of ASU 2016-02	$ 136,675	$ -
Creation of Right-of-Use Assets and Related Lease Liabilities	$ 109,511	$ -
Conversion of Preferred Stock into Common Stock	$ -	$ 80,388
Cancellation of Restricted Stock	$ 79	$ -

See Accompanying Notes to the Consolidated Financial Statements.

1. Organization, Business, and Liquidity

EyeGate Pharmaceuticals, Inc. ("EyeGate" or the "Company"), a Delaware corporation, began operations in December 2004 and is a clinical-stage pharmaceutical company focused on developing products for treating disorders of the eye. The Company's lead product in clinical development is the EyeGate Ocular Bandage Gel ("OBG"), a topically applied eye drop formulation of modified hyaluronic acid ("HA"). HA is a naturally occurring polymer that is important in many physiological processes, including wound healing, hydration, tissue homeostasis, and joint lubrication. EyeGate uniquely modifies the HA through chemical cross-linking, which allows it to adhere longer to the ocular surface providing protection and lubrication for the treatment of corneal wounds, defects, and epitheliopathies. As OBG is the first prescription HA eye drop in the United States, it is being developed under the *de novo* pathway for devices.

As of December 31, 2019, there were 4,077,755 shares of Common Stock outstanding, no shares of Series A Preferred Stock outstanding, no shares of Series B Preferred Stock outstanding, and 4,092 shares of Series C Preferred Stock outstanding.

Effective July 31, 2015, the Company's Common Stock began trading on the Nasdaq Capital Market under the symbol "EYEG".

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, 2019, EyeGate had unrestricted Cash and Cash Equivalents of $3,776,712, and an Accumulated Deficit of $100,246,894. EyeGate has incurred losses and negative cash flows since inception, and future losses are anticipated. Based on its cash on hand at December 31, 2019 and the approximately $4.5 million in net proceeds received from a registered direct offering that closed on January 3, 2020, the Company anticipates having sufficient cash to fund planned operations through December 31, 2020, however, the acceleration or reduction of cash outflows by Company management can significantly impact the timing for the need to raise additional capital to complete development of its products. To continue development, EyeGate will need to raise additional capital through equity financing, license agreements, and/or additional U.S. government grants. Although historically the Company has been successful at raising capital, additional capital may not be available on terms favorable to EyeGate, if at all. On May 13, 2019, the SEC declared effective EyeGate's registration statement on Form S-3, registering a total of $50,000,000 of its securities for sale to the public from time to time in what is known as a "shelf offering". The Company does not know if any future offerings, including offerings pursuant to its shelf registration statement, will succeed. Accordingly, no assurances can be given that Company management will succeed in these endeavors. The Company's recurring losses from operations have caused management to determine there is substantial doubt about the Company's ability to continue as a going concern. The Consolidated 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 its subsidiaries, EyeGate Pharma S.A.S. and Jade Therapeutics, Inc. ("Jade") (effective March 7, 2016 when the Company acquired all of the capital stock of Jade), collectively referred to as "the Company". 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 ("U.S. GAAP").

Reverse Stock Split

On August 9, 2019, the Board of Directors approved a 1-for-15 reverse stock split of the Company's outstanding common stock, effective August 30, 2019. Accordingly, all shares and per share amounts were retroactively adjusted to reflect this reverse stock split.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP 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 expenses during the reporting periods. The Company makes significant estimates and assumptions in recording the accruals for our clinical trial and research activities, establishing the useful lives of intangible assets and property and equipment, conducting impairment reviews of long-lived assets, revenue recognition, stock-based compensation, and contingent considerations payable. The Company bases its estimates on historical experience and various other assumptions that it believes to be reasonable under the circumstances. Although the Company monitors and regularly assesses these estimates, actual results could differ significantly from these estimates. The Company records changes in estimates in the period that it becomes aware of the change.

Foreign Currency Translation

Operations of EyeGate Pharma S.A.S. 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, are included in accumulated other comprehensive loss on the Consolidated Balance Sheets.

Cash and Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with a 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. The Company invests its cash in either U.S. government or treasury money market funds with maturities of 90 days or less. As of December 31, 2019 and 2018, the Company has classified $45,000 and $45,000 as restricted cash, respectively.

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 2 to 5 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.

2. Summary of Significant Accounting Policies - (continued)

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, or that the period of their recovery may have changed. 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, 2019. There is no assurance that management's estimates and assumptions will not change in future periods.

Research and Development Expenses

The Company expenses research and development ("R&D") expenditures as incurred. R&D expenses are comprised of costs incurred in performing R&D activities, including salaries, benefits, facilities, research-related overhead, sponsored research costs, contracted services, license fees, expenses related to generating, filing, and maintaining intellectual property and other external costs. Because the Company believes that, under its current process for developing its products, the viability of the products is essentially concurrent with the establishment of technological feasibility, no costs have been capitalized to date.

Goodwill

Goodwill is the excess of the acquisition cost of a business over the fair value of the identifiable net assets acquired. Goodwill at December 31, 2019 and 2018 was $1,525,896, which solely consists of the goodwill acquired in the acquisition of Jade. Goodwill is not amortized and is tested for impairment on an annual basis in the fourth quarter of each fiscal year and whenever events or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount. The Company performed qualitative impairment evaluations on its goodwill as of December 31, 2019 and determined that there were no indications that goodwill was impaired.

In-Process Research and Development

The Company records in-process R&D projects acquired in asset acquisitions that have not reached technological feasibility and which have no alternative future use. For in-process R&D projects acquired in business combinations, the Company capitalizes the in-process R&D project and periodically evaluates this asset for impairment until the R&D process has been completed. Once the R&D process is complete, the Company amortizes the R&D asset over its remaining useful life. At December 31, 2019 and 2018 there is $3,912,314 of in-process R&D, as part of intangible asset and in-process R&D on the Consolidated Balance Sheets.

Intangible Assets

The Company records intangible assets acquired in asset acquisitions of proprietary technology. The Company capitalizes intangible assets, amortizes them over the estimated useful life, and periodically evaluates the assets for impairment. At December 31, 2019 and 2018 there is $218,750 and $243,750, respectively, of net intangible assets, as part of intangible assets and in-process R&D, net on the Consolidated Balance Sheets.

Accrued Clinical Expenses

As part of our process of preparing the Consolidated Financial Statements, the Company is required to estimate its accrued expenses. This process includes reviewing open contracts and purchase orders, communicating with its applicable personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated costs incurred for the service when the Company has not yet been invoiced or otherwise notified of actual costs. The majority of the Company's service providers invoice monthly in arrears for services performed. The Company makes estimates of its accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known at the time. The Company periodically confirms the accuracy of these estimates with the service providers and makes adjustments if necessary.

2. Summary of Significant Accounting Policies - (continued)

Business Segment and Geographical Information

The Company identifies operating segments as components of the 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 as fully integrated and operating in one business segment (research and development), and the Company operates in one geographic segment.

Income Taxes

The Company will record a deferred income tax asset and liability for the expected future income tax consequences of events that have been recognized in the Company's Consolidated Financial Statements and income tax returns. The Company will record a deferred income tax asset and liability based on differences between the financial statement carrying, or "book", amounts of assets and liabilities, and the tax bases of the assets and liabilities using the enacted income tax regulations in effect in the years in which the differences are expected to reverse. A valuation allowance against deferred income tax asset will be recorded if, based on the weight of available evidence, it is more likely than not that some or all of the deferred income tax assets will not be realized. As of December 31, 2019 and 2018, all of the Company's net deferred income tax assets were subject to a full valuation allowance. As of December 31, 2019 and 2018, the Company has a net deferred tax liability of $365,364 and $269,968, respectively.

The Company recognizes the impact of an uncertain income tax position in the financial statements if it believes that the position is more likely than not to be sustained by the relevant taxing authority. As of December 31, 2019, the Company had no unrecognized uncertain income tax positions.

Refundable Tax Credits for Research and Development

EyeGate 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.

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.

2. Summary of Significant Accounting Policies - (continued)

Comprehensive Loss

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

Stock-Based Compensation

Stock-based compensation represents the cost related to stock-based awards granted to employees and others. The Company measures stock-based compensation cost to employees at grant date, based on the estimated fair value of the award, and recognizes the cost as expense on a straight-line basis over the employee requisite service period. The Company estimates the fair value of stock options using the 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's policy is to record forfeitures as they occur.

Net Loss per Share - Basic and Diluted

Basic and diluted net loss per share is computed by dividing net loss available to common shareholders by the weighted-average number of common shares outstanding for the period, which, for basic net loss per share, does not include unvested restricted common stock that has been issued but is subject to forfeiture of 50,187 shares for the year ended December 31, 2019 and 121,478 shares for the year ended December 31, 2018.

Dilutive common equivalent shares consist of stock options, warrants, and preferred stock and are calculated using the treasury stock method, which assumes the repurchase of common shares at the average market price during the period. Under the treasury stock method, options and warrants will have a dilutive effect when the average price of common stock during the period exceeds the exercise price of options or warrants. Common equivalent shares do not qualify as participating securities. In periods where the Company records a net loss, unvested restricted common stock and potential common stock equivalents are not included in the calculation of diluted net loss per share as their effect would be anti-dilutive. Potential common shares not included in calculating diluted net loss per share are as follows:

	Year Ended December 31,	
	2019	**2018**
Common Stock Warrants	2,875,006	2,722,967
Employee Stock Options	174,175	138,324
Preferred Stock	852,500	852,500
Total Shares of Common Stock Issuable	3,901,681	3,713,791

2. Summary of Significant Accounting Policies - (continued)

Related-Party Transactions

The Company has entered into certain related-party transactions, making payments for services to two vendors, eleven consultants and two public universities, all of whom also are stockholders of the Company. These transactions generally are ones that involve a stockholder or option holder of the Company to whom the Company also makes payments during the year, typically as a consultant or a service provider. The Company made payments related to clinical trial services to one vendor in the amount of approximately $978,000 during the year ended December 31, 2019. Additionally, on October 2, 2019, the Company completed a private placement of 600,000 shares of Common Stock and warrants to purchase up to 600,000 shares of Common Stock to an affiliate of Armistice Capital, LLC, with a combined purchase price per share and warrant of $3.125. Steven J. Boyd and Keith Maher, each of whom are members of our board of directors, are affiliates of Armistice Capital, LLC, and Mr. Boyd holds voting and investment power over such entity. The total gross proceeds from the private placement were approximately $1.9 million. Except as described above, the amounts recorded or paid to related parties are not material to the accompanying Consolidated Financial Statements.

Fair Value of Financial Instruments

The carrying amounts of Accounts Payable approximate their fair values due to the short-term nature of these items. As of December 31, 2019 and December 31, 2018, the fair value of the Company's contingent consideration was $1,710,000 and $1,210,000, respectively. The Company evaluates the present value of this earn-out payment on a quarterly basis and as a result of the 2019 fourth quarter assessment of the EyeGate OBG product, taking into consideration discount factors and the probability of FDA approval, recorded an increase of $500,000 to the present value of contingent consideration for the year ended December 31, 2019.

At December 31, 2019 and December 31, 2018, the Company had no other assets or liabilities that are subject to fair value methodology and estimation in accordance with U.S. GAAP.

Revenue Recognition

The Company's revenues are generated primarily through arrangements which generally contain multiple elements, or deliverables, including licenses and R&D activities to be performed by the Company on behalf of the licensor or grantor. Payments to EyeGate under these arrangements typically include one or more of the following: (1) nonrefundable, upfront license fees, (2) funding of discovery research efforts on a full-time equivalent basis, (3) reimbursement of research, development and intellectual property costs, (4) milestone payments, and (5) royalties on future product sales.

On July 9, 2015, the Company entered into an exclusive, worldwide licensing agreement with a subsidiary of Bausch Health Companies, Inc. ("BHC"), through which the Company granted to BHC an exclusive, worldwide commercial and manufacturing right to the Company's EGP-437 Combination Product in the field of anterior uveitis, as well as a right of last negotiation to license its EGP-437 Combination Product for indications other than anterior uveitis (the "BHC Agreement"). Under the BHC Agreement, BHC paid to the Company an initial upfront payment of $1.0 million and the Company was eligible to receive milestone payments totaling up to $32.5 million, upon and subject to the achievement of certain specified development and commercial progress of the EGP-437 Combination Product for the treatment of anterior uveitis. The Company received milestone payments totaling $5.4 million. The Company received payments both when it crossed certain thresholds on the way to each milestone, as well as once it achieved each milestone. The Company is entitled to retain all of these payments. Effective March 14, 2019, this license agreement was voluntarily terminated by BHC reinstating to the Company all of the rights and privileges of the EGP-437 platform. Upon termination of this agreement, all amounts remaining in deferred revenue were recognized as revenue, as the Company no longer had any remaining performance obligations.

On February 21, 2017, the Company entered into another exclusive, worldwide licensing agreement with a subsidiary of BHC (the "New BHC Agreement"), through which the Company granted BHC exclusive, worldwide commercial and manufacturing rights to its EGP-437 Combination Product in the field of ocular iontophoretic treatment for post-operative ocular inflammation and pain in ocular surgery patients (the "New Field"). Under the New BHC Agreement, BHC paid the Company an initial upfront payment of $4.0 million, and the Company was eligible to receive milestone payments totaling up to approximately $99.0 million, upon and subject to the achievement of certain specified developmental and commercial progress of the EGP-437 Combination Product for the New Field. The Company received milestone payments totaling $3.4 million. The Company received payments both when it crossed certain thresholds on the way to each milestone, as well as once it achieved each milestone. The Company is entitled to retain all of these payments. Effective March 14, 2019, this license agreement was voluntarily terminated by BHC reinstating to the Company all of the rights and privileges of the EGP-437 platform. Upon termination of this agreement, all amounts remaining in deferred revenue were recognized as revenue, as the Company no longer had any remaining performance obligations.

2. Summary of Significant Accounting Policies - (continued)

In May 2014, the FASB issued ASU No. 2014-09, *Revenues from Contracts with Customers* ("Topic 606"), as subsequently amended, that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most recent revenue recognition guidance, including industry-specific guidance. The core principle of the revenue model is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This standard was effective for public companies for years ending after December 15, 2017, with early adoption permitted.

The Company adopted the new standard on January 1, 2018, using the modified retrospective method, which resulted in a cumulative effect adjustment in the amount of $9.5 million to beginning 2018 accumulated deficit and to deferred and unbilled revenue for the BHC contracts impacted by the adoption of the new standard. The changes to the method and/or timing of the Company's revenue recognition associated with the adoption of the new standard primarily relate to the determination that there is one performance obligation in each contract with BHC and that the license combined with the R&D services is the performance obligation.

The Company recognizes revenue when its customer obtains control of promised services, in an amount that reflects the consideration which the Company expects to receive in exchange for those services. To determine whether arrangements are within the scope of this new guidance, the Company performs the following five steps: (i) identifies the contract with a customer; (ii) identifies the performance obligations in the contract; (iii) determines the transaction price; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when (or as) the Company satisfies its performance obligation. The Company applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Upon adoption of ASU No. 2014-09, the Company recognizes revenue from the transaction price applied to each single performance obligation over time as milestones are reached for each performance obligation. The Company only recognizes revenue on those milestones that are within the Company's control and any constrained variable consideration that requires regulatory approval will only be included in the transaction price when performance is complete.

The below table represents the changes in the Company's contract assets and contract liabilities:

	December 31, 2019	December 31, 2018
Contract Liabilities:		
Deferred Revenue	$ (2,686,000)	$ 2,686,000

	Twelve Months Ended December 31, 2019
Revenue recognized in the period from:	
Amounts included in contract liability at the beginning of the period	$ 2,686,000

In addition, the Company may receive government grant funds for specified ocular therapeutic research activities. Revenue under these grants will be recorded when the Company performs the activities specified by the terms of each grant and is entitled to the funds.

2. Summary of Significant Accounting Policies - (continued)

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02,*Leases*, which is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted. Under ASU No. 2016-02, lessees are required to recognize for all leases at the commencement date a lease liability, which is a lessee's obligation to make lease payments arising from a lease measured on a discounted basis, and the right-to-use assets, which are asset that represents the lessee's right to use or control the use of a specified asset for the lease term. The Company adopted the new standard effective January 1, 2019 using the modified retrospective method. As a result, the Company recorded right-of-use leased assets and corresponding liabilities of approximately $0.137 million on January 1, 2019.

On January 26, 2017, the FASB issued ASU No. 2017-04,*Intangibles—Goodwill and Other*, which simplifies the accounting for goodwill impairment. The guidance removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. All other goodwill impairment guidance will remain largely unchanged. Entities will continue to have the option to perform a qualitative assessment to determine if a quantitative impairment test is necessary. The same one-step impairment test will be applied to goodwill at all reporting units, even those with zero or negative carrying amounts. Entities will be required to disclose the amount of goodwill at reporting units with zero or negative carrying amounts. The new standard was effective for the Company on January 1, 2020 and is required to be applied prospectively. The Company has evaluated the effect of the new guidance and adopted ASU No. 2017-04 effective January 1, 2020. The adoption of this standard will not have a material impact on the Company's Consolidated Financial Statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13,*Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. ASU No. 2016-13 replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The new guidance is effective for smaller reporting companies in fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company does not expect the adoption of this standard to have a material effect on its financial statements.

3. Property and Equipment

Property and equipment at December 31, 2019 and 2018 consists of the following:

	Estimated Useful Life (Years)	2019	2018
Laboratory Equipment	3	$ 62,576	$ 62,576
Office Furniture	5	14,430	14,430
Leasehold Improvements	2	22,569	22,569
Total Property and Equipment, Gross		99,575	99,575
Less Accumulated Depreciation		82,729	56,057
Total Property and Equipment, Net		$ 16,846	$ 43,518

Depreciation expense was $26,672 and $32,233 for the years ended December 31, 2019 and 2018, respectively.

4. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2019	2018
Payroll and Benefits	$ 598,327	$ 722,178
Professional Fees	259,606	165,894
Clinical Trials	254,144	212,540
Consulting	8,403	9,401
Short-Term Portion of Capital Lease Obligation	-	4,715
Total Accrued Expenses	$ 1,120,480	$ 1,114,728

5. Debt

The Company has no indebtedness other than trade and accounts payable and capital lease obligations in the ordinary course of business as of the years ended December 31, 2019 and 2018.

6. Intangible Assets and In-Process R&D

Intangible assets at December 31, 2019 consist of the rights to trade secrets and know-how related to the manufacturing of the EyeGate Ocular Bandage Gel ("OBG"). During the third quarter of 2018, the Company entered into an intellectual property license agreement with SentrX Animal Care, Inc. ("SentrX") with respect to certain rights relating to the manufacturing of EyeGate OBG product. The intangible assets were recorded at $250,000, representing the upfront payment paid to SentrX. Additionally, SentrX is eligible to receive milestone payments totaling up to $4.75 million, upon and subject to the achievement of certain specified development and commercial milestones. These future milestone payments to SentrX will increase the carrying value of the intangible assets. The Company's intangible assets are amortized on a straight-line basis over the estimated useful lives. Additionally, in-process R&D at December 31, 2019 and 2018 consists of projects acquired from the acquisition of Jade that have not reached technological feasibility and which have no alternative future use. Once the R&D process is complete, the Company will amortize the R&D asset over its remaining useful life. The Company periodically evaluates these assets for impairment.

Intangible assets and in-process R&D at December 31, 2019 and 2018 consists of the following:

	Estimated Useful Life (Years)	2019	2018
Trade Secrets	10	$ 250,000	$ 250,000
Less: Accumulated Amortization		(31,250)	(6,250)
Intangible Assets, Net		218,750	243,750
In-Process R&D		3,912,314	3,912,314
Total Intangible Assets and In-Process R&D, Net		$ 4,131,064	$ 4,156,064

Amortization expense on intangible assets was $25,000 and $6,250 for the years ended December 31, 2019 and 2018, respectively.

7. Capital Stock

On May 24, 2016, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC (the "Sales Agent"), to create an at the market equity program under which the Company could from time to time offer and sell up to 87,952 shares of its Common Stock through the Sales Agent. The ATM Agreement terminated automatically pursuant to its terms on May 24, 2019.

On June 14, 2017, the Company completed a public offering of 355,777 shares of Common Stock and 1,995 shares of Series B Preferred Stock (convertible into 88,666 shares of Common Stock), along with warrants to purchase 444,443 shares of Common Stock. Following the 1-for-15 reverse stock split effected on August 30, 2019, the shares underlying these warrants were adjusted to reflect the reverse stock split and rounded up to the nearest whole share in accordance with their terms. The offering was priced at $22.50 per share of Common Stock (or share of Common Stock issuable upon conversion of a share of Series B Convertible Preferred Stock) and warrant. The total net proceeds to the Company from the offering, after deducting the placement agent fees and offering expenses, were approximately $8.8 million. Additionally, the investors received, for each share of Common Stock, or for each share of Common Stock issuable upon conversion of a share of Series B Preferred Stock purchased in the public offering, warrants to purchase one share of Common Stock at an exercise price of $22.50 per share, which in the aggregate represented warrants to purchase an aggregate of 444,443 shares of Common Stock. The warrants issued to investors became initially exercisable immediately upon issuance and terminate on June 14, 2022, five years following the date of issuance. All 1,995 shares of Series B Preferred Stock have been converted into an aggregate of 88,666 shares of Common Stock.

On April 17, 2018, the Company completed a public offering of 982,000 shares of Common Stock and 6,536.4 shares of Series C Preferred Stock (convertible into 1,361,750 shares of Common Stock), along with warrants to purchase 2,343,750 shares of Common Stock. Following the 1-for-15 reverse stock split effected on August 30, 2019, the shares underlying these warrants were adjusted to reflect the reverse stock split and rounded up to the nearest whole share in accordance with their terms. The offering was priced at $4.80 per share of Common Stock (or share of Common Stock issuable upon conversion of a share of Series C Convertible Preferred Stock) and warrant. The total net proceeds to the Company from the offering, after deducting the placement agent fees and offering expenses, were approximately $10.1 million. Additionally, the investors received, for each share of Common Stock, or for each share of Common Stock issuable upon conversion of a share of Series C Preferred Stock purchased in the public offering, warrants to purchase one share of Common Stock at an exercise price of $4.80 per share, which in the aggregate represented warrants to purchase an aggregate of 2,343,750 shares of Common Stock. The warrants issued to investors became initially exercisable immediately upon issuance and terminate on April 17, 2023, five years following the date of issuance. Concurrently with the closing of the public offering, a holder elected to convert 1,400 shares of Series C Preferred Stock into 291,667 shares of Common Stock. Subsequently, on April 18, 2018, April 23, 2018, and April 30, 2018, holders converted 1,044.4 shares of Series C Preferred stock into 217,583 shares of Common Stock.

On August 9, 2019, the Board of Directors approved a 1-for-15 reverse stock split and the filing of a Certificate of Amendment to the Restated Certificate of Incorporation of the Company to effect a reverse stock split. The Certificate of Amendment was filed with the Secretary of State of the State of Delaware on August 28, 2019, and the reverse stock split became effective in accordance with the terms of the Certificate of Amendment on August 30, 2019. The reverse stock split did not affect the number of authorized shares of common stock, which is 120,000,000 shares. A proportionate adjustment was made to (i) the per share exercise price and the number of shares issuable upon the exercise or conversion of the Company's outstanding equity awards, options and warrants to purchase shares of common stock, and (ii) the number of shares reserved for issuance pursuant to the Company's 2014 Equity Incentive Plan. Fractional shares were not issued as a result of the reverse stock split; instead, the Company paid out cash in lieu of any fractional shares.

On October 2, 2019, the Company completed a private placement with an affiliate of Armistice Capital, LLC for 600,000 shares of Common Stock and warrants to purchase 600,000 shares of Common Stock with a combined purchase price of $3.125 per share of Common Stock and warrant. The total gross proceeds to the Company from the offering were approximately $1.9 million. The warrants issued will become exercisable six months from the issuance date and terminate on October 2, 2024, five years following the date of issuance.

At December 31, 2019, the Company had 120,000,000 authorized shares of Common Stock, $0.01 par value, of which 4,077,755 shares were outstanding. At December 31, 2019, the Company had 9,994,184 authorized shares of Preferred Stock, $0.01 par value, of which 3,750 shares were designated as Series A Preferred Stock and 0 shares were issued and outstanding, 10,000 shares were designated as Series B Preferred Stock and 0 shares were issued and outstanding, and 10,000 shares were designated as Series C Preferred Stock and 4,092 shares were issued and outstanding. At December 31, 2019, there were 0 shares of Common Stock underlying the outstanding shares of Series A Preferred Stock, 0 shares of Common Stock underlying the outstanding shares of Series B Preferred Stock, and 852,500 shares of Common Stock underlying the outstanding shares of Series C Preferred Stock.

8. Warrants

At December 31, 2019 and 2018, the following warrants were outstanding:

	Number of Awards	Weighted Average Exercise Price	Weighted Average Remaining Term in Years
Outstanding at December 31, 2017	630,415	$ 48.90	4.23
Issued	2,343,777[1]	4.80[3]	4.30
Exercised	(251,225)	4.80	4.30
Outstanding at December 31, 2018	2,722,967	$ 15.00	4.05
Issued	600,000[2]	3.13[3]	4.76
Exercised	(447,961)	4.80	3.30
Outstanding at December 31, 2019	2,875,006	$ 14.14	3.37

1 Consists of 2,343,777 warrants to purchase 2,343,777 shares of Common Stock issued in connection with the Company's public offering on April 17, 2018.

2 Consists of 600,000 warrants to purchase 600,000 shares of Common Stock issued in connection with the Company's private placement with an affiliate of Armistice Capital, LLC on October 2, 2019.

3 Warrant exercise price for a full share of Common Stock.

All of the warrant agreements provide for a cashless exercise in the event a registration statement covering the issuance of the shares of common stock underlying the warrants is not effective, whereby the number of shares to be issued upon exercise of such warrants will be reduced based on the exercise price and the market value of the shares at the time of exercise. The outstanding warrants expire from 2020 through 2024.

9. 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 shares of Common Stock that may be issued pursuant to the 2005 Plan was increased to 59,414 shares. The Board of Directors (the "Board") is responsible for administration of the 2005 Plan. The Company's 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. Following adoption of the 2014 Equity Incentive Plan (the "2014 Plan"), no further grants were made under the 2005 Plan. General terms of the 2014 Plan remain the same as that of the 2005 Plan.

The Company's Board adopted the 2014 Plan and the Employee Stock Purchase Plan (the "ESPP") and the Company's Stockholders approved the 2014 Plan and the ESPP Plan in February 2015. As of December 31, 2019, the maximum number of shares of Common Stock that may be issued pursuant to the 2014 Plan and the ESPP was 559,339 and 11,371 shares, respectively.

In January 2019, the number of shares of common stock issuable under the 2014 Plan automatically increased by 23,333 shares pursuant to the terms of the 2014 Plan. These additional shares are included in the total of 559,339 shares issuable under the 2014 Plan.

The following is a summary of stock option activity for the twelve months ended December 31, 2019 and December 31, 2018:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Contractual Life (In Years)
Outstanding at December 31, 2017	127,310	$ 38.14	5.83
Granted	27,687	8.55	
Expired	(10,526)	25.76	
Forfeited	(6,147)	15.44	
Outstanding at December 31, 2018	138,324	$ 34.17	5.95
Granted	49,994	7.20	
Expired	(9,274)	28.58	
Forfeited	(4,869)	9.19	
Outstanding at December 31, 2019	174,175	$ 27.42	6.22
Exercisable at December 31, 2019	117,534	$ 36.78	5.18
Vested and Expected to Vest at December 31, 2019	174,175	$ 27.42	6.22

During the years ended December 31, 2019 and December 31, 2018, the Board approved the grant of options to purchase 49,994 and 27,687 shares of its Common Stock, respectively. All option grants were pursuant to the 2014 Plan. In general, options granted under the 2014 Plan vest with respect to one-third of the underlying shares on the one-year anniversary of the grant date and the remainder ratably over a 24-month period.

9. Equity Incentive Plan - (continued)

For the twelve months ended December 31, 2019 and 2018, the fair value of each option grant has been estimated on the date of grant using the Black-Scholes Option Pricing Model with the following weighted-average assumptions:

	2019	2018
Risk-Free Interest Rate	1.82%	1.82%
Expected Life	5.00 years	8.01 years
Expected Volatility	152%	158%
Expected Dividend Yield	0%	0%

Using the Black-Scholes Option Pricing Model, the estimated weighted average fair value of an option to purchase one share of common stock granted during the twelve months ended December 31, 2019 and 2018 was $7.11 and $8.33, respectively.

The following is a summary of restricted stock activity for the twelve months ended December 31, 2019 and December 31, 2018:

	Number of Shares	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Recognition Period
Non-vested Outstanding at December 31, 2017	6,865	$ 22.81	
Awarded	125,989	8.55	
Vested	(4,152)	22.81	
Forfeited	(7,224)	9.00	
Non-vested Outstanding at December 31, 2018	121,478	8.84	2.25
Vested	(63,632)	9.00	
Forfeited	(7,659)	8.86	
Non-vested Outstanding at December 31, 2019	50,187	$ 8.64	1.49

During the years ended December 31, 2019 and 2018, the Board approved the grant of 0 and 125,989 restricted shares of its Common Stock, respectively. All grants of restricted shares were pursuant to the 2014 Plan. These vest with respect to one-third of the underlying shares on the one-year anniversary of the grant date and the remainder ratably over a 24-month period. During the year ended December 31, 2019, 7,659 shares of restricted stock, respectively, which had not vested were forfeited and returned to the Company. During the year ended December 31, 2018, 7,224 shares of restricted stock, which had not vested were forfeited and returned to the Company.

The total stock-based compensation expense for employees and non-employees is included in the accompanying Consolidated Statements of Operations and as follows:

	Year Ended December 31,	
	2019	2018
Research and Development	$ 203,512	$ 255,505
General and Administrative	648,718	619,782
Total Stock-Based Compensation Expense	$ 852,230	$ 875,287

The fair value of options granted for the twelve months ended December 31, 2019 and 2018 was approximately $355,000 and $212,000, respectively. The fair value of restricted stock granted for the twelve months ended December 31, 2019 and 2018 was approximately $0 and $1,049,000 respectively. As of December 31, 2019 and 2018, there was approximately $627,000 and $1,236,000 of total unrecognized compensation expense related to unvested stock-based compensation arrangements granted, which cost is expected to be recognized over a weighted average period of 1.62 and 2.27 years, respectively. The aggregate intrinsic value of stock options outstanding and exercisable at December 31, 2019 and 2018 was approximately $32,000 and $0, respectively.

As of December 31, 2019, there were 288,690 shares of Common Stock available for grant under the 2014 Plan and 7,806 shares available under the Company's ESPP.

10. Income Taxes

The components of loss before income taxes are as follows:

	Year Ended December 31,	
	2019	2018
Domestic	$ (7,523,695)	$ (11,242,646)
Foreign	522,395	517,268
Total Loss Before Income Taxes	$ (7,001,300)	$ (10,725,378)

The components of income tax expense are as follows:

	Year Ended December 31,	
	2019	2018
Deferred Taxes:		
Federal	$ (4,182)	$ 1,814
State	99,578	84,231
Total Deferred Taxes	$ 95,396	$ 86,045
Income Tax Expense	$ 95,396	$ 86,045

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,	
	2019	2018
United States Federal Income Tax Rate	21.00%	21.00%
State Taxes, Net of Federal Benefit	13.82	(0.38)
Permanent Differences	(4.18)	(1.48)
Change in Valuation Allowance	(37.40)	3.88
Research and Development Credits	6.53	1.06
Tax Rate Differential	(1.15)	(1.33)
Topic 606 Adoption	-	(20.90)
Stock-Based Compensation	0.45	0.00
Other	(0.43)	(2.65)
Effective Tax Rate Expense	(1.36)%	(0.80)%

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

	Year Ended December 31,	
	2019	2018
Net Deferred Tax Liability:		
Net Operating Loss Carryforwards	$ 15,230,646	$ 13,601,705
Research and Development Credit Carryforwards	2,594,055	2,124,949
Capitalized Research and Development	6,521,705	5,861,675
Stock-Based Compensation	814,438	639,729
Depreciation and Amortization	170	(3,217)
Cash Versus Accrual Adjustments	1,738,482	2,069,985
Total Deferred Tax Assets	26,899,496	24,294,826
Valuation Allowance	(26,278,147)	(23,659,844)
Net Deferred Tax Asset	621,349	634,982
In-Process Research and Development	(986,713)	(904,950)
Net Deferred Tax Liability	$ (365,364)	$ (269,968)

10. Income Taxes - (continued)

As of December 31, 2019, the Company has federal and state net operating loss carryforwards of approximately $59,013,000 and $41,088,000, respectively, to offset future federal and state taxable income. Federal NOL carryforwards as of December 31, 2017 totaling $46.055 million and state NOL carryforwards as of December 31, 2019 totaling $41.088 million will expire at various times through 2039. Federal NOL carryforwards generated during the years ended December 31, 2019 and 2018 totaling $12.958 million will carry forward indefinitely, but their utilization will be limited to 80% of taxable income. The Company has foreign net operating loss carryforwards of $1,565,000 as of December 31, 2019, which can be carried forward indefinitely. As of December 31, 2019, the Company also has federal, state and foreign research and development tax credit carryforwards of approximately $2,171,000, $504,000, and $25,000, respectively, to offset future income taxes, which expire at various times through 2039. 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. Approximately $638,000 of the federal net operating loss attributable to Jade is subject to a Section 382 limitation. Jade's carryover of its research and development credits will be subject to the Section 383 limitation.

The Company files United States federal income tax returns and income tax returns in the Commonwealth of Massachusetts, Utah, and New Jersey, 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, 2019, and 2018 because the Company's management believes that it is more likely than not that these assets will not be realized. The valuation allowance increased (decreased) by approximately $2,618,000 and ($416,000) during the years ended December 31, 2019 and 2018, respectively, primarily as a result of adjustments for accrual to cash basis items, the adoption of Topic 606, capitalized research and development expenses, and a reduction in the U.S. federal tax rate.

Effective January 1, 2019, the Company adopted ASU 2016-02, which resulted in recognition of lease liabilities and right-of-use assets. The adoption did not have material impact on the deferred tax balances as of December 31, 2019.

As of December 31, 2019 and 2018, 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, which are fully reserved for. This study may result in an adjustment to the Company's R&D credit carryforwards and related valuation allowance, 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 tax credit 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 as the result of the Company's additional sales of common stock by the Company could have a material adverse effect on the Company's results of operations in future years.

11. Commitments and Contingencies

Leases

The Company is a party to a real property operating lease for the rental of office space in Waltham, Massachusetts of up to 4,516 square feet, that is used for its corporate headquarters. This lease was to originally terminate in December 2019 and was amended during the third quarter of 2019 to extend its term until June 2020. On July 6, 2016, the Company entered into a real property operating lease for office and laboratory space of approximately 2,300 square feet in Salt Lake City, Utah. This lease was amended during the second quarter of 2019 to extend its term until June 2020.

Operating lease assets and liabilities are recognized at the lease commencement date at the present value of lease payments to be paid. Operating lease assets represent the Company's right to use an underlying asset and are based upon the operating lease liabilities adjusted for prepayments or accrued lease payments. To determine the present value of lease payments to be paid, the Company estimated incremental secured borrowing rates corresponding to the maturities of the leases. The Company estimated a rate of 10% based on prevailing financial market conditions, comparable company and credit analysis, and management judgment. The Company recognizes expense for its leases on a straight-line basis over the lease term.

Maturities of lease liabilities were as follows as of December 31, 2019:

	Operating Leases
Year Ending December 31, 2020	$ 86,390
Less: Imputed Interest	(2,464)
Lease Liabilities	$ 83,926

License Agreements

The Company is a party to four license agreements as described below. These license agreements require the Company to pay royalties or fees to the licensor based on revenue or milestones related to the licensed technology.

On February 15, 1999, the Company entered into an exclusive worldwide license agreement with the University of Miami School of Medicine to license technology relating to the Company's EyeGate® II Delivery System. This agreement, which was amended in December 2005, requires the Company to pay to the University of Miami an annual license fee of $12,500. This license also requires payments to the University of Miami 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 23, 1999, the Company entered into a perpetual Transaction Protocol agreement with Francine Behar-Cohen to acknowledge the Company's right to use certain patents that Ms. Behar-Cohen had certain ownership rights with respect to and which are used in the Company's EGP-437 Combination Product. The agreement also provides for the Company to pay Ms. Behar-Cohen a fee based on a percentage of the pre-tax turnover generated from sales of the Company's EGP-437 Combination Product relating to its inclusion of the EyeGate® II Delivery System. The fees due under the agreement expired in January 2018, but the Company continues to maintain its rights under the agreement.

On September 12, 2013, Jade entered into an agreement with BioTime, Inc. granting to it the exclusive worldwide right to commercialize cross-linked thiolated carboxymethyl hyaluronic acid ("CMHA-S") for ophthalmic treatments in humans. The agreement calls for a license issue fee paid to BioTime of $50,000 and requires the Company (through its Jade subsidiary) to pay an annual fee of $30,000 and royalties to BioTime based on revenue relating to any product incorporating the CMHA-S technology. The agreement expires when patent protection for the CMHA-S technology lapses, which is expected to occur in the U.S. in 2028.

11. Commitments and Contingencies - (continued)

On September 26, 2018, the Company entered into an intellectual property licensing agreement (the "SentrX Agreement") with SentrX,a veterinary medical device company that develops and manufactures veterinary wound care products. Under the SentrX Agreement, the Company will in-license the rights to trade-secrets and know-how related to the manufacturing of its EyeGate OBG. The SentrX Agreement will enable the Company to pursue a different vendor with a larger capacity for manufacturing and an FDA-inspected facility for commercialization of a product for human use. Under the SentrX Agreement, the Company paid SentrX an upfront payment of $250,000 recorded as intangible assets on the Condensed Consolidated Balance Sheets. SentrX is eligible to receive milestone payments totaling up to $4.75 million, upon and subject to the achievement of certain specified developmental and commercial milestones. These future milestone payments to SentrX will increase the carrying value of the intangible assets.

On July 9, 2015, the Company entered into an exclusive worldwide licensing agreement with a subsidiary of BHC through which EyeGate granted BHC exclusive, worldwide commercial and manufacturing rights to its EGP-437 Combination Product in the field of anterior uveitis, as well as a right of last negotiation to license the EGP-437 Combination Product for other indications. Under the agreement, BHC paid the Company an upfront payment of $1.0 million. The Company was eligible to receive milestone payments totaling up to $32.5 million, upon and subject to the achievement of certain specified developmental and commercial milestones. In addition, the Company was eligible to receive royalties based on a specified percent of net sales of the EGP-437 Combination Product throughout the world, subject to adjustment in certain circumstances. BHC voluntarily terminated this license agreement effective March 14, 2019.

On February 21, 2017, the Company entered into an exclusive, worldwide licensing agreement with a subsidiary of BHC (the "New BHC Agreement"), through which the Company granted BHC exclusive, worldwide commercial and manufacturing rights to its EGP-437 Combination Product in the field of ocular iontophoretic treatment for post-operative ocular inflammation and pain in ocular surgery patients (the "New Field"). Under the New BHC Agreement, BHC paid the Company an initial upfront payment of $4.0 million, and the Company was eligible to receive milestone payments totaling up to approximately $99.0 million, upon and subject to the achievement of certain specified developmental and commercial progress of the EGP-437 Combination Product for the New Field. In addition, the Company was eligible under the New BHC Agreement to receive royalties based on a specified percent of net sales of its EGP-437 Combination Product for the New Field throughout the world, subject to adjustment in certain circumstances. BHC voluntarily terminated this license agreement effective March 14, 2019.

The Company was previously a party to an exclusive worldwide license agreement with the University of Utah Research Foundation to further the commercial development of the NASH technology, together with alkylated HA. The agreement called for payments due to the University of Utah, consisting of a license grant fee of $15,000 due within 30 days of signing, and an annual licensing fee, initially $5,000, and escalating ratably up to $20,000 in 2021. On October 8, 2019, the Company provided written notice to terminate this agreement effective 120 days from this written notice, or February 5, 2020.

12. 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. As a result of the 401(k) plan compliance review for the year ended December 31, 2018, the Company contributed approximately $29,700 to eligible employees. The Company has accrued an estimate of approximately $36,000 for contributions likely due as a result of the 401(k) plan compliance review for the year ended December 31, 2019. The Company made no matching contribution for each of the twelve months ending December 31, 2019 and 2018.

13. Subsequent Event

On January 3, 2020, the Company completed a registered direct offering for 500,000 shares of Common Stock with a purchase price of $10.00 per share. The total net proceeds to the Company from the offering were approximately $4.5 million.

Item 16. ***Form 10-K Summary.***

None.

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 4, 2020

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)	March 4, 2020
/s/ Sarah Romano Sarah Romano	Chief Financial Officer (principal financial and accounting officer)	March 4, 2020
/s/ Paul Chaney Paul Chaney	Chairman	March 4, 2020
/s/ Morton Goldberg Morton Goldberg	Director	March 4, 2020
/s/ Praveen Tyle Praveen Tyle	Director	March 4, 2020
/s/ Thomas E. Hancock Thomas E. Hancock	Director	March 4, 2020
/s/ Bernard Malfroy-Camine Bernard Malfroy-Camine	Director	March 4, 2020
/s/ Keith Maher Keith Maher	Director	March 4, 2020
/s/ Steve Boyd Steve Boyd	Director	March 4, 2020

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
2.1[1]	Stock Purchase Agreement, dated as of March 7, 2016, by and among the Registrant and the Sellers named therein.
3.1[2]	Restated Certificate of Incorporation of the Registrant.
3.2[14]	Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant, filed July 10, 2018.
3.3[17]	Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant, filed August 28, 2019.
3.4[2]	Amended and Restated By-laws of the Registrant.
3.5[7]	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.
3.6[8]	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock.
3.7[13]	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock.
4.1*	Description of Securities.
4.2[3]	Specimen Stock Certificate evidencing the shares of common stock.
4.3[7]	Form of Common Stock Purchase Warrant, dated June 30, 2016.
4.4[9]	Form of Common Stock Purchase Warrant, dated June 14, 2017.
4.5[12]	Form of Common Stock Purchase Warrant, dated April 17, 2018.
4.6[18]	Form of Common Stock Purchase Warrant, dated October 2, 2019.
4.7[20]	Form of Common Stock Purchase Warrant, dated January 3, 2020.
10.1[4]	2005 Equity Incentive Plan, as amended.
10.2[15]	2014 Equity Incentive Plan, as amended.
10.3[5]	Employee Stock Purchase Plan.
10.4†[4]	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†[4]	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†[4]	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[6]	Form of Warrant Agency Agreement, dated August 5, 2015, by and between the Registrant and VStock Transfer, LLC.
10.8[4]	Form of Indemnification Agreement.
10.9[4]	Form of Notice of Stock Option Grant pertaining to the 2014 Equity Incentive Plan.
10.10[4]	Form of Notice of Stock Unit Award pertaining to the 2014 Equity Incentive Plan.

10.11#[10]	Third Amended and Restated Employment Agreement, dated as of November 29, 2017, by and between the Registrant and Stephen From.
10.12#[19]	Amendment to Third Amended and Restated Employment Agreement, dated as of December 3, 2019, by and between the Registrant and Stephen From.
10.13#[4]	Form of Amended and Restated Offer of Employment by and between the Registrant and Michael Manzo.
10.14#[11]	Offer Letter, dated as of January 1, 2018, by and between the Registrant and Sarah Romano.
10.15†[16]	Intellectual Property License Agreement, dated as of September 26, 2018, by and between the Registrant and SentrX Animal Care, Inc.
10.16[18]	Registration Rights Agreement between the Registrant and Armistice Capital Master Fund, Ltd. dated as of September 29, 2019
10.17[19]	EyeGate Pharmaceuticals, Inc. Amended and Restated Change in Control Severance Plan.
10.18[20]	Form of Securities Purchase Agreement, dated as of December 31, 2019, by and among the Registrant and the Purchasers named therein.
10.19[20]	Engagement Letter, dated as of December 30, 2019, by and between the Registrant and H.C. Wainwright & Co., LLC.
10.20*††	Exclusive Sub-License Agreement, dated as of September 12, 2013, by and between Jade Therapeutics, Inc. and Biotime, Inc.
10.21*††	Amendment No. 1 to Sub-License Agreement, dated as of September 18, 2015, by and between Jade Therapeutics, Inc. and Biotime, Inc.
10.22*††	Amendment No. 2 to Sub-License Agreement, dated as of February 17, 2016, by and between Jade Therapeutics, Inc. and Biotime, Inc.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1**	Certification of principal executive officer pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of principal financial and accounting officer 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 of principal executive officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of principal financial and accounting officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS* XBRL Instance Document.

101.SCH* XBRL Taxonomy Extension Schema Document.

101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF* XBRL Taxonomy Extension Definition Linkbase Document.

101.LAB* XBRL Taxonomy Extension Labels Linkbase Document.

101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document.

1 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed March 7, 2016) and incorporated by reference thereto.

2 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed February 20, 2015) and incorporated by reference thereto.

3 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.

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

5 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.

6 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed August 5, 2015) and incorporated by reference thereto.

7 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed June 27, 2016) and incorporated by reference thereto.

8 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed June 14, 2017) and incorporated by reference thereto.

9 Previously filed as an exhibit to Amendment No. 2 to the Company's Registration Statement on Form S-1 (filed June 5, 2017) and incorporated by reference thereto.

10 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed November 29, 2017) and incorporated by reference thereto.

11 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed January 4, 2018) and incorporated by reference thereto.

12 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed April 13, 2018) and incorporated by reference thereto.

13 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed April 17, 2018) and incorporated by reference thereto.

14 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed July 11, 2018) and incorporated by reference thereto.

15 Previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q (filed August 3, 2018) and incorporated by reference thereto.

16 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed October 2, 2018) and incorporated by reference thereto.

17 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed August 29, 2019) and incorporated by reference thereto.

18 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed September 30, 2019) and incorporated by reference thereto.

19 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed December 3, 2019) and incorporated by reference thereto.

20 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed December 31, 2019) 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.

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

†† Certain confidential portions of this exhibit were omitted because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

Management contract or compensatory plan or arrangement.

EYEGATE PHARMACEUTICALS, INC.
DESCRIPTION OF SECURITIES REGISTERED UNDER
SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of registered securities of EyeGate Pharmaceuticals, Inc. ("us," "our," "we" or the "Company") is intended as a summary only and therefore is not a complete description. This description is based upon, and is qualified by reference to, our restated certificate of incorporation, as amended, our amended and restated bylaws and applicable provisions of the Delaware General Corporation Law (the "DGCL"). You should read our restated certificate of incorporation, as amended, and amended and restated bylaws, which are incorporated by reference as Exhibits 3.1, 3.3, 3.4, 3.5, 3.6 and Exhibit 3.7 to the Annual Report on Form 10-K of which this Exhibit 4.1 is a part, for the provisions that are important to you.

General

Our authorized capital stock consists of 120,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of preferred stock, par value $0.01 per share, of which 3,750 are designated as Series A Convertible Preferred Stock, 10,000 are designated as Series B Convertible Preferred Stock and 10,000 are designated as Series C Convertible Preferred Stock.

Common Stock

Voting Rights. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. Except as otherwise provided by law or our restated certificate of incorporation or amended and restated bylaws, all matters other than the election of directors submitted to the stockholders at any meeting shall be decided by the affirmative vote of a majority of the outstanding shares of common stock present in person or represented by proxy at the meeting and entitled to vote thereon. Directors are elected by a plurality of the votes cast at the meeting. Our restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. At present, we have no plans to issue dividends. See the section titled "Dividend Policy".

Liquidation. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Other Rights and Preferences. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable. All of our outstanding shares of common stock are fully paid and nonassessable.

Provisions in our restated certificate of incorporation provide that our board of directors is authorized to issue preferred stock in one or more series, to establish the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of such shares and any qualifications, limitations or restrictions thereof. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of our company without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. The issuance of preferred stock with voting and conversion rights may adversely affect the voting power of the holders of common stock, including the loss of voting control to others. At present, we have no plans to issue any preferred stock.

Registered Warrants

In August 2015, we issued warrants to investors in our follow-on public offering of a class of warrants that are registered pursuant to Section 12(b) of the Securities Exchange Act of 1934, as amended. The principal terms of such warrants are described below.

Exercisability. The warrants are exercisable immediately upon issuance and at any time up to the date that is five years from the date of issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. In the event that a registration statement covering shares of common stock underlying the warrants, or an exemption from registration, is not available for the resale of such shares of common stock underlying the warrants, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. In no event shall we be required to make any cash payments or net cash settlement to the registered holder in lieu of issuance of common stock underlying the warrants.

Exercise Price. The initial exercise price per share of common stock purchasable upon exercise of the warrants is $159.30. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Certain Adjustments. The exercise price and the number of shares of common stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of our common stock.

Transferability. Subject to applicable laws, the warrants may be transferred at the option of the holders upon surrender of the warrants to us together with the appropriate instruments of transfer.

Fundamental Transaction. If, at any time while the warrants are outstanding, (1) we consolidate or merge with or into another corporation and we are not the surviving corporation, (2) we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets, (3) any purchase offer, tender offer or exchange offer (whether by us or another individual or entity) is completed pursuant to which holders of our shares of common stock are permitted to sell, tender or exchange their shares of common stock for other securities, cash or property and has been accepted by the holders of 50% or more of our outstanding shares of common stock, (4) we effect any reclassification or recapitalization of our shares of common stock or any compulsory share exchange pursuant to which our shares of common stock are converted into or exchanged for other securities, cash or property, or (5) we consummate a stock or share purchase agreement or other business combination with another person or entity whereby such other person or entity acquires more than 50% of our outstanding shares of common stock, each, a 'Fundamental Transaction,' then upon any subsequent exercise of the warrants, the holders thereof will have the right to receive the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of warrant shares then issuable upon exercise of the warrant, and any additional consideration payable as part of the Fundamental Transaction.

Rights as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock. The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings. Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board or chief executive officer (or president, if there is no chief executive officer), or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent. Our restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board. Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors. Our restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds (2/3) of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting. Our restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute. We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Amendment of Charter Provisions. The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least 66 2/3% of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer and Warrant Agent and Registrar

The transfer and warrant agent and registrar for our common stock and registered warrants is VStock Transfer, LLC.

Listing

Our shares of common are quoted on The Nasdaq Capital Market under the symbol “EYEG.”

Exhibit 10.20

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL TO THE REGISTRANT AND (II) WOULD BE COMPETITIVELY HARMFUL TO THE REGISTRANT IF PUBLICLY DISCLOSED. REDACTED PORTIONS OF THIS EXHIBIT ARE MARKED BY [***].

EXCLUSIVE SUB-LICENSE AGREEMENT

dated September 12, 2013

between

JADE THERAPEUTICS, INC.

and

BIOTIME, INC.

CONFIDENTIAL DOCUMENT

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CONFIDENTIAL DOCUMENT

EXCLUSIVE SUB-LICENSE AGREEMENT

THIS EXCLUSIVE SUB-LICENSE Agreement ("Agreement") is entered into this 12th day of September, 2013 by and between BIOTIME, INC., a California corporation having a place of business at 1301 Harbor Bay Parkway, Alameda, CA 94502, hereinafter referred to as "Licensor," and JADE THERAPEUTICS, INC., having its principal place of business at 675 Arapeen Drive, Suite 302, Salt Lake City, UT 84108-1228, hereinafter referred to as "Licensee."

WITNESSETH

WHEREAS, Licensor has certain exclusive rights under a License Agreement from the UNIVERSITY OF UTAH RESEARCH FOUNDATION, a Utah non-profit corporation, having its principal place of business at 615 Arapeen Drive, Suite 310, Salt Lake City, UT 84108 ("UURF"), and relating to hydrogels suitable for human use and more particularly relating to Licensor's HyStem® hydrogels (the "UURF License"); and

WHEREAS, Licensor and Licensee have previously entered into an exclusive sublicense agreement dated June 25, 2012 and the parties wish to supersede and replace the previous agreement with this Exclusive Sublicense Agreement; and

WHEREAS, Licensor desires that the Licensee should be enabled to pursue human use of the Technology (as defined herein) within a specified field as more particularly described herein; and

WHEREAS, Licensee wishes to obtain from Licensor a worldwide, exclusive license in the Field of Use to make, have made, manufacture, import, use and sell Licensed Products and/or use Licensed Methods for (i) pre-clinical and clinical studies; and (ii) commercial sale and use upon regulatory approval; and Licensor is willing to grant such a license upon the terms and conditions hereinafter set forth; and

WHEREAS, Licensor's rights to the Technology were developed in the course of research sponsored in part by the U.S. Government, and as a consequence are subject to overriding obligations of UURF to the U.S. Government as more particularly provided in the UURF License, the relevant parts of which are stated in full this Agreement;

NOW THEREFORE, for and in consideration of the covenants, conditions and undertakings hereinafter set forth, the parties hereby agree as follows:

ARTICLE 1 DEFINITIONS

1.1 **"Affiliate"** means any company or other business entity that, directly or indirectly, controls, or is controlled by, or is under common control by Licensee. Solely for purposes of this definition, the term **"control"** means the possession of the power to direct or cause the direction of the management and policies of the entity, whether through ownership of voting securities or by contract. Control will be presumed if an entity owns either of record or beneficially, at least fifty percent (50%) of the voting stock of the other entity. An entity will be deemed an Affiliate during the period such ownership or control relationship is in effect.

1.2 **"Collaboration Agreement"** means an agreement which is: (a) negotiated and entered into between Licensee or an Affiliate of Licensee and a Development Partner; (b) to develop, sell, use or commercialize a Licensed Product and/or a Licensed Method in collaboration with Licensee; and (c) which requires Licensor to grant to the Development Partner a sublicense to Patent Rights and/or Technology.

1.3 **"Covered By"** means a claim or claims within any pending or issued patent included in the Patent Rights claiming all, a portion, or a component or step of a Licensed Product or Licensed Method.

1.4 **"Development Partner"** means any third party non-affiliate of Licensee with whom Licensee, or an Affiliate of Licensee, decides to negotiate and enter into a Collaboration Agreement.

1.5 **"Effective Date"** means September 12, 2013.

1.6 **"Entity"** means a corporation, an association, a joint venture, a partnership, a trust, a business, an institution, an individual, a government or political subdivision thereof, including an agency, or any other organization that can exercise independent legal standing.

1.7 **"Equity Financing Transaction"** means any event subsequent to the Effective Date of this agreement, whereby the Licensee receives value of any kind in exchange for an ownership or equity position in Licensee. Excluded from Equity Financing Transactions are: (a) any funds provided to Jade by Original Licensee Investors; and/or (b) the value of any services performed by a third party for Licensee in consideration for an ownership or equity position in Licensee; for example, consulting services.

1.8 **"Fair Market Value"** means the cash consideration which Licensee would actually receive from an unaffiliated, unrelated buyer in an arm's length sale of an identical item sold in the same quantity, under the same terms, and at the same time and place.

1.9 **"First Commercial Sale"** means, with respect to a given Licensed Product or Licensed Method, the first sale for use or consumption by the public of such Licensed Product or Licensed Method in a country after all required approvals, including marketing and pricing approvals, have been granted by the applicable governmental drug regulatory agency.

1.10 **"Field of Use"** means use of the Technology for pre-clinical and clinical, and/or commercial purposes in humans to deliver a Licensed Product or Licensed Method, alone or in conjunction with any Therapeutic Molecule(s), to, on, or in the eyeball, eye lid, or conjunctiva. Specifically excluded from Field of Use is the use of the Licensed Product or Licensed Method (i) to deliver cells, (ii) and/or in conjunction with any molecule(s) necessary for the successful therapeutic benefit of said cells, provided that use of such molecule(s) separately and not in conjunction with cells shall be included in the "Field of Use" , (iii) to create and/or insert a punctal plug in the eye, (iv) for diagnostic and research reagents, and (v) for any applications or uses in animal health or veterinary medicine.

1.11 "**HyStem®**" means the "HyStem®" hydrogel developed by Licensor and its derivatives. For clarity, the parties agree that "HyStem®" and its derivatives are each a Licensed Product hereunder.

1.12 "**Insolvent**" means being unable to meet one's debt obligations to another Entity as such debt obligations become due and not being able to provide reasonable financial assurances of becoming able to meet such obligations, consistent with the applicable Chapter of Title 11 of the United States Code.

1.13 "**License Issue Fee**" means the fee paid by Licensee to Licensor as set forth in Section 4.1 of this Agreement.

1.14 "**Licensed Product**" means any product, apparatus, kit or component part thereof, or any other subject matter, the manufacture, design, creation, use, importation, distribution, or sale of which is Covered By any claim or claims included within the Patent Rights.

1.15 "**Licensed Method**" means any method, procedure, process or other subject matter, the practice, manufacture, use, or sale of which is Covered By any claim or claims included within the Patent Rights.

1.16 "**Licensee Original Investors**" means and includes Mark Halan, Arthur Klausner, MaryJane Rafii, and Barbara Wirostko.

I.17 "**Net Sales**" means the gross invoiced sales price for commercial sale of Licensed Products and/or commercial use of Licensed Method arising after regulatory approval by Licensee or any of its Affiliates; however, sales or other transfers of Licensed Products and/or practice of Licensed Methods between Licensee and its Affiliates shall be excluded from the computation of Net Sales, and no payments will be payable to Licensor on such sales or transfers except where such Affiliates are end users; less the following deductions, directly attributable to the sale of such Licensed Product and/or Licensed Method and specifically identified on the invoice, and borne by the seller to the extent they are included in such gross revenue or other consideration:

a. [***]:

b. [***];

c. [***]; and

d. [***].

A Licensed Product and/or Licensed Method shall be considered sold when it is shipped, delivered, or invoiced for purposes of commercial sale or commercial use, whichever is earlier. No deductions shall be made from Net Sales for commission paid to individuals whether they are with independent sales agencies or are regularly employed by Licensee or its Affiliates and are on its or their payroll, or for the cost of collections. In the event

Licensee transfers a Licensed Product to and/or transfers or performs a Licensed Method for a third party in a bona fide arm's length transaction, for consideration, in whole or in part, other than cash, then the Net Sales price for such Licensed Product and/or Licensed Method shall be deemed to be the standard invoice price then being invoiced by Licensee in an arm's length transaction with similar companies and in the absence of such standard invoice price, then the reasonable Fair Market Value of the Licensed Product and/or Licensed Method. Components of Net Sales shall be determined in the ordinary course of business using the accrual method of accounting in accordance with generally accepted accounting practices.

If Licensee or any Affiliate sells, leases or otherwise commercializes any Licensed Product and/or Licensed Method at a reduced fee or price for the purpose of promoting other products, goods or services or for the purpose of facilitating the sale, license or lease of other products, goods or services, then Licensee shall pay to Licensor and each such Affiliate shall be obligated to pay to Licensor, a Royalty under Article 4 based upon the Fair Market Value of the License Product and/or Licensed Method.

1.18 **"Patent Right(s)"** means and include all of the following Licensor intellectual property: The patents and/or patent applications listed in Exhibit "A"; patents issued from the applications listed in Exhibit "A" and from divisionals and continuations (other than continuations in part) of these applications and/or patents and any reissues or re-exams of such patents; claims of continuation-in-part applications and patents directed to subject matter specifically described in the patent(s) and/or patent application(s) listed in Exhibit "A"; and claims of all foreign applications and patents which are directed to subject matter specifically described in the United States patents and/or patent applications listed in Exhibit "A"; and any other Licensor intellectual property during the Term that the parties mutually agree will facilitate the development and commercialization of Licensed Method or Licensed Product.

1.19 **"Technology"** means any technology in the control of Licensor that relates to Licensed Products or Licensed Methods, including and relating to Licensor's *HyStem*® hydrogels.

1.20 **"Territory"** means worldwide.

1.21 **"Therapeutic Molecule(s)"** means a molecule(s) being tested or administered because the mechanism of action thereof is believed to be substantially responsible for the desired therapeutic benefit, where said therapeutic molecule(s) is not a cell.

1.22 **"University"** means University of Utah Research Foundation.

1.23 **"Valid Claim"** means a patent claim included in the Patent Rights that has not lapsed or become abandoned or been declared invalid or unenforceable by a court or agency of competent jurisdiction from which no appeal can be or has been taken.

ARTICLE 2 LICENSE GRANT AND LICENSEE'S RESTRICTIVE COVENANT

2.1 Exclusive Grant. Subject to the terms and conditions and Licensee's Restrictive

Covenant set forth in Section 2.6 of this Agreement, Licensor hereby grants to Licensee a worldwide, royalty-bearing, exclusive (even as to Licensor) license in the Territory to make, have made, manufacture, import, use and sell the Licensed Product and to practice the Licensed Method in the Field of Use under Licensor's UURF License (the "License") and the Patent Rights. This grant is subject to the terms and conditions of this Agreement, and to any rights of the Government of the United States as set forth in the UURF License by UURF and the University to:

a. publish the general scientific findings from research conducted in whole or in part at the University related to the Patent Rights;

b. manufacture, have manufactured, use, and/or practice, or transfer the Patent Rights for research, teaching and other educationally-related non-commercial purposes.

2.2 Affiliates. Licensee may extend the license granted herein to any Affiliate if the Affiliate consents in writing to be bound by this Agreement to the same extent as Licensee.

2.3 Development Partners. Should Licensee determine that a Development Partner is necessary to develop, market, and/or sell Licensed Product or Licensed Method, Licensee shall submit to Licensor written justification for such Development Partner. Should Licensor approve of such Development Partner, such approval to not be unreasonably withheld, Licensor will grant a sub-license for the Patent Rights to said Development Partner (Development Partner Sublicense): (i) the terms of which shall be materially consistent with the UURF License; and (ii) the scope of sublicense granted shall be consistent with the Collaboration Agreement between Licensee and the Development Partner ("Development Partner Sublicense") including field of use. Such Development Partner Sublicense shall provide for a royalty payment of [***]% (or such lower amount as Licensor may in its sole and absolute discretion approve) on the Net Sales of Licensed Products or Licensed Methods by the Development Partner, payable directly to Licensor ("Development Partner Sublicense Royalty"); and no other or additional financial payments or consideration from the Development Partner to Licensor will be due under the Development Partner Sublicense. For clarity, all consideration related to the Collaboration Agreement other than the Development Partner Licensor Royalty shall be paid by the Development Partner solely to Licensee or a Licensee Affiliate. Notwithstanding the foregoing, each Development Partner must be approved by Licensor in writing, such approval not to be unreasonably withheld. Each Development Partner Sublicense must be approved in writing by Licensee prior to execution by Licensor, such approval not to be unreasonably withheld.

2.4 Collaboration Agreement Payments Other Than Royalty.

a. If Licensee receives consideration of any kind for a Collaboration Agreement other than a royalty on Net Sales to be paid by the Development Partner, Licensee shall pay to Licensor a percentage, as given below, of any fee or payment received by Licensee regardless of how the Licensee and the Development Partner characterizes such payments, including but not limited to license fees, minimum annual royalties, milestone payments, etc. ("Collaboration Agreement Payments"). Licensee shall not receive from a Development Partner anything of value in lieu of cash payments in consideration for any Collaboration Agreement, without the express prior written consent of Licensor.

b. Licensor's percentage of Collaboration Agreement Payments, other than or in addition to (x) a royalty on the Net Sales of Licensed Products or Licensed Methods or (y) paid in consideration for the purchase of the stock of Licensee, shall be:

(i) [***]% if prior to FDA Clearance to proceed with clinical trials of the most advanced product covered in the Development Partner Sublicense. "Clearance" or "Cleared" shall mean that Licensee has submitted an Investigational New Drug Application ("IND") for the most advanced Licensed Product covered in the Development Partner Sublicense; and the FDA has not placed a clinical hold on such IND on or before [***] following the date of submission.

(ii) [***] if an Investigational New Drug Application has been Cleared by the FDA but Phase II or equivalent clinical investigation has not begun of the most advanced product covered in the Development Partner Sublicense.

(iii) [***]% if the first dose in a Phase II or equivalent clinical investigation has taken place for the most advanced product covered in the Development Partner Sublicense.

(iv) [***]% if a New Drug Application or equivalent has been approved for the most advanced product covered in the Development Partner Sublicense.

c. Payments due Licensor from Licensee as a result of any Collaboration Agreement entered into between a Development Partner and Licensee (or its Affiliate) shall be paid by Licensee (or its Affiliate) within [***] of Licensee's (or its Affiliate's) receipt of the Collaboration Agreement Payment. Payments to Licensor for its share Collaboration Agreement Payments received by Licensee shall be fully creditable against any minimum annual royalties or royalties otherwise due to Licensor by Licensee in the calendar year in which the Collaboration Agreement is executed or, in the case of milestone or other payments received by Licensee subsequent to the year in which the Collaboration Agreement is executed, in the calendar year the payment is received.

2.5 Development Partner Royalties. For clarity, Licensor agrees that the only royalty payments that it shall be entitled to receive as the result of a Collaboration Agreement

shall be the royalty referenced in Section 2.3. No other royalty payments, or percentage of royalty payments, shall be due or owing from Licensee or a Licensee Affiliate, including the Royalty set forth in Section 4.2, as a result of a Collaboration Agreement entered into between the Development Partner and the Licensee. Notwithstanding the foregoing the Licensor and Licensee acknowledge that paragraph 2.5 does not negate any payments due Licensor from Licensee specified in paragraph 2.4 a-c or Sections 4.1 or 4.3.

2.6 Restrictive Covenant - License to Prospective Licensee for Proposed Product.From and after the first anniversary of the Effective Date, Licensor shall provide written notice to Licensee of any request Licensor receives for an exclusive or non-exclusive license relating to any method or process, composition, product or component part thereof for which rights granted to Licensee by Licensor in the License are necessary for manufacture, sale, use, distribution, or as applicable the reproduction, preparation of derivatives of, or other practice of a proposed product or service (a "Proposed Product") from any third party that desires to make, use, and sell such Proposed Product (a "Prospective Licensee") within [***] of receiving such request. In the event neither Licensee, any Affiliate, or Development Partner is then developing or commercializing or has plans to develop or commercialize a Licensed Product or Licensed Method for use or sale in the same general industry as proposed by the Prospective Licensee for the Proposed Product, as identified in a report provided to Licensor pursuant to Section 10.1 of this Agreement, then within [***] of receipt of the notice by Licensee from Licensor that Licensor desires to negotiate with the Prospective Licensee for the purpose of granting a sublicense under the License to develop and commercialize the Proposed Product within the relevant portion of the Field of Use, Licensee shall elect one of the following options:

Provide Licensor with documentation demonstrating to Licensor's reasonable satisfaction that Licensee, an Affiliate, or Development Partner has initiated commercially reasonable efforts to develop, make, use, sell, distribute, and as applicable reproduce, prepare derivatives of, publicly perform, or publicly display a Licensed Product for use or sale that would commercially compete with the Proposed Product in the same general industry. For purposes of this Section 2.6, commercially reasonable efforts shall include but are not limited to (i) [***], (ii) [***], (iii) [***], (iv) [***], and (v) [***].

(ii) Grant back to Licensor limited rights in the License for the sole purpose of allowing Licensor to grant the License to the extent necessary for such Prospective Licensee to develop, make, use, sell, distribute, and as applicable reproduce, prepare derivatives of, publicly perform, or publicly display such Proposed Product in the relevant portion of the Field of Use.

(iii) Provide Licensor with written notice demonstrating to Licensor's reasonable satisfaction that the development or commercialization of such Proposed Product would have a reasonable likelihood of materially and adversely affecting the development or commercialization of any Licensed Product or Licensed Service then being developed or commercialized by Licensee, an Affiliate, or Development Partner.

ARTICLE 3 TERM OF AGREEMENT

This Agreement shall be in full force and effect from the Effective Date until the end of the term of the last-to-expire of Licensor's Patent Rights licensed under this Agreement, unless otherwise terminated by operation of law or by acts of the parties pursuant to the terms of this Agreement ("Term").

ARTICLE 4 FEES & ROYALTIES

4.1 License Issue Fee. Licensee shall pay to Licensor a non-refundable "License Issue Fee" of fifty thousand dollars ($50,000). Once the Licensee has raised five hundred thousand dollars ($500,000) from sources other than the Licensee Original Investors, Licensee shall begin paying the License Issue Fee incrementally by paying to Licensor [***] percent ([***]%) of any subsequent proceeds received by Licensee from investors other than investment made by Licensee Original Investors, in Equity Financing Transactions that are consummated following the Effective Date, until an aggregate of fifty thousand dollars ($50,000) has been paid to Licensor. Licensee will notify Licensor in writing within [***] of the consummation of any Equity Financing Transaction. The applicable increment of the License Fee shall be paid to Licensor within [***] of the closing of each such Equity Financing Transaction.

4.2 Royalty. Licensee shall pay to Licensor, on a country by country basis, an earned running royalty on Net Sales in the amount of[***] percent ([***]%) ("Royalty"). No Royalty shall be due for (a) any use or sale of Licensed Product or Licensed Method required in or for the purpose of any pre-clinical or clinical trial conducted in advance of a government regulatory body approval to market a Licensed Product or Licensed Method, or (b) any Licensed Product or Licensed Method provided without consideration for use in a post marketing clinical study, or other research or development purpose conducted by Licensee, an Affiliate of Licensee, or a Development Partner.

4.3 Annual Minimum Royalty. Licensee will pay an annual minimum royalty of thirty thousand dollars ($30,000) ("Annual Minimum Royalty") starting with a first payment due on January 1, 2017 and annually each January 1st of each calendar year during the

Term. Licensor shall filly credit each payment of Annual Minimum Royalty against any earned Royalty payable by Licensee with respect to the calendar year in which the minimum annual royalty is due. Only one Annual Minimum Royalty payment shall be due and owing regardless of the number of Licensed Products or Licensed Methods.

4.4 Royalty Period. The Royalty shall be payable for each Licensed Product or Licensed Method on a product by product and country-by-country basis from the time of the First Commercial Sale of Licensed Product or Licensed Method in such country until the expiration of the last to expire patent containing a Valid Claim with respect to such Licensed Product or Licensed Method.

4.5 Royalty Conditions. The Royalty shall be subject to the following conditions:

a. only one Royalty shall be due with respect to: (i) same unit of Licensed Product; (ii) same use of Licensed Method; or (iii) the use of the Licensed Method for the purpose of making, manufacturing, having manufactured, using and selling Licensed Product.

b. for clarity, no Royalty shall be due upon the sale or other transfer amount between Licensee and its Affiliates, but in such cases the Royalty shall be due and calculated upon Licensee's or its Affiliate's Net Sales to the first Non-Affiliate third party;

c. no Royalty shall accrue on the disposition of any Licensed Product or Licensed Method in reasonable quantities by Licensee or its Affiliates as part of an expanded access program or as bona fide samples or as donations to non-profit institutions or government agencies for non-commercial purposes; and

d. notwithstanding the above Royalty rates, upon Licensee's request, the parties agree to discuss in good faith a reduction of such Royalty rate in any given country in the event the available patent protection materially decreases the commercial viability of the Licensed Product or Licensed Method under such Royalty rate.

4.6 Reduction Because of Third Party Payments. In the event Licensee makes a payment to one or more third parties for patent rights or know-how which Licensor reasonably agrees (i) is necessary or proper to develop or commercialize a Licensed Product or Licensed Method; and (ii) arises as a result of the use of the Technology, the Royalty due hereunder shall be reduced by the amount of the payment made to said third parties, provided however, the Royalty from Licensee to Licensor shall not be reduced to less than [***] percent ([***]%) of the Royalty due in any period but for such payments to third parties, however, said reduction shall not apply to Royalties due from a Development Partner in Section 2.3.

4.7 Patent Expenses. Licensee will be required to pay no part of Licensor's or the University of Utah's patent costs.

ARTICLE 5 COMMERCIAL DILIGENCE & MILESTONES

5.1 Licensee agrees to use good faith reasonable commercial efforts to accomplish the following milestones by the dates shown:

a. Raise [***] dollars ($[***]) in operating capital from Equity Financing Transactions within two years of the Effective Date, excluding any and all monies provided to or on behalf of Licensee by the Original Investors;

b. Submit first Investigational New Drug Application in a major market by December 31, 2015.

c. Complete first dosing in man of a Phase II or equivalent clinical trial by December 31, 2016.

d. Have First Commercial Sale in a country of a Licensed Product or Licensed Method by January 1, 2023.

ARTICLE 6 TECHNOLOGY TRANSFER AND ASSISTANCE

6.1 Information and Know-How. Licensor agrees to use good faith and reasonable efforts to answer technical questions, from time to time, that Licensee might have regarding the Technology. The Licensor will not, however, be required to divulge any information or know how that the Licensee considers a trade secret or otherwise proprietary. Any Licensor information disclosed under this paragraph shall be considered the Confidential Information of Licensor and subject to the limitations and exceptions of Article 9 of this Agreement.

6.2 Regulatory Assistance. Licensor shall, upon the request of Licensee, provide a letter of authorization allowing regulatory bodies and governmental agencies access, and a right of reference, to any and all of Licensor's Device Manufacturing Master Files for the Technology in the Territory ("Licensor Regulatory Filings") for use with regard to, and on behalf of, Licensee's regulator), filings relating to Licensed Product and Licensed Method. In addition, Licensor shall reasonably assist, to the extent that it is able to without undue burden, in answering any questions regarding Licensor Regulatory Filings by providing information concerning Licensor's Regulatory Filings, provided, that such information is in Licensor's possession and can be disclosed without violating any confidentiality agreement with any third party; provided, further that Licensor shall not be obligated to obtain, derive, or generate any new or additional data or information.

6.3 Safety Information. Each Party agrees to notify the other Party of any reports of serious adverse events concerning the Licensed Product or Licensed Method sold, within the Territory or regarding the Technology within [***] of the date that such Party becomes aware of the complaint. Each such report shall be directed to the party pursuant to the notice provisions of Article 22.

ARTICLE 7 MANUFACTURE AND SUPPLY OF TECHNOLOGY

7.1 For the purpose of clarity, Licensor hereby grants to Licensee a non-royalty bearing,exclusive license in the Territory to use the Technology to make, have made and manufacture Licensed Products and/or Licensed Methods in the Field of Use tinder Licensor's UURF License and Patent Rights.

7.2 Licensee hereby grants to Licensor a right of first negotiation with respect to the manufacturing of Licensed Products (ROFN) during the Term. If during the Term, Licensee desires to pursue clinical and/or commercial manufacturing of a Licensed Product, then Licensee shall notify Licensor. Licensor shall, within [***] after receipt of such notice, indicate to Licensee in writing whether or not it wishes to enter into a manufacturing agreement with Licensee for the Licensed Product, it being understood and agreed that entering into negotiations for a manufacturing agreement does not require either Party to propose or accept any offer. If either (a) Licensor indicates it does not wish to manufacture Licensed Products, (b) Licensor fails to indicate its interest within [***], or (c) Licensor indicates it wishes to manufacture Licensed Products but the Parties fail to reach agreement on the terms of said manufacturing of a Licensed Product within [***] after the date of Licensor's indication of interest, then the ROFN right shall expire and Licensee shall be free, without any further obligation to Licensor, to enter into negotiations with a Third Party, and the provisions in Section 7.3 shall be in effect.

7.3 Upon request from Licensee, Licensor shall authorize its subcontract manufacturers of[***] to supply those components directly to Licensee using Licensor's production methods. Licensee will be responsible for entering into supply agreements with Licensor's subcontractors, and for paying all cost of such production and supply. Such agreements may provide for, among other things, the right for Licensee to reasonably audit and inspect the facilities in which the [***] components are manufactured and packaged at no expense to Licensor. Licensee acknowledges, however, that Licensor's [***], [***], and [***], including [***] and [***] from [***], may only be inspected and reviewed at the subcontractor's facility. No copies or photographs of these documents may be made or the documents otherwise removed from the manufacturer's facilities.

ARTICLE 8 INVENTIONS

8.1 Ownership of any art, method, process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, whether patented or unpatented under the Patent Laws of the United States of the America or any foreign country which relates to the Technology and is conceived and/or reduced to practice by Licensee or Licensee's employees, alone or jointly with Licensor and/or Licensor's employees during the term of this Agreement (the "Inventions") shall be determined in accordance with the Patent Laws of the United States of America, Title 35 of the United States Code.

Licensor shall own all right, title and interest in all developments, inventions and know-

how (whether or not protectable under state, federal, or foreign intellectual property laws) to the Technology conceived and/or reduced to practice by solely by Licensor or by Licensor's employees during the term of this Agreement ("Licensor's Inventions"). Licensee shall own all right, title and interest in all developments, inventions and know-how (whether or not protectable under state, federal, or foreign intellectual property laws) to the Technology conceived and/or reduced to practice solely by Licensee or by Licensees' employees during the term of this Agreement ("Licensee's Inventions"). Licensee and Licensor shall jointly own all right, title and interest in all developments, inventions and know-how (whether or not protectable under state, federal, or foreign intellectual property laws) to the Technology conceived and/or reduced to practice jointly by Licensee (or Licensee's employees) and Licensor (or Licensor's employees) during the term of this agreement ("Joint Inventions").

8.2 Licensee hereby grants to Licensor, a worldwide, non-exclusive license in all of Licensee's right, title and interest in and to all Licensee's Inventions for use other than and outside of the Field of Use.

8.3 Licensor hereby grants to Licensee, for no additional consideration, a worldwide, non-exclusive license in the Field to any and all rights and ownership interest Licensor may have in Joint Inventions ("Licensor Joint Invention Rights"). The Parties hereby agree that Licensor Joint Invention Rights are, upon conception and/or reduction to practice, deemed included in Patent Rights and included in the License granted to Licensee in Article 2 of this Agreement. The Parties hereby agree that Licensee's obligation to pay to Licensor a Royalty, if any, based on Licensor Joint Invention Rights shall terminate upon expiration of the last to expire patent or patent application listed in Exhibit "A", regardless of any new patents or patent applications that may be included in Patent Rights as the result of Joint Inventions. Licensor shall retain exclusive rights to all Joint Inventions outside of the Field of Use.

8.4 Licensee shall have the sole right to prepare, file and prosecute patent applications on, and otherwise protect, all Licensee's Inventions. Licensor shall have the sole right to prepare, file and prosecute patent applications on, and otherwise protect, all Licensor's Inventions. The Parties jointly will share the right to prepare, file and prosecute patent applications on, and otherwise protect, all Joint Inventions. If one party declines to participate in the filing and prosecution of patent applications relating to Joint Inventions, the other party will have the sole right to file and prosecute said patent application and will retain all ownership rights in the patent application and any patent issuing from said patent application.

8.5 The Parties shall execute any such documents and perform such acts as may reasonably be necessary for the Parties to prepare, file and prosecute such patent applications and otherwise to protect the Joint Inventions. In the event that one Party (the First Party) is unable or unwilling for any reason to supply its signature to any document the other Party (the Second Party) is required to execute for the Assignment or filing or prosecution of patent applications relating to Joint Inventions, the First Party hereby irrevocably designates and appoints the Second Party and its duly authorized officers and agents as the First Party's agents and attorneys-in-fact to act for and on the First Party's behalf and
instead of the First Party, to execute such document with the same legal force and effect as if executed by the First Party.

ARTICLE 9 CONFIDENTIALITY

9.1 Licensee and Licensor acknowledge that either party may provide certain information to the other with regard to the Technology and/or Licensed Products/Licensed Methods that is considered to be and is identified as confidential. Licensee and Licensor shall take all reasonable precautions to protect such confidential information. Such precautions shall involve at least the same degree of care and precaution that the receiving party customarily uses to protect its own confidential information, but in no circumstance less than reasonable care. Information shall not be deemed confidential if it:

a. was already known to the receiving party, other than under an obligation of confidentiality to the disclosing party;

b. was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party;

c. becomes generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving party in breach of this Agreement;

d. was subsequently lawfully disclosed to the receiving party by a third party;

e. can be shown by written records to have been independently developed by the receiving party without reference to the confidential information received from the disclosing party and without breach of any of the provisions of this Agreement; or

f. may be disclosed by the receiving party pursuant to a specific written agreement of the disclosing party.

9.2 A receiving party may disclose a disclosing party's confidential information to the extent it is required by applicable law or court order to be disclosed; provided, however, that the receiving party provides the disclosing party with prior written notice of such disclosure in order to permit the disclosing party to seek confidential treatment of such confidential information.

9.3 Each patty agrees that the breach of this Article 9 may cause the disclosing party irreparable harm and that monetary damages may be an inadequate remedy for such harm. Therefore, in the event of any such breach, the disclosing party shall be entitled to equitable relief (including injunctions and specific performance remedies) in addition to other remedies that may be available to the disclosing party.

9.4 a. Each party agrees that the financial terms of this Agreement shall be kept confidential, except that a party may disclose financial terms of this Agreement: (i) in connection with any lawsuit or other proceeding relating to the enforcement of the rights of either party under this Agreement; (ii) to the extent the party determines, in good faith, that such disclosure is required by law; provided, that before filing a copy of this Agreement as an exhibit to any registration statement or report under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, or under any state securities law, the party will file an application for confidential treatment of those financial terms that the party has determined are not required to be disclosed by law; (iii) to the party's accountants and attorneys, (iv) to the party's consultants and advisors other than accountants and attorneys pursuant to a written agreement of confidentiality, and (v) to potential underwriters and investors pursuant to a written agreement of confidentiality. Licensee acknowledges that this sublicense agreement must be reviewed and approved by the University of Utah's Technology Commercialization Office pursuant to a written agreement of confidentiality between the Licensee and the University of Utah Technology Commercialization Office prior to execution by the Parties.

b. Either party may issue a press release in connection with the execution of this Agreement, provided that the other party is provided an opportunity to review and comment upon the content of the press release at least two business days prior to publication. The press release shall not disclose financial terms of this Agreement unless both parties consent to the disclosure.

ARTICLE 10 QUARTERLY & ANNUAL REPORTS

10.1 Progress Report and Commercialization Plan. Commencing on December 1, 2013, and on each June 1st and December 1st thereafter, until the First Commercial Sale in the first country, and annually thereafter on each December 1st, Licensee shall submit to Licensor a written report covering Licensee's progress in (a) development and testing of all Licensed Products and Licensed Methods; (b) achieving the commercial diligence milestones specified in Article 5; (c) preparing and filing applications, and obtaining any approvals necessary for marketing the Licensed Products and Licensed Methods, and (d) plans for the upcoming year in commercializing the Licensed Product(s). Each report shall be in substantially similar form and contain at least the information required by Exhibit "B" attached hereto and incorporated herein.

10.2 Quarterly Royalty Report. Within [***] after the calendar year in which the First Commercial Sale in the first country occurs, and within[***] after each calendar quarter thereafter, Licensee shall provide Licensor with a written report detailing all sales and commercial uses, if any, made of Licensed Products and Licensed Methods during such calendar quarter, and detailing the amount of Net Sales made during such quarter and calculating the royalties due pursuant to Article 4 hereof. Each report shall include at least the following:

a. number of Licensed Products manufactured, leased and sold by and/or for Licensee and its Affiliates;

b. accounting for all Licensed Methods commercially used or sold by and/or for Licensee, its Affiliates and Development Partners;

c. accounting for Net Sales, noting the deductions applicable as provided in Section 1.17;

d. royalties due under Article 4;

e. total royalties due;

f. the amount spent on product development; and

g. the number of full-time equivalent employees working on the Licensed Products and/or Licensed Methods.

Each report shall be in substantially similar form as Exhibit "C" attached hereto. Each such report shall be signed by an officer of Licensee (or the officer's designee). With each such report submitted, Licensee shall pay to Licensor the Royalties due and payable under this Agreement. If no Royalties shall be due, Licensee shall so report. Licensee's failure to submit a Royalty report in the required form will constitute a breach of this Agreement. Licensee will continue to deliver Royalty reports to Licensor after the termination or expiration of this Agreement until such time as all Licensed Product(s) permitted to be sold after termination have been sold or destroyed.

10.3 Reporting First Foreign Sales. In addition to the regular reports required by Section 10.1 and 10.2, Licensee shall provide a written report to Licensor of the date of first occurrence of Net Sales in each country within [***] of its occurrence.

10.4 Publication of Scientific Findings.

Licensee will provide Licensor with a copy of any manuscript reporting scientific finding involving the Licensed Method or Licensed Product [***] prior to publication.

ARTICLE 11 PAYMENTS, RECORDS AND AUDITS

11.1 Payments. All Royalty payments shall be made in United States of America Dollars. Royalties shall be payable from the country in which they are earned and subject to foreign exchange rates then prevailing in such country. The exchange rate for purposes of this Agreement will be the rate of exchange to United States Dollars from the currency of the country of sale, as listed in the Wall Street Journal on the Royalty payment date or, if not listed in such publication, an equivalent fair market rate. Royalty payments shall be made within [***] following the calendar quarter in which Net Sales occur. Each payment will reference the Agreement. Payments shall be made to such address and using such arrangements as Licensor may reasonably specify from time to time. In the event that any royalty payment or other fee or payment is not received by Licensor when due, Licensee shall pay to Licensor .interest charges at the rate of [***] percent ([***]%) per annum on the total royalties due for the reporting period.

11.2 Records. Licensee shall keep, and cause its Affiliates to keep, complete, true and accurate records and books containing all commercially reasonable particulars that may be needed for the purpose of showing the amounts payable to Licensor hereunder.

Records and books shall be kept at Licensee's principal place of business or the principal place of business of the appropriate division of Licensee to which this Agreement relates.

11.3 Audit Related to Royalty Payments. Such books and the supporting data shall be open to inspection by Licensor or an independent certified public accountant selected by Licensor and reasonably acceptable to Licensee, at all reasonable times for a term of [***] following the end of the calendar year to which they pertain, upon reasonable prior notice to Licensee, for the purpose of verifying Licensee's royalty statement or compliance in other respects with this Agreement. Such access will be available to Licensor upon not less than [***] written notice to Licensee, not more than [***] each [***] of the Term, during normal business hours, and [***] for [***] after the expiration or termination of this Agreement. Should such inspection lead to the discovery of a greater than [***] percent ([***]%) or [***] dollar ($[***]) US, discrepancy in reporting to Licensor's detriment, Licensee agrees to pay the full cost of such inspection, and once during the next [***] Licensor shall have the right to audit Licensee's books and records under this Section 11.3. Whenever Licensee has its books and records audited by an independent certified public accountant, Licensee will, within [***] of the conclusion of such audit, provide Licensor with a written statement, certified by said auditor, setting forth the calculation of royalties, fees, and other payments due to Licensor over the time period audited as determined from the books and records of Licensee. All information obtained by Licensor as the result of this Section 11.3 shall be deemed the confidential information of Licensee and subject to the protections of Article 9 of this Agreement. Any independent certified public accountant retained by Licensor pursuant to this Section 11.3 shall enter in a written confidentiality agreement with Licensee that is acceptable to Licensee.

ARTICLE 12 PATENT MARKING

Licensee shall permanently and legibly mark all Licensed Products used or sold tinder the terms of this Agreement, or their containers, in accordance with all applicable patent-marking and notice provisions under Title 35, United States Code.

ARTICLE 13 TERMINATION BY LICENSOR

13.1 If Licensee should: (a) fail to deliver to Licensor any statement or report required hereunder when due; (b) fail to make any payment at the time that the same should be due; (c) violate or fail to perform any covenant, condition, milestone, or undertaking to be performed by it under this Agreement; (d) cease active commercially reasonable effort to commercialize Licensed Product(s); (e) fail to meet the milestones stated in Sections 5.2 (a), (b), (c) and (d); (f) file a petition for relief under the United States Bankruptcy Code, or have a petition under the United States Bankruptcy Code filed against it, or become Insolvent; or (g) enter into a composition with creditors, or have a receiver appointed for it, then Licensee shall be in default. If Licensee should fail to cure such default within (i) [***] after Licensor delivers a notice of default in making any payment, or (ii) [***] after Licensor delivers a notice of default other than a default in making a payment, the rights, privileges, and license granted hereunder shall automatically terminate.

13.2 If Licensee shall cease to carry on its business with respect to the rights granted in this Agreement, this Agreement shall terminate upon [***] written notice by Licensor.

13.3 No termination of this Agreement by Licensor shall relieve Licensee of its obligation to pay any monetary obligation due or owing at the time of such termination and shall not impair any accrued right of Licensor. Licensee shall pay all attorneys' fees and costs incurred by Licensor in enforcing any obligation of Licensee or accrued right of Licensor. Articles 8, 9, 10, 11.3, 15, 16, 18, 19 and 21 hereof shall survive any termination of this Agreement.

ARTICLE 14 TERMINATION BY LICENSEE

14.1 Licensee may terminate this Agreement at any time and from time to time without cause, by giving written notice thereof to Licensor. Such termination shall be effective [***] after such notice and all Licensee's rights associated therewith shall cease as of that date.

14.2 Licensee may terminate this Agreement immediately upon notice to Licensor in the event that Licensee reasonably believes that safety or regulatory issues require termination of the development or commercialization of Licensed Product or Licensed Method.

14.3 Any termination pursuant to Section 14.1 or 14.2 shall not relieve Licensee of any obligation or liability accrued hereunder prior to such termination, or rescind or give rise to any right to rescind any payments made or other consideration given to Licensor hereunder prior to the time such termination becomes effective. Such termination shall not affect in any manner any rights of Licensor arising under this Agreement prior to the date of such termination.

14.4 No termination of this Agreement by Licensee shall relieve Licensee of its obligation to pay any monetary obligation due or owing at the time of such termination and shall not impair any accrued right of Licensor. Articles 8, 9, 10, 11.3, 15, 16, 18, 19 and 21 hereof shall survive any termination of this Agreement by Licensee.

ARTICLE 15 DISPOSITION OF LICENSED PRODUCTS ON HAND

Upon expiration or termination of this Agreement by either party, Licensee shall provide Licensor with a written inventory of all Licensed Products in process of manufacture, in use or in stock. Licensee may dispose of any such Licensed Products within the [***] period following such expiration or termination, provided, however, that Licensee shall pay Royalties and render reports to Licensor thereon in the manner specified herein.

ARTICLE 16 REPRESENTATIONS AND WARRANTIES

16.1 Licensor represents and warrants that it has the lawful right to grant the license set forth in this Agreement.

16.2 Licensor further represents and warrants as of the Effective Date:

a. Licensor has not granted, and during the term of this Agreement will not grant, any security interest, option, lien, license, or encumbrance of any nature with respect to any Patent Rights which would conflict with the License granted to Licensee tinder this Agreement;

b. As of the Effective Date, all applicable maintenance fees, annuity payments, and similar payments relating to the Patent Rights have been made, and during the term of this Agreement will be made, in a timely manner;

c. As of the Effective Date, Licensor has not received written notice of a pending or threatened proceeding, nor has Licensor received written notice of any claim, which challenges or challenged the validity or enforceability of any Patent Right;

d. As of the Effective Date, Licensor is unaware of any infringement or possible infringement of any Patent Right by any third party and has not asserted any claim against, or sent any notice of infringement to, any third party;

e. Exhibit A includes all pending patent applications and issued patents licensed by Licensor from UURF or developed by Licensor using patents licensed from UURF that relate to the Field of Use; and

This Agreement sets forth in full each and every obligation owed by Licensee as a result of the UURF License; and Licensee has no other duty or obligation to Licensor, UURF or any Third Party as a result of the UURF License except as stated herein.

16.3 Each Party offers no warranty that the grant of any rights or licenses under this Agreement will result in the discovery or successful commercialization of any Licensed Product or Licensed Method in the Field of Use.

16.4 EXCEPT AS EXPRESSLY PROVIDED IN THIS ARTICLE 16, THE PARTIES ACKNOWLEDGE AND AGREE THAT LICENSOR HAS MADE NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

16.5 IN NO EVENT SHALL EITHER PARTY BE HELD RESPONSIBLE FOR ANY SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE USE OF PATENT RIGHTS, EVEN IF IT IS ADVISED IN ADVANCE OF THE POSSIBILITY OF SUCH DAMAGES.

16.6 Nothing in this Agreement shall be construed as:

a. a warranty or representation by Licensor as to the validity or scope of any Patent Rights.

b. a warranty or representation by Licensor that anything made, used, sold or otherwise disposed of pursuant to any license granted under this Agreement is or will be free from infringement of intellectual property rights of third parties.

c. an obligation by Licensor to bring or prosecute actions or suits against third parties for patent infringement.

d. conferring by implication, estoppel or otherwise any license or rights under any patents of Licensor other than Patent Rights.

16.7 Any breach of the representations or warranties made by Licensor in this Article 16 which results in a loss of rights to develop, manufacture, have manufactured, sell, have sold, or use Licensed Products or Licensed Methods in the Field of Use shall entitle Licensee to a refund of all payments made to Licensor as consideration for the rights granted under this Agreement, and said refund shall be deemed liquidated damages and the sole remedy available to Licensee for breach or violation of any provisions contained in this Article 16.

ARTICLE 17 INFRINGEMENT

17.1 If either party learns of a claim of infringement of any of Licensor's Patent Rights licensed under this Agreement, that party shall give written notice of such claim to the other party. In the event Licensor fails to abate the infringing activity within [***] after such written notice or to bring legal action against the third party within such [***] period, Licensee may bring suit for patent infringement. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of Licensor, which consent shall not be unreasonably withheld. Nothing in this Section 17.1 shall obligate either party to commence any lawsuit or other proceeding against any third party.

17.2 Any legal action brought under Section 17.1 shall be at the expense of the party to this Agreement that commenced the legal action or filed the first cross-claim in an action brought by a third party, hereinafter referred to as the "Litigating Party". Any damages or costs recovered by Licensee in connection with a legal action filed by it hereunder, provided that the Litigating Party is reimbursed for its costs and expenses reasonably incurred in the lawsuit, shall be paid to Licensee and deemed Net Sales, and Licensee shall pay a Royalty to Licensor thereon in the manner provided by Article 4 of this Agreement. Any damages or costs recovered by Licensor in the Field of Use in connection with a legal action filed by it hereunder, provided that the Litigating Party is reimbursed for its costs and expenses reasonably incurred in the lawsuit, shall be paid to Licensee and deemed Net Sales, and Licensee shall pay a Royalty to Licensor thereon in the manner provided by Article 4 of this Agreement.

17.3 Licensee and Licensor shall cooperate with each other in litigation proceedings instituted hereunder, provided that such cooperation shall be at the expense of the litigating Party, and such litigation shall be controlled by the litigating Party.

ARTICLE 18 INSURANCE

18.1 Insurance Requirements. Beginning at the time any Licensed Product and/or Licensed Method is to be used in human clinical trials and/or is being distributed or sold (including for the purpose of obtaining any required regulatory approvals) by Licensee or Affiliate, Licensee will, at its sole cost and expense, procure and maintain commercial general liability insurance issued by an insurance carrier with an A.M. Best rating of "A" or better in amounts not less than $[***] per incident and $[***] annual aggregate. Licensee will use reasonable efforts to have Licensor, the University of Utah, UURF, and their respective officers, employees and agents, named as additional insureds. All rights of subrogation will be waived against Licensor and its insurers. Such commercial general liability insurance will provide (i) product liability coverage; (ii) broad form contractual liability coverage for Licensee's indemnification under this Agreement; and (iii) coverage for litigation costs. The specified minimum insurance amounts will not constitute a limitation on Licensee's obligation to indemnify Licensor, the University of Utah, and their respective officers, employees and agents, under this Agreement.

18.2 Evidence of Insurance and Notice of Changes. Licensee will provide Licensor with written evidence of such insurance upon request by Licensor. Licensee will provide Licensor with written notice of at least [***] prior to the cancellation, non-renewal, or material change in such insurance.

18.3 Continuing Insurance Obligations. Licensee will maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any Licensed Product(s) and/or Licensed Method(s) developed pursuant to this Agreement is being commercially distributed or sold by Licensee, Affiliate, or agent of Licensee; and (ii) for five (5) years after such period.

ARTICLE 19 WAIVER

No waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default.

ARTICLE 20 ASSIGNABILITY

This Agreement is not assignable or otherwise transferable (including by operation of law, merger, or other business combination) by Licensee without the prior written consent of the Licensor, not to be unreasonably withheld.

ARTICLE 21 INDEMNIFICATION BY LICENSEE

21.1 Licensee shall indemnify, hold harmless and defend Licensor, UURF, the University of Utah, and their respective officers, employees and agents, against any and all third party claims, suits, losses, damages, costs, liabilities, fees and expenses (including reasonable fees of attorneys) resulting from or arising out of exercise of: (a) any license granted under this Agreement; or (b) any act, error, or omission of Licensee, its agents, employees or Affiliates except where such claims, suits, losses, damages, costs, fees, or expenses result solely from the negligent acts or omissions, or misconduct of the Licensor, UURF, the University of Utah and their respective affiliates, officers,employees or agents. Licensee shall give Licensor timely notice of any claim or suit instituted of which Licensee has knowledge that in any way, directly or indirectly, affects or might affect Licensor and the University of Utah Research Foundation and Licensor shall have the right at its own expense to participate in the defense of the same.

21.2 Licensor shall indemnify, hold harmless and defend Licensee, its Affiliates and their respective officers, employees and agents, against any and all third party claims, suits, losses, damages, costs, liabilities, fees and expenses (including reasonable fees of attorneys) resulting from or arising out of any act, error, or omission of Licensor, its agents, employees or Affiliates, except where such claims, suits, losses, damages, costs, fees, or expenses result solely from the negligent acts or omissions, or misconduct of the Licensee, its Affiliates, officers, employees or agents. Licensor shall give Licensee timely notice of any claim or suit instituted of which Licensor has knowledge that in any way, directly or indirectly, affects or might affect Licensee or its Affiliates and Licensee shall have the right at its own expense to participate in the defense of the same.

ARTICLE 22 NOTICES

The parties will give the other party timely and current information about the person and location/address to which notices and payments are to be given and made hereunder. Any payment, notice or other communication required or permitted to be given to either party hereto shall be in writing and shall be deemed to have been properly given and effective: (a) on the date of delivery if delivered in person during recipient's normal business hours; or (b) on the date of attempted delivery if delivered by courier, express mail service or first-class mail, registered or certified. Such notice shall be sent or delivered to the respective addresses given below or to such other address as either party shall designate by written notice given to the other party as follows:

BioTime, Inc.
1301 Harbor Bay Parkway
Alameda, CA 94502
Attn: Chief Commercial Officer.

Jade Therapeutics, Inc.
675 Arapeen Drive
Suite 302
Salt Lake City, Utah 84108
Attn: Chief Executive Officer

ARTICLE 23 GOVERNING LAW

This Agreement shall be interpreted and construed in accordance with the laws of the State of California, without application of any principles of choice of laws.

ARTICLE 24 RELATIONSHIP OF PARTIES

In assuming and performing the respective obligations under this Agreement, Licensee and Licensor are each acting as independent parties and neither shall be considered or represent itself as a joint venture, partner, agent or employee of the other.

ARTICLE 25 DISPUTE RESOLUTION

Any and all claims, disputes or controversies arising under, out of, or in connection with this Agreement, including any dispute relating to patent validity or infringement, shall be resolved through arbitration if the parties mutually consent in writing, or through any judicial proceeding either in the courts of the State of California or in the United States District Court for the District of Northern California, to whose jurisdiction for such purposes Licensee and Licensor each hereby irrevocably consents and submits. All costs and expenses, including reasonable attorneys' fees, of the prevailing party in connection with resolution of a dispute by arbitration or litigation of such controversy or claim shall be borne by the other party.

ARTICLE 26 GENERAL PROVISIONS

26.1 The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

26.2 This Agreement shall not be binding upon the parties until it has been signed below by or on behalf of each party.

26.3 No amendment or modification of this Agreement shall be valid or binding upon the parties unless made in writing and signed by both parties hereto.

26.4 This Agreement embodies the entire understanding of the parties and supersedes all previous communications, representations or understandings, either oral or written, between the parties relating to the subject matter thereof. For clarity, the parties agree that (i) the Exclusive Sub-license Agreement between Jade Therapeutics, Inc. and BioTime, Inc. dated June 25, 2012, as amended, was in full force and effect from June 25, 2012 up to the Effective Date; and (ii) is terminated and superseded by this Agreement as of the Effective Date.

26.5 The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of the law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof.

26.6 The parties acknowledge and agree that this Agreement is a contract under which Licensor is a licensor of intellectual property as provided in Section 365(n) of Title 11, United States Code (the "Bankruptcy Code"). Licensor acknowledges that if Licensor, as a debtor in possession, or a trustee in bankruptcy in a case under the Bankruptcy Code (the "Bankruptcy Trustee") rejects this Agreement, Licensee may elect to retain its rights under this Agreement as provided in Section 365(n) of the Bankruptcy Code. Upon the written request of Licensee to Licensor, Licensor will not interfere with the rights of Licensee as provided in this Agreement.

26.7 This Agreement may be signed in counterparts, each of which When taken together shall constitute one fully executed document. Each individual executing this Agreement on behalf of a legal Entity does hereby represent and warrant to e411 other person so signing that he or she has been duly authorized to execute this Agreement on behalf of such Entity.

IN WITNESS WHEREOF, Licensor and Licensee have executed this Agreement by their respective officers hereunto duly authorized, on the day and year hereinafter written.

"Licensee"		**"Licensor"**	
JADE THERAPEUTICS, INC.		**BIOTIME, INC.**	
By:	/s/ Arthur Klausner (Signature)	By:	/s/ William P. Tew, PhD (Signature)
Name:	Arthur Klausner	Name:	William P. Tew, PhD
Title:	Chief Executive Officer	Title:	Chief Commercial Officer
Date:	Sept. 12, 2013	Date:	12 Sept. '13

Exhibit A
Patent Rights

University No.	Country/ Territory	Application/ Patent No.	Title	Inventor(s)
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

CONFIDENTIAL DOCUMENT

EXHIBIT "B"

Due Diligence
Jade Therapeutics

Date: _____

Period Covering: _____

Progress Regarding Specific Due Diligence Milestones:

_____
_____
_____
_____
_____
_____
_____
_____
_____

Projected Date of First Sale: _____

Please provide the commercial name of any FDA-approved products, utilizing this invention, that have first reached the market during the designated reporting period. This information is necessary for federal funding reporting requirements.

Product Name(s): _____
_____
_____

Yes ___No In the designated reporting period, did your company have 500 or more employees? This information is required to determine and report large or small entity status in the United States.

___ Yes ___No In the designated reporting period, did your company have more than 50 employees? This information is required to determine and report large or small entity status in Canada

CONFIDENTIAL DOCUMENT

EXHIBIT "C"

Quarterly Royalty Report
Jade Therapeutics Sublicense

Date: _____

Period Covered: _____

Royalties

A. Number of units sold: _____
B. Price per unit: _____
C. Gross sales amount (AxB): _____
D. Deductions:

[***]) [***] [***] [***] _____
Total Deductions _____
E. Net Sales (C-D): _____
F. Total royalty due (___% of E): _____
G. Total royalty payment made: _____

Exhibit 10.21

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL TO THE REGISTRANT AND (II) WOULD BE COMPETITIVELY HARMFUL TO THE REGISTRANT IF PUBLICLY DISCLOSED. REDACTED PORTIONS OF THIS EXHIBIT ARE MARKED BY [***].

Jade Therapeutics Inc.

Innovations in Ophthalmic Drug Delivery

September 18, 2015

BioTime, Inc.
1301 Harbor Bay Parkway
Alameda, CA 94502
Attn: Adi Mohanty, Chief Operating Officer

Dear Adi:

This letter shall serve as "Amendment Number One" to the Exclusive Sub-License Agreement dated September 12, 2013 ("Agreement") between BioTime, Inc. ("Licensor") and Jade Therapeutics, Inc. ("Licensee").

Licensor and Licensee hereby agree as follows:

1. All defined terms in this Amendment Number One shall have the same meaning(s) set forth in the Agreement.

2. This Amendment Number One is effective as of September 1, 2015.

3. Article 5.1(a) of the Agreement is hereby amended to read as follows

   a. By [***], raise [***] dollars ($[***]) in operating capital through equity financing; debt that is convertible into equity; provided that such debt is not secured by a security interest or other lien on any of Licensee's assets; or funding for research and development or clinical trials from third parties through joint development agreements or similar arrangements, excluding any and all monies provided to or on behalf of Licensee by the Original Investors;

4. Article 5.1(b) of the Agreement is hereby amended to read as follows: "By December 31, 2015

   (i) submit to the United States Food and Drug Administration (FDA) an Investigational New Drug Application to commence a Phase I or Phase IIa clinical trial of a Licensed Product within the Field of Use;

   (ii) provide Licensor with market research data as reasonably requested by Licensor regarding the projected commercial sales in the United States for the Licensed Product in the indication for use in the aforesaid clinical trial; and

(iii) by February 28, 2016 provide to Licensor in writing a remediation plan for achieving Notified Body ISO 13484 certification ("Remediation Plan"). The 675 Arapeen Drive, Suite 302, Salt Lake City, UT 84108 Parties will then discuss in good faith the reasonableness of the timing of the Remediation Plan, and whether it is commercially acceptable. To the extent that the Parties agree that the timetable set forth in Remediation Plan is commercially acceptable, such agreement not to be unreasonable withheld, this milestone will be deemed to have been achieved. If the Remediation Plan, if any, is not acceptable, then Licensee may instead achieve this milestone by providing to Licensor, on or before April 1, 2016, written confirmation of receipt of "Positive Results" of a Notified Body ISO 13485 audit for the design, development, and manufacture of the Licensed Product. For purposes of this Amendment Number One, "Positive Results" shall mean that there are no material observations that prevent 13485 certification for Licensed Product."

All other terms and conditions of the Agreement shall remain in full force and effect.

This Amendment Number One may be signed in counterparts, each of which when taken together shall constitute one fully executed document. Each individual executing this Agreement on behalf of a legal Entity does hereby represent and warrant to each other person so signing that he or she has been duly authorized to execute this Agreement on behalf of such Entity.

Please indicate your agreement to the terms set forth in this letter by signing two copies of this letter, returning one signed to copy to me by email to following address: arthunklausnergadetherapeutics.com; and by overnight courier to Jade Therapeutics, Inc., 675 Arapeen Drive, Suite 302, Salt Lake City, UT 84108-1228, Attn: Chief Executive Officer, and retaining one copy for your records.

Many thanks.

Very truly yours,

/s/ Arthur Klausner

Arthur Klausner
Chief Executive Officer
Jade Therapeutics, Inc.

Acknowledged and agreed by Licensor:

BioTime, Inc.

Name:	Adi Mohanty
Signature:	/s/ Adi Mohanty
Title:	COO
Date:	Sept. 22, 2015

Exhibit 10.22

AMENDMENT NUMBER TWO TO SUBLICENSE AGREEMENT

This Amendment Number Two, effective as of February 17, 2016 (the "Effective Date") is by and between BioTime, Inc. having an address at 1010 Atlantic Avenue, Suite 102, Alameda, CA 94501 ("Licensor") and Jade Therapeutics, Inc. having an address at 675 Arapeen Drive, Suite 302, Salt Lake City, UT 84108 ("Licensee") (collectively referred to as the "Parties"). Capitalized terms shall have their meaning as provided in the Agreement as Amended (as defined below) unless otherwise indicated herein.

RECITALS

WHEREAS, Licensor and Licensee previously entered into a sublicense agreement on September 12, 2013 (the "Agreement");

WHEREAS, Licensor and Licensee amended the Agreement by Amendment Number One as of September 18, 2015 ("Amendment Number One", and together with the Agreement, the "AA"); and

WHEREAS, Licensor and Licensee desire to amend the AA to add provisions for performance of a QMS (Quality Management System) as provided in this Amendment Number Two (the "Amendment Number Two");

NOW THEREFORE, for and in consideration of the covenants, conditions and undertakings hereinafter set forth, the Parties hereby agree as follows:

AMENDMENT NUMBER TWO

1. Section 5.1 (b) of the Agreement is hereby amended by adding subsection (iv) as follows:

   (iv) build the QMS and Implement described in the attached Exhibit A, to be implemented, adopted and operative by December 31, 2016. Licensee will file with Licensor a progress report about the build of the QMS and Implementation on or before June 30, 2016 and November 30, 2016.

2. Ratification of the AA: Except as provided herein or as may be required to effectuate the intent of the parties with respect to this Amendment Number Two, the Parties hereby reaffirm and ratify the terms of the AA in their entirety and no other change in the AA is made hereby.

3. Entire Understanding. This Amendment Number Two constitutes the entire understanding between the Parties with respect to the subject matter hereof, and any modification of this Amendment shall be in writing and shall be signed by a duly authorized representative of each party.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized representatives as of the Effective Date first written above.

JADE THERAPEUTICS, INC.		BIOTIME, INC.	
By:	/s/ Barbara Wirostko, MD	By:	/s/ Aditya P. Mohanty
Name:	Barbara Wirostko, MD	Name:	Aditya P. Mohanty
Title:	Co-Founder and CMO	Title:	Co-CEO

Exhibit 21.1

Subsidiaries of the Registrant

EyeGate Pharma S.A.S.	**(France)**
Jade Therapeutics, Inc.	**(United States)**

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of EyeGate Pharmaceuticals, Inc. on Form S-8 (Nos. 333-202207, 333-209441, 333-216227, 333-223431 and 333-231207) and on Form S-3 (Nos. 333-231204 and 333-234255) of our report dated March 4, 2020, on our audits of the Consolidated Financial Statements as of December 31, 2019 and 2018 and for each of the years then ended, which report is included in this Annual Report on Form 10-K, to be filed on or about March 4, 2020. 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

EISNERAMPER LLP
New York, New York
March 4, 2020

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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer 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 4, 2020

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

Exhibit 31.2

Certification

I, Sarah Romano, 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer 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 4, 2020

/s/ Sarah Romano
Sarah Romano
Chief Financial Officer
(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, 2019 (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 4, 2020

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

Exhibit 32.2

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 her knowledge that the Company's Annual Report on Form 10-K for the year ended December 31, 2019 (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 4, 2020

/s/ Sarah Romano
Sarah Romano
Chief Financial Officer
(Principal financial and accounting officer)