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, 2020

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

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☐

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, 2020 was approximately $16,289,960. 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 23, 2021, there were 7,097,912 shares of the registrant’s common stock issued and outstanding.

EYEGATE PHARMACEUTICALS, INC.
Table of Contents
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2020
INDEX

		Page
PART I		
Item 1.	Business	2
Item 1A.	Risk Factors	24
Item 1B.	Unresolved Staff Comments	52
Item 2.	Properties	52
Item 3.	Legal Proceedings	52
Item 4.	Mine Safety Disclosures	52
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	53
Item 6.	Selected Financial Data	53
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	53
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	65
Item 8.	Financial Statements and Supplementary Data	65
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	65
Item 9A.	Controls and Procedures	66
Item 9B.	Other Information	67
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	67
Item 11.	Executive Compensation	67
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	67
Item 13.	Certain Relationships and Related Transactions, and Director Independence	67
Item 14.	Principal Accounting Fees and Services	67
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	68
	Index to Consolidated Financial Statements	F-1
Item 16.	Form 10-K Summary	69
	Signatures	70

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. Forward looking statements include, but are not limited to, statements about:

- the timing and success of preclinical studies and clinical trials conducted by us and our development partners;
- the ability to obtain and maintain regulatory approval of our product candidates, and the labeling for any approved products;
- the scope, progress, expansion, and costs of developing and commercializing our product candidates;
- the size and growth of the potential markets for our product candidates and the ability to serve those markets;
- our expectations regarding our expenses and revenue, the sufficiency of our cash resources and needs for additional financing;
- the rate and degree of market acceptance of any of our product candidates;
- our expectations regarding competition;
- our anticipated growth strategies;
- our ability to attract or retain key personnel;
- our ability to establish and maintain development partnerships;
- our expectations regarding federal, state and foreign regulatory requirements;
- regulatory developments in the U.S. and foreign countries;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the anticipated trends and challenges in our business and the market in which we operate; and
- the impact of the evolving COVID-19 pandemic and the global response thereto.

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 24 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 developing and commercializing products for treating inflammatory and immune diseases with a focus on the eye and nervous system.

In the fourth quarter of 2020, we acquired Panoptes Ges.m.b.H. ("Panoptes"), transforming our pipeline with the addition of PP-001, a clinical stage Dihydroorotate Dehydrogenase ("DHODH") inhibitor. PP-001, is a next-generation, non-steroidal, immuno-modulatory and small-molecule inhibitor of DHODH with what we believe to be best-in-class picomolar potency and a validated immune modulating mechanism designed to overcome the off-target side effects and safety issues typically associated with DHODH inhibitors. PP-001 has been developed in two clinical-stage ophthalmic formulations: PaniJect, an intravitreal injection for inflammatory diseases of the eye including posterior uveitis, and PaniDrop, a novel nano carrier technology eye drop for ocular surface diseases such as conjunctivitis, dry eye disease and others. Other administration routes are also in development and Investigational New Drug ("IND") enabling studies are underway for conditions outside the ocular space.

In addition, we are developing Ocular Bandage Gel ("OBG"), a modified form of the natural polymer hyaluronic acid, designed to protect the ocular surface to permit re-epithelialization of the cornea and improve ocular surface integrity. OBG, with unique properties that help hydrate and protect the ocular surface, is in clinical evaluation for patients undergoing photorefractive keratectomy ("PRK") surgery for corneal wound repair after refractive surgery and patients with punctate epitheliopathies ("PE") as a result of dry eye. We are currently developing OBG as a device, but are evaluating the potential to reclassify OBG as a drug. We attended a type-B meeting with the U.S. Food and Drug Administration's ("FDA") Center for Drug Evaluation and Research ("CDER") division during the first quarter of 2021 to discuss OBG's path forward as a drug and will continue to evaluate the feedback received as we move towards reaching a decision on the reclassification.

Our Strategy

Our goal is to continue developing products for treating disorders of the eye and to expand development to indications outside of ophthalmology. The key elements of this strategy are to:

- Evaluate the current clinical development programs in ophthalmology of the newly acquired small molecule, PP-001. This includes PaniJect for retinal diseases and PaniDrop for diseases of the ocular surface, which have completed dose-ascending human clinical safety studies in Europe.

- Evaluate the research and development programs for other routes of administration of PP-001, specifically outside of ophthalmology. We are assessing a broad range of potential therapeutic areas including oncology, autoimmune disease, and viral infection.

- Finalize the evaluation to determine reclassification of OBG from a device to a drug. This includes assessing the feedback from a type-B meeting with the FDA's CDER division during the first quarter of 2021.

- Continue clinical development of OBG for the treatment of dry eye disease. In the first quarter of 2020, we announced positive topline data in our follow-on pilot study, which evaluated several different exploratory endpoints.

- We completed clinical development as a device for the indication of wound healing in patients who have undergone PRK surgery. We will assess the path forward for this indication if OBG is reclassified as a drug.

- Pursue strategic collaborations. We plan to evaluate opportunities to enter 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.

Market Opportunity

PP-001 Overview

PP-001 is a third-generation small molecule DHODH inhibitor. DHODH is extensively exploited as potential drug targets for immunological disorders, oncology, and infectious diseases. DHODH is a key enzyme in the de novo pyrimidine synthesis pathway. This enzyme is located in the mitochondria and catalyzes the conversion of dihydroorotate ("DHO") to orotate as the fourth step in the de novo synthesis of pyrimidines that are ultimately used in the production of nucleotides.

Nucleotides are required for cell growth and replication. Nucleotides are the activated precursors of nucleic acids and are necessary for the replication of the genome and the transcription of the genetic information into RNA. Nucleotides also serve as an energy source for a more select group of biological processes (ATP and GTP). They also play a role in the formation of glycogen, signal-transduction pathways, and as components of co-enzymes (NAD and FAD). An ample supply of nucleotides in the cell is essential for all cellular processes.

There are two pathways for the biosynthesis of nucleotides: salvage and de novo. The main difference is where the nucleotide bases come from. In the salvage pathway, the bases are recovered (salvaged) from RNA and DNA degradation. In the de novo pathway, the bases are assembled from simple precursor molecules (made from scratch).

One critical requirement of fast-growing or proliferating cells, such as the expansion of activated B and T-cells, cancer cells, and pathogen infected host cells, is the requirement of an abundance of nucleotide bases. These metabolic activities will predominately utilize the de novo pathway for nucleotide biosynthesis. A key advantage of DHODH inhibition is the selectivity towards metabolically activated cells (with a high need for RNA and DNA production), which should mitigate any negative impact on normal cells. Depletion of cellular pyrimidine pools through the selective inhibition of DHODH has been shown to be a successful approach for therapeutic development.

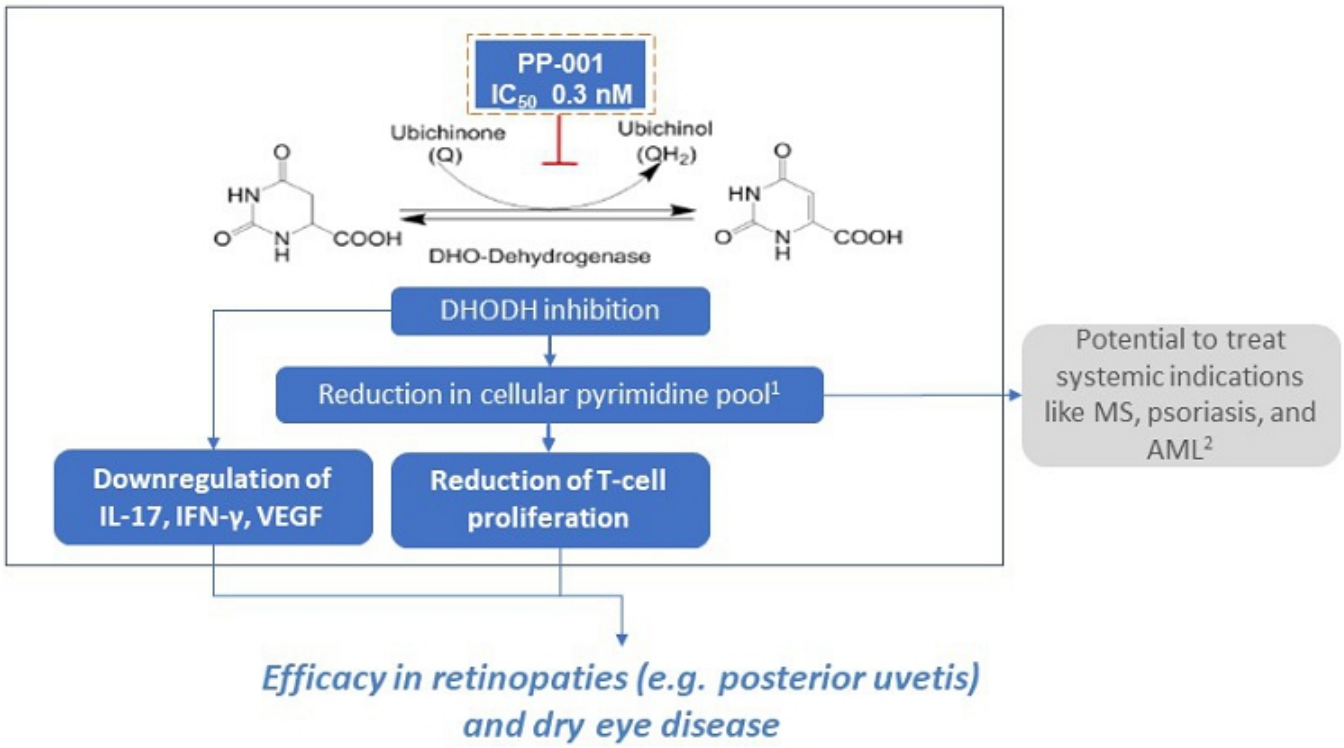
Currently, two first generation DHODH inhibitors have been approved in the U.S. and abroad and are marketed by Sanofi as leflunomide (Arava®) and the active metabolite teriflunomide (Aubagio®). These oral tablets are approved for the treatment of rheumatoid and psoriatic arthritis and multiple sclerosis ("MS"), respectively. Both diseases are autoimmune disorders. One potential explanation for the therapeutic effects of Arava® in arthritis is the reduction in the numbers or reactivity of activated T-cells, which are involved in the pathogenesis of arthritis. The generally accepted view of human MS pathogenesis implicates peripheral activation of myelin-specific autoreactive T-cells that lead to inflammatory disease in the central nervous system ("CNS"). By blocking the de novo pyrimidine synthesis pathway via DHODH inhibition, it is suggested that Aubagio® reduces T-cell proliferation in the periphery. Arava® and Aubagio® are formulated as oral drugs and it is established that leflunomide will be metabolized in the liver to the active metabolite teriflunomide. Hepatotoxicity was reported as a major side effect after oral administration, possibly as a result of extensive liver metabolization. Moreover, it was shown that apart from DHOHD, a series of protein kinases are inhibited by Arava® and Aubagio®.

PP-001 was identified as a promising novel third generation DHODH inhibitor, with a half-maximal inhibitory concentration IC_{50}-value of 0.3 nM. Based on internal work completed, we believe that this is more than 1,000-fold more potent than teriflunomide (IC_{50} DHODH 415 nM). Furthermore, PP-001 represses the expression of key pro-inflammatory cytokines such as IL-17, IFN-g,VEGF and others, potentially as a consequence of inhibiting DHODH. IL-17 and IFN-g are the hallmark cytokines expressed by Th1 and Th17 T-cells, respectively, and play a crucial role in initiating the inflammatory processes in several ocular diseases, including non-noninfectious uveitis and dry eye disease. PP-001 is structurally and mechanistically different from Arava®. The IC_{50} of PP-001 on selected tyrosine kinases, such as PI3K, AKT and JAK, is more than 10,000-fold above the IC_{50} of PP-001 for DHODH. In general, side effects are not expected and have not been observed to date in animal and human studies after PP-001 administration.

Despite the fact that the DHODH protein is ubiquitously expressed in most cells, malignant cells seem to be more metabolically dependent on de novo pyrimidine production, forming the potential basis of a therapeutic window. Inhibiting DHODH alone or in combination with standard-of-care has been shown to be very active in a series of different *in vivo* cancer models for AML, breast, lung, and others.

Additionally, viral replication and viral cell metabolism is dependent on a large nucleotide pool. Therefore, PP-001 demonstrates antiviral efficacy, which is likely due to pyrimidine depletion caused by DHODH inhibition. The postulated DHODH directed mode of action of PP-001 is underlined by reversibility of the antiviral activity by co-application of uridine or other pyrimidine precursors.

The postulated mode of action of PP-001 is depicted below.



[1] Normal cells have sufficient pyrimidines by the salvage pathway and are not affected by the treatment
[2] Sykes et al, Cell 2016

OBG Overview

OBG is a synthetic modified hyaluronic acid ("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. If OBG is approved by the FDA, we expect that it will be the only prescription eye drop available in the U.S. based on HA.

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. We have demonstrated in animal studies that OBG remains on the ocular surface for up to two hours and further demonstrated in a human clinical study that OBG does not cause blurriness while on the ocular surface. This enhances ocular surface protection and patient comfort.

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. OBG has demonstrated statistical significance in a pivotal clinical study for its ability to accelerate wound healing against the current standard-of-care, a bandage contact lens.

We believe that 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. OBG demonstrated its ability to reduce corneal staining, which occurs when the compromised corneal epithelial defects heal, in a pilot study in dry eye patients when compared against Refresh® lubricating eye drops.

Potential Targeted Indications

We are undergoing an assessment of routes of administration for PP-001 and which diseases to focus our resources on. This will include a review of existing routes of delivery, specifically PaniJect and PaniDrop, and may determine that it is not in our best interest to continue with both ophthalmic routes of administration.

PaniJect

PaniJect is being considered for multiple diseases that affect the posterior region of the eye (the retina), including Non-Infectious Posterior Uveitis ("NIPU") and Diabetic Macular Edema ("DME").

PaniDrop

PaniDrop is being considered for multiple diseases that affect the ocular surface and anterior region of the eye, including Allergic Conjunctivitis, Viral Conjunctivitis and Dry Eye Disease ("DED").

OBG

Punctate Epitheliopathies due to 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 by 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 daytime use.

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.

Corneal Wound Repair

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.

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

Clinical Trial Results

PaniJect: Non-Infectious Posterior Uveitis

Phase 1a/2b Safety Study

A first in human clinical study to evaluate the safety of intravitreally applied PP-001 in patients with chronic, non-infectious uveitis has been completed. PP-001 was applied as a single, intravitreal injection of 300, 600 and 1,200 ng per eye. The primary objective of the study was to assess the safety and tolerability of ascending doses of PP-001 in patients. The secondary objectives were to assess improvement of intraocular inflammation and to evaluate the pharmacokinetics of PP-001 in patients. For this study, PP-001 was formulated as a sterile, aqueous solution for intravitreal injection.

The purpose of this study was to assess safety, pharmacokinetic ("PK"), and efficacy data of 12 treated patients. PP-001 showed an excellent safety profile and promising efficacy signals in improvement of inflammatory parameters and visual acuity in uveitis patients.

Assessment of the evaluated efficacy parameters shows a clear dose dependent treatment effect in improvement of visual acuity at day 14 post dosing. Figure 1 shows the mean change in letters read from baseline for patients treated in cohorts 1, 2, and 3 (300, 600, and 1,200 ng per eye).

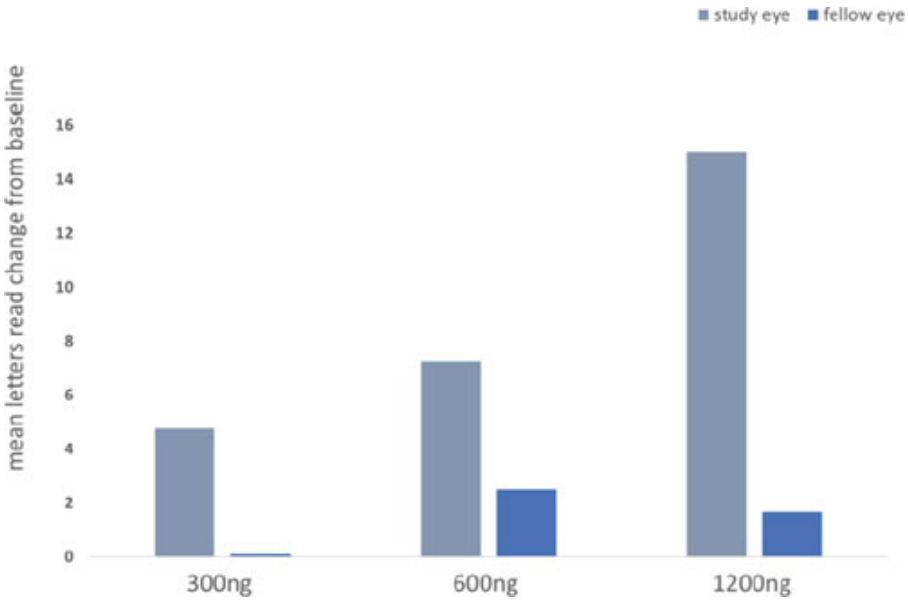


Figure 1: Improvement of visual acuity in cohorts 1, 2, and 3 at day 14 post dose

Analyzing only the highest dose group (1200 ng per eye, cohort 3), a fundamental mean improvement of visual acuity is seen in the patients, which started within the first week post injection (day 7) and lasted beyond the last study visit (day 28). Figure 2 shows the mean letters read change from baseline to study days 7, 14, and 28 for patients treated in cohort 3.

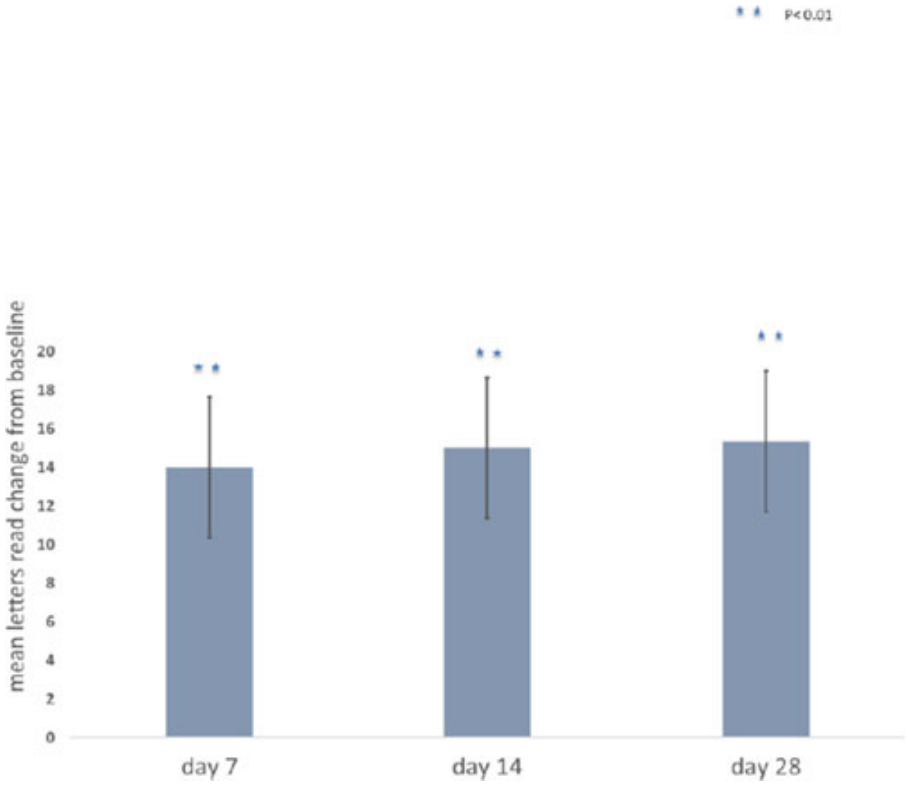


Figure 2: Improvement of visual acuity in cohort 3 on study days 7, 14, and 28

Apart from improved visual acuity, improvements in vitreous haze and reduction in macular edema were observed in the patients treated with PP-001.

PaniDrop: Healthy Volunteers

Phase 1 Safety Study:

A Phase I safety and tolerability study of PP-001 eye drops in healthy adult volunteers was completed. In this study, healthy volunteers were repeatedly treated with ascending doses of PP-001 and placebo eyedrops. 0.05 and 0.15% eyedrops showed excellent tolerability. Both doses can be used for future studies in patients having an infection or inflammation on the ocular surface.

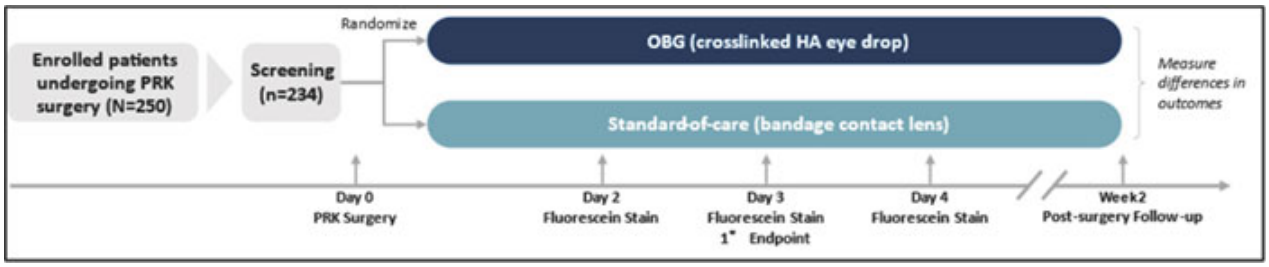
OBG: Corneal Wound Repair

Pivotal Study:

In the fourth quarter of 2019, we reported positive topline results from our corneal wound repair pivotal clinical trial of 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 bandage contact lens ("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 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 OBG QID for two weeks after surgery.
- Arm 2 (n=117) was comprised of BCL administered four times daily.



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.

OBG: Punctate Epitheliopathies with a Focus on Dry Eye

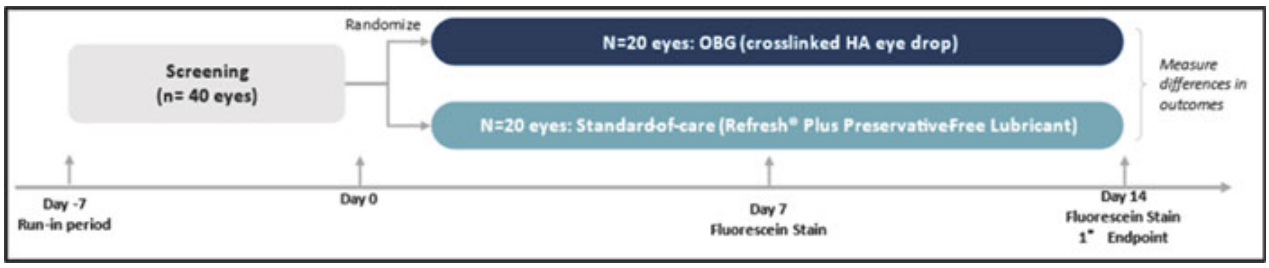
Follow-On Pilot Study:

In the first quarter of 2020, we reported positive topline results from the follow-on clinical trial of OBG evaluating the potential to help clinicians better manage patients with dry eye. This positive controlled, investigator masked study enrolled 20 patients, or 40 eyes, with dry eye. This study confirmed the ability of OBG eye drops to demonstrate improvement of the ocular surface for several important ophthalmic endpoints. OBG eye drops showed an improvement in central corneal region staining, high order ocular aberrations ("HOA") and best corrected visual acuity ("BCVA"), outperforming the positive control, Allergan's Refresh Plus Preservative-Free ("Refresh Plus") lubricant eye drop.

Prior to randomization there was a one-week run in period where all patients took Refresh eye drops only in both eyes. Patients with a corneal staining score of ≥4, using the NEI scale, and a tear film break-up time ("TFBUT") of ≤7 seconds at Day 0, or at the end of the 7-day run-in period, then entered the 14-day treatment phase. To be randomized at Day 0, both eyes had to qualify and have similar scores for staining and TFBUT. The patient acted as their own control and one eye was treated with Refresh Plus eye drops and the other eye was treated with OBG eye drops.

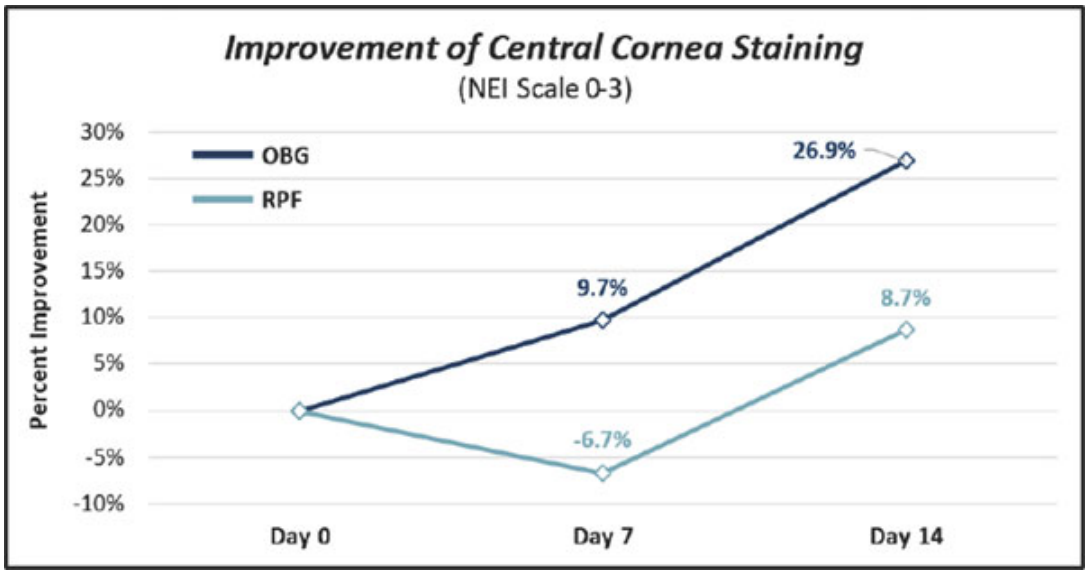
The twenty enrolled patients had one eye randomized to the OBG treatment group and the other eye randomized to the Refresh Plus treatment group, for a total of 40 eyes randomized:

- Arm 1 (n=20 eyes) received OBG eye drops four times daily for four weeks.
- Arm 2 (n=20 eyes) received Refresh Plus eye drops four times daily for four weeks.

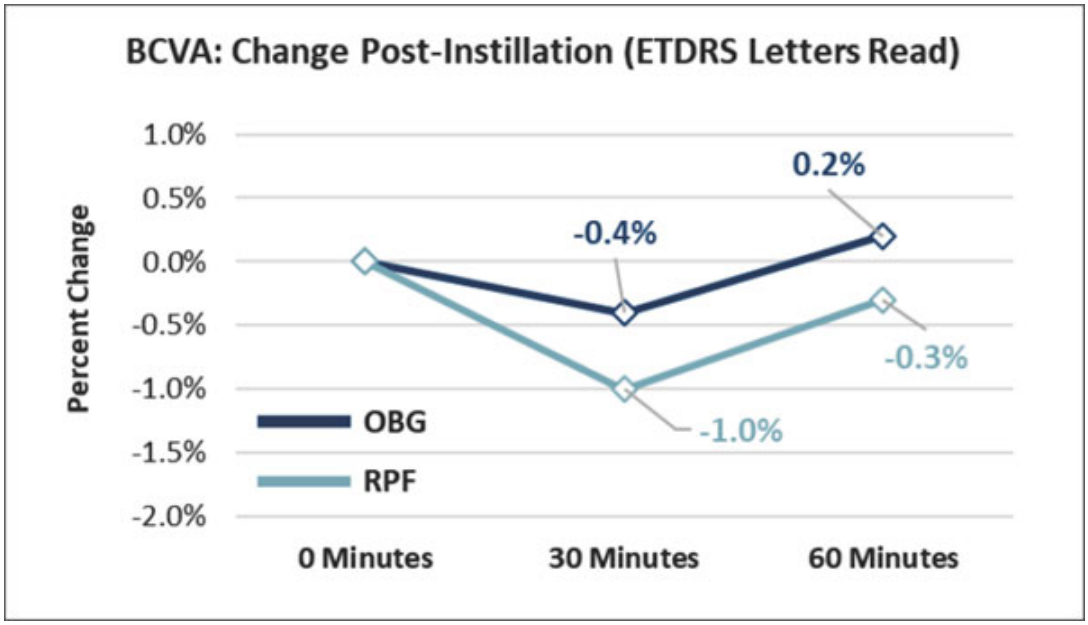


The primary endpoint was based on corneal epithelial healing as measured by fluorescein staining. Punctates are a sign of epithelial compromise (corneal barrier disruption) which is characterized by a breakdown of the epithelium of the cornea and an increased permeability to fluorescein dye. Thus, fluorescein dye is used to clinically evaluate the severity of corneal barrier disruption. The National Eye Institutes ("NEI") scale was used, which divides the cornea into five different regions. Each region was scored on a scale from 0 to 3 for a total maximum score of 15 (a higher score represented a more severe disruption of the corneal barrier). To be randomized into the study, each eye had to have a minimum total score of 4.

At all visits, all corneal regions were assessed, but of particular interest due to vision quality involvement and corneal sensitivity, is the central region of the cornea. All 20 patients randomized had a minimum scoring for the whole cornea (i.e., all 5 regions) of at least 4 (maximum score = 15) in both eyes, and 16 of these patients also had a minimum score of at least 1 (maximum score = 3) in the central region of the cornea in both eyes. OBG demonstrated a positive treatment effect as compared to Refresh Plus at both Day 7 and Day 14. The overall improvement (i.e., reduction in staining) at Day 14 was approximately 27% from baseline versus only approximately 9% for the positive control, Refresh Plus eye drops. OBG also showed improvement more quickly than Refresh Plus eye drops with an approximately 10% reduction in staining versus an increase in staining of approximately 7% for the Refresh Plus treatment group.



The uniqueness of OBG is the combination of the high viscosity profile with a high shear rate. This means that with blinking or other sources of shearing or energy that the viscosity of OBG temporarily drops. Thus, this clinical study was also used to confirm that OBG does not result in blurriness of vision while on the eye. After all endpoint assessments were completed, one drop of OBG and one drop of Refresh Plus was instilled onto each eye. This was completed in a masked fashion based on randomization of each eye per drop. BCVA measurements were taken at 30 and 60 minutes to determine if instillation of either OBG or Refresh Plus caused blurriness or a change in vision. At all assessment time points there was essentially no change in BCVA for OBG or Refresh Plus, but OBG did perform better than Refresh Plus. At 30 minutes post instillation, OBG saw a negative change of 0.4% versus a negative change of 1.0% for Refresh Plus. At 60 minutes, OBG had a positive effect of 0.2% versus a negative effect of 0.3% for Refresh Plus.



Clinical Development Plan

PP-001

The clinical development plan for all PP-001 routes of delivery is under assessment.

OBG

We are currently developing OBG as a device but are evaluating the potential to reclassify OBG as a drug. We attended a type-B meeting with the FDA's CDER division during the first quarter of 2021 to discuss OBG's path forward as a drug and will continue to evaluate the feedback received as we move towards reaching a decision on the reclassification.

Intellectual Property and Proprietary Rights

Overview

We are building an intellectual property portfolio for our PP-001 and modified HA platforms 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 PP-001 as composition-of-matter, formulations thereof and its therapeutic uses in the treatment of viral and ocular disorders and diseases. In addition, further patent applications are directed to the modified HA platform in combination with active therapeutics to treat ocular diseases. These issued patents will expire between 2021 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 or NDA. See “Government Regulation—Patent Term Restoration and Marketing Exclusivity” below.

We and our subsidiaries 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 11 U.S. patents and 43 international patents.

License Agreements

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

On July 2, 2013, we (through our Panoptes subsidiary) entered into a patent and know-how assignment agreement with 4SC Discovery GmbH ("4SC") transferring to us all patent rights and know-how to the compound PP-001. We are responsible for paying royalties based on a specified percentage of net sales of PP-001.

On July 2, 2013, we (through our Panoptes subsidiary) entered into an out-license agreement with 4SC Discovery GmbH ("4SC") granting 4SC the exclusive worldwide right to commercialize the compound PP-001 for rheumatoid arthritis and inflammatory bowel disease, including Crohn's Disease and Ulcerative Colitis. We are eligible to receive milestone payments totaling up to 155 million euros, upon and subject to the achievement of certain specified developmental and commercial milestones. In addition, we are eligible to receive royalties based on a specified percentage of net sales of PP-001.

On September 12, 2013, we (through our subsidiary, Jade Therapeutics, Inc.) entered into an agreement with BioTime, Inc. granting to it the exclusive worldwide right to commercialize modified HA for ophthalmic treatments in humans. The agreement calls for a license issue fee paid to BioTime of $50,000 and requires us to pay an annual fee of $30,000 and royalties to BioTime based on revenue relating to any product incorporating the modified HA technology. The agreement expires when patent protection for the modified HA 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 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 Miami School of Medicine to license technology relating to our former EyeGate® II Delivery System. This agreement, which was amended in December 2005, required us to pay to the University of Miami an annual license fee of $12,500. This license also required payments to the University of Miami upon our achievement of certain milestones. On July 9, 2020, we provided written notice to terminate this agreement effective 90 days from the written notice. Effective October 7, 2020, the Company's agreement with the University of Miami School of Medicine terminated.

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 the written notice. Effective February 5, 2020, the Company's agreement with the University of Utah Research Foundation terminated.

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 percentage 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 percentage 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 PP-001 or OBG is approved by the FDA for commercial sale, we may enter into agreements with third parties to sell PP-001 or OBG, or we may choose to market these directly to physicians in the United States or globally through our own sales and marketing force and related internal commercialization infrastructure. If we market PP-001 or 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 PP-001 or 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 PP-001, 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.

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 Investigational New Drug or 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 current Good Manufacturing Practice or 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 National Institutes of Health-maintained website ClinicalTrials.gov, the 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. 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 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.

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 PP-001 and 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 PP-001 and 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 and Human Capital Resources

As of December 31, 2020, we had fourteen full time employees. None of our employees is represented by a collective bargaining agreement and we have never experienced any work stoppage. We believe that we maintain good relations with our employees. Our employees are highly skilled, and many hold advanced degrees and have experience with drug development. Our future performance depends significantly upon the continued service of our key scientific, technical and senior management personnel and our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth, and a robust employment package that promotes well-being across all aspects of their lives. In addition to salaries, these programs include potential annual discretionary bonuses, equity awards, healthcare and insurance benefits, paid time off, family leave, and flexible work schedules, among other benefits. We have taken proactive steps throughout the COVID-19 pandemic to protect the health and safety of our employees. We expect to continue to implement these measures until we determine that the COVID-19 pandemic is adequately contained for purposes of our business. We may take further actions, in compliance with all appropriate government regulations, that we determine to be in the best interest of our 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. We have two wholly owned subsidiaries, Jade Therapeutics, Inc. and Panoptes Pharma Ges.m.b.H. The Company’s third subsidiary, EyeGate Pharma S.A.S. was dissolved effective December 31, 2020. 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.

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC before making an investment decision regarding our common stock.

- 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.
- 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.
- 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.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- The coronavirus pandemic could adversely impact our business, including clinical trials.
- We depend heavily on the success of PP-001 and OBG. If we are unable to successfully obtain marketing approval for PP-001 or OBG, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize PP-001 or OBG, our business will be materially harmed.
- If clinical trials of PP-001, OBG, or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA or foreign 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 PP-001, OBG, or any other product candidate.
- Even if PP-001, 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 our product candidates may be smaller than we estimate.
- If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in PP-001, OBG, or any other product candidates that we may develop if and when they are approved.
- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.
- Even if we are able to commercialize PP-001, 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.
- 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.
- 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.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.
- 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.

- If we are not able to obtain required regulatory approvals, we will not be able to commercialize PP-001, OBG, or any other product candidate that we may develop, and our ability to generate revenue will be materially impaired.

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

- 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.

- 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.

Risk Factors

The following factors should be reviewed carefully, in conjunction with the other information contained in this Annual Report on Form 10-K. As previously discussed, our actual results could differ materially from our forward-looking statements. Our business faces a variety of risks. These risks include those described below and may include additional risks and uncertainties not presently known to us or that we currently deem immaterial. If any of the events or circumstances described in the following risk factors occur, our business operations, performance and financial condition could be adversely affected and the trading price of our common stock could decline.

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 $8.1 million for the year ended December 31, 2020, $7.1 million for the year ended December 31, 2019 and $108.3 million from the period of inception (December 26, 2004) through December 31, 2020. 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, 2020 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 PP-001 and OBG products.

Our expenses will also increase if and as we:

- seek marketing approval for PP-001 and 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;

- 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 PP-001 and 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 PP-001, 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 PP-001 and 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 PP-001 and 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 PP-001 and 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 PP-001 and OBG products. In the future, we expect to raise additional financial resources for the continued clinical development of PP-001, 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, 2020, we had cash and cash equivalents of $1.2 million. With the net proceeds of approximately $8.0 million received from closing a private placement on January 6, 2021, we believe we will have sufficient cash to fund planned operations through August 31, 2021, 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 U.S. or foreign 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 PP-001, 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, any 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 PP-001 and OBG. 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.

Foreign currency exchange rate fluctuations may have a negative impact on our financial results.

We are subject to the risks of fluctuating foreign currency exchange rates, which could have an adverse effect on the costs and expenses of our foreign subsidiary. As a result, currency fluctuations among the United States dollar, euro and the other currencies in which we do business have caused and will continue to cause foreign currency translation and transaction gains and losses. We have not used forward exchange contracts to hedge our foreign currency exposures. In the future, we may undertake to manage foreign currency risk through hedging methods, including foreign currency contracts. We recognize foreign currency gains or losses arising from our operations in the period incurred. We cannot guarantee that we will be successful in managing foreign currency risk or in predicting the effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure and the potential volatility of currency exchange rates. We cannot predict with any certainty changes in foreign currency exchange rates or the degree to which we can address these risks.

Risks Related to the Discovery and Development of Our Product Candidates

We depend heavily on the success of PP-001 and OBG. If we are unable to successfully obtain marketing approval for PP-001 and OBG, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize PP-001 and OBG, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of OBG, and we expect to invest a significant portion of our efforts and financial resources in the development of PP-001 in the future. There remains a significant risk that we will fail to successfully develop either product candidate.

We cannot accurately predict when or if PP-001 or 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 PP-001 and OBG.

The success of PP-001 and OBG will depend on several factors, including the following:

- obtaining favorable results from clinical trials;
- applying for and receiving marketing approvals from applicable regulatory authorities for PP-001 and OBG;
- making arrangements with third-party manufacturers for commercial quantities of PP-001 and 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 PP-001 and OBG, if and when approved, whether alone or in collaboration with others;
- acceptance of PP-001 and 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 PP-001 and 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 PP-001 and 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 PP-001 and OBG, which would materially harm our business.

If clinical trials of PP-001, OBG or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA or foreign 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 PP-001, OBG, or any other product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, 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 PP-001, 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 PP-001 and 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 PP-001 and 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 PP-001, 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 PP-001, 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 our product candidates may be smaller than we estimate.

If PP-001, 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.

Our assessment of the potential market opportunity for PP-001 and 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 PP-001 and 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 PP-001, 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 sales and marketing infrastructure to market or co-promote PP-001 and OBG products and possibly other product candidates that we develop, 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 PP-001, 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 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 our product candidates. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our 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 our 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 PP-001, 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 PP-001, 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.

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 our product candidates. Our competitors also may obtain FDA or foreign 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 PP-001, 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 PP-001, 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 PP-001, 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 our product candidates 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 any 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 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. The future growth of our business may depend in part on our ability to in-license or acquire the rights to approved products, additional product candidates or technologies. However, we may be unable to in-license or acquire the rights to any such products, product candidates or technologies from third parties. The in-licensing and acquisition of pharmaceutical products is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire products, product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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

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

We face an inherent risk of product liability exposure related to the use of the 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 any 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. 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 PP-001 and 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 our product candidates, and do not plan to independently conduct clinical trials of our product candidates. 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 PP-001 and OBG for clinical trials and expect to continue to do so in connection with the commercialization of PP-001, 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 PP-001, 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 PP-001 and 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 PP-001, 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 PP-001 and OBG on a purchase order basis. We do not currently have any contractual commitments for commercial supply of bulk drug substance for PP-001 and 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 PP-001 and OBG, or for fill-finish services. The prices at which we are able to obtain supplies of PP-001, OBG and fill-finish services may vary substantially over time and adversely affect our financial results.

If our third-party manufacturers for PP-001 or 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 PP-001, 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:

- PP-001, 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 43 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 PP-001, OBG, 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 PP-001, 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 PP-001, OBG, or any other product candidate.

The activities associated with the development and commercialization of our product candidates, including PP-001 and 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 PP-001, 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 PP-001, 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 PP-001, 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 PP-001, 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 PP-001, 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 PP-001 and 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.

Previously 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 PP-001 and 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.

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 Franz Obermayr, our Acting 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 employment agreements with Mr. Obermayr and 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.

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 may 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 potential 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 potential 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, including our recent acquisition of Panoptes Pharma Ges.m.b.H. 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 47.2% 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 3,733,186 shares of common stock. 1,602,085 of 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 either 4.99% or 9.99% 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.

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.

General Risk Factors

The coronavirus pandemic could adversely impact our business, including clinical trials.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread globally. As the COVID-19 pandemic continues, we could experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global manufacturing and shipping that may affect the transport of clinical trial materials and materials, including testing equipment and personal protective equipment, used at our facilities;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which clinical trials are conducted, which may result in unexpected costs;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- delay in the timing of interactions with the FDA due to absenteeism by federal employees or by the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19.

The global outbreak of the COVID-19 coronavirus continues to rapidly evolve. The extent to which the COVID-19 coronavirus may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and other countries to contain and treat the disease.

Laws and regulations governing international operations 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.

We must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate, including our operations in Austria. 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. Our foreign operations 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.

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.

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 PP-001, 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 PP-001 or 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.

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

As of December 31, 2020, we had federal net operating loss carryforwards of approximately $62.1 million, state net operating loss carryforwards of approximately $43.2 million and aggregate federal and state research and development tax credit carryforwards of approximately $2.3 million and $0.495 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, subsequent public and private 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 a smaller reporting company and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a smaller reporting company ("SRC") and a non-accelerated filer, which allows us to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not SRCs or non-accelerated filers, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, reduced disclosure obligations, including disclosures regarding executive compensation, in our Annual Report and our periodic reports and proxy statements and providing only two years of audited financial statements in our Annual Report and our periodic reports. We will remain an SRC until (a) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $250 million or (b) in the event we have over $100 million in annual revenues, the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $700 million. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of 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 and may decline.

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, 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 a non-accelerated filer, 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, 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.

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

None.

Item 2. ***Properties.***

We currently have three facilities including our principal executive office located at 271 Waverley Oaks Road, Suite 108, Waltham, MA 02452, our office located at 391 Chipeta Way, Suite H, Salt Lake City UT, 84108, and our office located at Reisnerstraße 34/1, 1030 Wien, Austria. 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 began trading on The NASDAQ Capital Market under the symbol "EYEG". In connection with this listing, the Common Stock ceased being quoted on the OTCQB Venture Marketplace.

There were 61 holders of record of our common stock as of March 23, 2021. 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 24 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 developing and commercializing products for treating inflammatory and immune diseases with a focus on the eye and nervous system.

In the fourth quarter of 2020, we acquired Panoptes, transforming our pipeline with the addition of PP-001. PP-001, is a next-generation, non-steroidal, immuno-modulatory and small-molecule inhibitor of DHODH with what we believe to be best-in-class picomolar potency and a validated immune modulating mechanism designed to overcome the off-target side effects and safety issues associated with DHODH inhibitors. PP-001 has been developed in two clinical-stage ophthalmic formulations: PaniJect, an intravitreal injection for inflammatory diseases of the eye including posterior uveitis, and PaniDrop, a novel nano carrier technology eye drop for ocular surface diseases such as conjunctivitis, dry eye disease and others. Other administration routes are also in development and IND enabling studies are underway for conditions outside the ocular space.

In addition, we are developing Ocular Bandage Gel (“OBG”), a modified form of the natural polymer hyaluronic acid, designed to protect the ocular surface to permit re-epithelialization of the cornea and improve ocular surface integrity. OBG, with unique properties that help hydrate and protect the ocular surface, is in clinical evaluation for patients undergoing PRK surgery for corneal wound repair after refractive surgery and patients with PE as a result of dry eye. We are currently developing OBG as a device but are evaluating the potential to reclassify OBG as a drug. We attended a type-B meeting with the FDA’s CDER division during the first quarter of 2021 to discuss OBG’s path forward as a drug and will continue to evaluate this feedback in reaching a decision.

In May 2020, we were granted a loan (the "Loan") from Silicon Valley Bank in the amount of approximately $0.278 million pursuant to the Paycheck Protection Program (the "PPP") under Division A, Title I of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), which was enacted in March 2020. The Loan may be prepaid by the Company at any time prior to maturity with no prepayment penalties. Funds from the Loan may only be used for payroll costs, costs used to continue group health care benefits, mortgage payments, rent, utilities, and interest on other debt obligations incurred before February 15, 2020 ("Qualifying Expenses"). We used the entire Loan amount for Qualifying Expenses. Under the terms of the PPP, certain amounts of the Loan may be forgiven if they are used for Qualifying Expenses as described in the CARES Act. If the Loan is not forgiven, the Loan will mature in May 2022 and bear interest at a rate of 1.0% per annum, payable monthly commencing in September 2021.

Throughout our history, we have not generated significant revenue. We have never been profitable, and from inception through December 31, 2020, our losses from operations have aggregated $108.3 million. Our Net Loss was approximately $8.1 million and $7.1 million for the twelve months ended December 31, 2020 and 2019, 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 PP-001 and OBG product candidates, and any other product candidates we advance to clinical development. If we obtain regulatory approval for PP-001 and OBG, we expect to incur significant expenses to create an infrastructure to support the commercialization of PP-001 and OBG including sales, marketing and distribution functions.

The continued spread of the COVID-19 pandemic could adversely impact our clinical studies. In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, and business shutdowns. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which could negatively affect our ability to raise additional capital on attractive terms or at all. See "Item 1A. Risk Factors" beginning on page 24 of this Annual Report on Form 10-K. The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the emergence of new variants, and the effectiveness of actions to contain and treat COVID-19. We cannot presently predict the scope and severity of any potential disruptions to our business, including to our ongoing and planned clinical studies. Any such shutdowns or other business interruptions could result in material and negative effects to our ability to conduct our business in the manner and on the timelines presently planned, which could have a material adverse impact on our business, results of operation, and financial condition. As of the date of this report, there have been no material adverse effects to our ongoing business operations from COVID-19.

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. EyeGate Pharma S.A.S. was dissolved effective December 30, 2020.

Jade Therapeutics, Inc. ("Jade") was formed in Delaware on December 31, 2012. Panoptes Pharma Ges.m.b.H. ("Panoptes") was formed in Austria on July 2, 2013. Jade and Panoptes are wholly owned subsidiaries of EyeGate Pharmaceuticals, Inc.

Financial Overview

Revenues

To date, we have recognized collaboration revenue from U.S. and foreign government grants made to Jade and Panoptes, 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 therapeutic assets, consisting of our DHODH and modified HA-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 OBG and our former legacy products. We expect our research and development expenses to increase for the near future as we advance PP-001, 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 PP-001, 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 DHODH and modified HA-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.

Business Combinations

We applied the provisions of Accounting Standards Codification ("ASC") Topic 805, "Business Combinations," in the accounting for our acquisition of Panoptes. It required us to recognize the assets acquired and the liabilities assumed at their acquisition date fair values, which were determined using market, income, and cost approaches, or a combination. Goodwill as of the respective acquisition date was measured as the excess of consideration transferred over the net of the acquisition date fair value of the assets acquired and the liabilities assumed. Goodwill is generally the result of expected synergies of the combined company or an assembled workforce. Indefinite-lived intangible assets acquired were in-process research and development. The fair value for these intangible assets was determined using the income approach. Under the income approach, fair value reflects the present value of the projected cash flows that are expected to be generated by the products incorporating the in-process research and development, if successful.

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.

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 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 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 adopted ASU No. 2017-04 effective January 1, 2020 and the adoption of this standard did 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 Consolidated Financial Statements and related disclosures.

Other Information

Net Operating Loss Carryforwards

As of December 31, 2020, we have federal and state income tax net operating loss ("NOL") carryovers of approximately $62.1 million and $43.2 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, 2020, 2019 and 2018 totaling $16.1 million will be carried forward indefinitely, but their utilization will be limited to 80% of taxable income. As of December 31, 2020 we also have federal and state research and development tax credit carryforwards of approximately $2.3 million and $0.495 million, respectively, to offset future income taxes, which expire at various times through 2040.

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

Effective December 31, 2020, we are no longer considered an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012.

Results of Operations

Comparison of Years Ended December 31, 2020 and 2019

The following table summarizes the results of our operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		
	2020	**2019**	**Change**
Collaboration Revenue	$ 12,059	$ 2,686,000	$ (2,673,941)
Operating Expenses:			
Research and Development	(3,566,045)	(5,389,357)	(1,823,312)
General and Administrative	(4,658,769)	(4,405,684)	253,085
Total Operating Expenses	(8,224,814)	(9,795,041)	(1,570,227)
Other Income, Net:			
Gain on Disposal of Foreign Entity	113,717	-	113,717
Interest Income, Net	19,153	107,741	(88,588)
Total Other Income, Net	132,870	107,741	25,129
Loss Before Income Tax Expense	(8,079,885)	(7,001,300)	(1,078,585)
Income Tax Expense	(12,055)	(95,396)	83,341
Net Loss	$ (8,091,940)	$ (7,096,696)	$ 995,244

Collaboration Revenue. Collaboration Revenue was $0.012 million for the year ended December 31, 2020, compared to $2.686 million for the year ended December 31, 2019. The revenue recognized for the year ended December 31, 2020 related to the Panoptes acquisition and the accompanying revenue we now generate from government funds from the date of its acquisition. The revenue recognized in 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.

Research and Development Expenses. Research and Development Expenses were $3.566 million for the year ended December 31, 2020 compared to $5.389 million for the year ended December 31, 2019. The decrease of $1.823 million was primarily due to a decrease in OBG clinical activities following the completion of the PRK pivotal study in 2019, as well as the $0.500 million adjustment recorded in 2019 to the present value of the Jade earn-out payment due upon FDA approval of OBG. These decreases were partially offset by increases in OBG manufacturing and the expiration of a prepaid agreement in 2020 with a research vendor.

General and Administrative Expenses. General and Administrative Expenses were $4.659 million for the year ended December 31, 2020, compared to $4.406 million for the year ended December 31, 2019. The increase of $0.253 million was mainly due to increases in professional fees and acquisition costs as a result of the Panoptes acquisition. These increases were partially offset by a decrease in personnel-related costs.

Other Income, Net. Other Income, Net was $0.133 million for the year ended December 31, 2020, compared to $0.108 million for the year ended December 31, 2019. The increase of $0.025 million was mainly due to a gain recognized on the dissolution of EyeGate Pharma S.A.S. in 2020, partially offset by less interest earned on our cash balances.

Income Tax Expense. Income Tax Expense was $0.012 million for the year ended December 31, 2020, compared to $0.095 million for the year ended December 31, 2019. The 2020 and 2019 tax expense was a result of an increase in the state blended tax rate, which was applied to the deferred tax liability balance.

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, payments from license agreements, and U.S. and foreign government grants. From inception through March 25, 2021, we have raised a total of approximately $108.9 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 government grants and $0.278 million received pursuant to the Loan under the PPP.

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 net proceeds from the private placement were approximately $1.8 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.

On January 6, 2021, we completed a private placement of 1,531,101 shares of Common Stock and warrants to purchase up to 1,531,101 shares of Common Stock to an affiliate of Armistice Capital, LLC, with a combined purchase price per share and warrant of $5.225. The total net proceeds from the private placement were approximately $8.0 million. The warrants have an exercise price of $5.225 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.

At December 31, 2020, we had unrestricted cash and cash equivalents totaling approximately $1.2 million.

The following table sets forth the primary sources and uses of cash for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
Net Cash Used in Operating Activities	$ (7,317,169)	$ (8,153,833)
Net Cash Used in Investing Activities	(244,438)	-
Net Cash Provided by Financing Activities	$ 4,997,503	$ 3,920,805

Comparison of Years Ended December 31, 2020 and 2019

Operating Activities. Net cash used in operating activities was $7.317 million for the year ended December 31, 2020, compared to $8.154 million for the year ended December 31, 2019. During the year ended December 31, 2020, we recorded a net loss of $8.092 million, partially offset by non-cash expense for stock-based compensation in the amount of $0.724 million. 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.

Investing Activities. Net cash used in investing activities was $0.244 million for the year ended December 31, 2020, compared to $0 million for the year ended December 31, 2019 primarily due to the acquisition of Panoptes and the dissolution of EyeGate Pharma S.A.S. during the year ended December 31, 2020.

Financing Activities. We received $4.998 million in cash from financing activities for the year ended December 31, 2020, compared to $3.921 million for the year ended December 31, 2019. During the year ended December 31, 2020, we received net proceeds of $4.501 million from the completion of a registered direct stock offering, $0.278 from the Loan under the PPP, and $0.218 million from the exercise of warrants. 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.

Funding Requirements and Other Liquidity Matters

Our PP-001 and modified HA-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 PP-001 or modified HA-based products or any other products that we successfully develop;
- establish a sales and marketing infrastructure to commercialize our PP-001 or modified HA-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 PP-001 and modified HA-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 PP-001 and modified HA-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, 2020 and the approximately $8.0 million in net proceeds received from a private placement that closed on January 6, 2021, we believe we will have sufficient cash to fund planned operations through August 31, 2021. 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 U.S. and/or foreign 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, 2020.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2020:

	Total	Less Than 1 Year	1-3 Years	3 Years & Thereafter
Leases (1)	$ 450,379	$ 217,641	$ 232,738	$ -
Licensing Agreement (2)	240,000	30,000	60,000	150,000
Total (3)	$ 690,379	$ 247,641	$ 292,738	$ 150,000

(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 agreement with 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, (b) contracts that are entered into in the ordinary course of business that are not material in the aggregate in any period presented above, and (c) contingent consideration in connection with acquisitions.

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 Acting 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 Acting 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 Acting 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, 2020. 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 Acting 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 Acting 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.

The scope of our management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2020 includes all of our subsidiaries with the exception of Panoptes. This exclusion is in accordance with the general guidance from the Staff of the Securities and Exchange Commission that an assessment of a recently acquired business may be omitted from the scope of management's assessment of internal control over financial reporting for up to one year following the acquisition. We are in the process of implementing our internal control over financial reporting for the Panoptes acquisition. The operating expenses and total assets of Panoptes represented approximately 1% and 3%, respectively, of the corresponding amounts in our Consolidated Financial Statements as of and for the year ended December 31, 2020.

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, 2020 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, 2020.

As a smaller reporting company under the Jumpstart Our Business Startups Act and a non-accelerated filer, 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, 2020.

(c) Changes in Internal Controls Over Financial Reporting

Our management, with the participation of the Acting 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, 2020. 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, 2020 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 2021 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 2021 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 2021 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 2021 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 2021 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:

	Page
Index to Consolidated Financial Statements	F-1
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2020 and 2019	F-3
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2020 and 2019	F-4
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2020 and 2019	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2020 and 2019	F-7
Notes to Consolidated Financial Statements	F-8

(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	F-2
Consolidated Balance Sheets as of December 31, 2020 and 2019	F-3
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2020 and 2019	F-4
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2020 and 2019	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2020 and 2019	F-7
Notes to Consolidated Financial Statements	F-8

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To 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, 2020 and 2019, and the related consolidated statements of operations and comprehensive income, 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, 2020 and 2019, 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Estimating Fair Value in a Business Combination

As described in Note 13 to the consolidated financial statements, the Company accounted for a significant acquisition as a business combination and allocated the purchase price amongst the tangible and intangible assets acquired and liabilities assumed. Auditing the accounting for the acquisition was complex due to the significant estimation uncertainty in determining the fair values of acquired intangible assets and contingent liabilities. The recorded assets and liabilities included goodwill of approximately $2.0 million, in- process research and development of approximately $4.6 million and a contingent value rights obligation of approximately $3.6 million.

We identified accounting for the acquisition as a critical audit matter. The fair value estimates were based on underlying assumptions about future performance of the acquired business, which involves significant estimation uncertainty. The significant assumptions used to form the basis of the forecasted results included revenue growth rates, earnings metrics, and discount rates. These significant assumptions were forward- looking and could be affected by future economic and market conditions. This in turn led to a high degree of auditor judgment and subjectivity and significant audit effort was required in performing procedures to evaluate management's accounting for the acquisition.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. We obtained an understanding of and evaluated the design and implementation of controls over the Company's estimation of the fair value of assets acquired and liabilities assumed, including controls over inputs used by management to make the estimates and the completeness and accuracy of the data used in the estimates. Our procedures also included, among others, obtaining management's purchase price allocation detailing fair values assigned to acquired tangible and intangible assets and contingent liabilities, and the valuation report prepared by a valuation specialist engaged by management to assist in the purchase price allocation, including determination of fair values assigned to acquired intangible assets and contingent liabilities, and examined valuation methods used and qualifications of specialist. We also examined the completeness and accuracy of the underlying data supporting the significant assumptions and estimates used in the valuation report, including historical and projected financial information. These procedures also included, among others, the involvement of professionals with specialized skills and knowledge to assist in reviewing management's valuation specialist's report, including review of valuation methods, assumptions, and conclusions.

/s/ EisnerAmper LLP

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

EISNERAMPER LLP
New York, New York
March 25, 2021

EYEGATE PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2020	**2019**
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 1,185,677	$ 3,776,712
Prepaid Expenses and Other Current Assets	449,569	458,810
Right-of-Use Assets	83,928	83,926
Other Receivables	90,975	4,857
Total Current Assets	1,810,149	4,324,305
Property and Equipment, Net	30,566	16,846
Restricted Cash	45,000	45,000
Goodwill	3,484,607	1,525,896
Intangible Assets and In-Process R&D, Net	9,730,164	4,131,064
Other Assets	57,073	69,403
Total Assets	$ 15,157,559	$ 10,112,514
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 434,763	$ 210,289
Accrued Expenses	1,289,261	1,120,480
Lease Liabilities	48,303	83,926
Total Current Liabilities	1,772,327	1,414,695
Non-Current Liabilities:		
Contingent Consideration	5,342,950	1,710,000
Deferred Tax Liability	728,926	365,364
Paycheck Protection Program Loan	278,190	-
Lease Liabilities	35,625	-
Total Non-Current Liabilities	6,385,691	2,075,364
Total Liabilities	8,158,018	3,490,059
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, 2020 and 2019, 10,000 designated Series B, 0 shares issued and outstanding at December 31, 2020 and 2019; 10,000 shares designated Series C, 4,092 shares issued and outstanding at December 31, 2020 and 2019, 20,000 shares designated Series D, 46 and 0 shares issued and outstanding at December 31, 2020 and 2019, respectively	41	41
Common Stock, $0.01 Par Value: 50,000,000 and 120,000,000 shares authorized at December 31, 2020 and 2019, respectively; 5,556,394 and 4,077,755 shares issued and outstanding at December 31, 2020 and 2019, respectively	55,564	40,778
Additional Paid-In Capital	115,283,572	106,689,065
Accumulated Deficit	(108,338,834)	(100,246,894)
Accumulated Other Comprehensive Income	(802)	139,465
Total Stockholders' Equity	6,999,541	6,622,455
Total Liabilities and Stockholders' Equity	$ 15,157,559	$ 10,112,514

See Accompanying Notes to the Consolidated Financial Statements.

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

	Year Ended December 31,	
	2020	**2019**
Collaboration Revenue	$ 12,059	$ 2,686,000
Operating Expenses:		
Research and Development	3,566,045	5,389,357
General and Administrative	4,658,769	4,405,684
Total Operating Expenses	8,224,814	9,795,041
Other Income, Net:		
Gain on Disposal of Foreign Entity	113,717	-
Interest Income	23,339	108,066
Interest Expense	(4,186)	(325)
Total Other Income, Net	132,870	107,741
Loss Before Income Tax Expense	(8,079,885)	(7,001,300)
Income Tax Expense	(12,055)	(95,396)
Net Loss	$ (8,091,940)	$ (7,096,696)
Net Loss per Common Share - Basic and Diluted	$ (1.77)	$ (2.23)
Weighted Average Shares Outstanding - Basic and Diluted	4,576,058	3,181,019
Net Loss	$ (8,091,940)	$ (7,096,696)
Other Comprehensive Loss:		
Dissolution of Foreign Entity	(113,717)	-
Foreign Currency Translation Adjustments	(26,550)	5,134
Comprehensive Loss	$ (8,232,207)	$ (7,091,562)

See Accompanying Notes to the Consolidated Financial Statements.

EYEGATE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
Years Ended December 31, 2020 and 2019

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2019	**4,092**	**$ 41**	**4,077,755**	**$ 40,778**	**$ 106,689,065**	**$ 139,465**	**$ (100,246,894)**	**$ 6,622,455**
Stock-Based Compensation					723,856			723,856
Issuance of Common Stock in Offerings, Net of Offering Costs of $498,687			500,000	5,000	4,496,313			4,501,313
Issuance of Shares of Common Stock from Warrant Exercises			45,417	454	217,546			218,000
Shares Issued to Panoptes Stockholders at Acquisition	46	-	884,222	8,842	3,157,282			3,166,124
Dissolution of Foreign Entity						(113,717)		(113,717)
Issuance of Common Stock from Restricted Stock Award Grants			49,000	490	(490)			-
Foreign Currency Translation Adjustment						(26,550)		(26,550)
Net Loss							(8,091,940)	(8,091,940)
Balance December 31, 2020	**4,138**	**$ 41**	**5,556,394**	**$ 55,564**	**$ 115,283,572**	**$ (802)**	**$ (108,338,834)**	**$ 6,999,541**

See Accompanying Notes to the Consolidated Financial Statements.

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

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
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 Consolidated Financial Statements.

EYEGATE PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2020	**2019**
Operating Activities		
Net Loss	$ (8,091,940)	$ (7,096,696)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Depreciation and Amortization of Intangible Assets	33,399	51,672
Reduction of Right-of-Use Assets	166,822	162,261
Stock-Based Compensation	723,856	852,230
Contingent Consideration	-	500,000
Expiration of Prepaid Agreement	159,848	-
Deferred Taxes	12,055	95,396
Changes in Operating Assets and Liabilities, Net of Effects of Business Acquired:		
Prepaid Expenses and Other Current Assets	(146,971)	(3,051)
Refundable Tax Credit Receivable	(18,957)	13,210
Other Assets	18,916	(37,697)
Accounts Payable	136,697	146,636
Lease Liabilities	(166,822)	(162,261)
Deferred Revenue	-	(2,686,000)
Accrued Expenses	(144,072)	10,467
Net Cash Used in Operating Activities	(7,317,169)	(8,153,833)
Investing Activities:		
Purchase of Property and Equipment	(20,077)	-
Acquisition of Panoptes (Net of Cash Acquired)	(110,644)	-
Dissolution of Foreign Entity	(113,717)	-
Net Cash Used in Investing Activities	(244,438)	-
Financing Activities:		
Proceeds from Stock Offerings	5,000,000	1,875,000
Stock Issuance Costs	(498,687)	(97,082)
Exercise of Warrants	218,000	2,150,216
Paycheck Protection Program Loan Proceeds	278,190	-
Settlement of Fractional Shares	-	(2,614)
Equipment Financing Payments	-	(4,715)
Net Cash Provided by Financing Activities	4,997,503	3,920,805
Effect of Exchange Rate Changes on Cash	(26,931)	5,503
Net (Decrease) Increase in Cash	(2,591,035)	(4,227,525)
Cash, Including Restricted Cash, Beginning of Year	3,821,712	8,049,237
Cash, Including Restricted Cash, End of Year	$ 1,230,677	$ 3,821,712
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	$ 166,824	$ 109,511
Cancellation of Restricted Stock	$ -	$ 79
Issuance of Restricted Stock Awards	$ 490	$ -

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 developing and commercializing products for treating inflammatory and immune diseases with a focus on the eye and nervous system.

In the fourth quarter of 2020, EyeGate acquired Panoptes Pharma Ges.m.b.H. ("Panoptes"), transforming EyeGate's pipeline with the addition of PP-001. PP-001, is a next-generation, non-steroidal, immuno-modulatory and small-molecule inhibitor of Dihydroorotate Dehydrogenase ("DHODH") with what EyeGate believes to be best-in-class picomolar potency and a validated immune modulating mechanism designed to overcome the off-target side effects and safety issues associated with DHODH inhibitors. PP-001 has been developed in two clinical-stage ophthalmic formulations: PaniJect, an intravitreal injection for inflammatory diseases of the eye including posterior uveitis, and PaniDrop, a novel nano carrier technology eye drop for ocular surface diseases such as conjunctivitis, dry eye disease and others. Other administration routes are also in development and IND enabling studies are underway for conditions outside the ocular space.

In addition, EyeGate is developing Ocular Bandage Gel ("OBG"), a modified form of the natural polymer hyaluronic acid, designed to protect the ocular surface to permit re-epithelialization of the cornea and improve ocular surface integrity. OBG, with unique properties that help hydrate and protect the ocular surface, is in clinical evaluation for patients undergoing photorefractive keratectomy ("PRK") surgery for corneal wound repair after refractive surgery and patients with punctate epitheliopathies ("PE") as a result of dry eye. EyeGate is currently developing OBG as a device but is evaluating the potential to reclassify OBG as a drug. EyeGate attended a type-B meeting with the U.S. Food and Drug Administration's ("FDA") Center for Drug Evaluation and Research ("CDER") division during the first quarter of 2021 to discuss OBG's path forward as a drug and will continue to evaluate this feedback in reaching a decision.

As of December 31, 2020, there were 5,556,394 shares of Common Stock outstanding, no shares of Series A Preferred Stock outstanding, no shares of Series B Preferred Stock outstanding, 4,092 shares of Series C Preferred Stock outstanding, and 46 shares of Series D Preferred Stock outstanding.

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, 2020, EyeGate had unrestricted Cash and Cash Equivalents of approximately $1.2 million and an Accumulated Deficit of approximately $108.3 million. EyeGate has incurred losses and negative cash flows since inception, and future losses are anticipated. Based on its cash on hand at December 31, 2020 and the approximately $8.0 million in net proceeds received from a private placement that closed on January 6, 2021, the Company anticipates having sufficient cash to fund planned operations through August 31, 2021, 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 financings, license agreements, and/or additional U.S. or foreign 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. (through its dissolution on December 30, 2020), Jade Therapeutics, Inc. ("Jade") and Panoptes Pharma Ges.m.b.H. ("Panoptes") (effective December 18, 2020 when the Company acquired all of the capital stock of Panoptes), 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 the Company's 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 Panoptes are, and prior to its dissolution on December 31, 2020, operations of EyeGate Pharma S.A.S. were, conducted in euros which represent its functional currency. Balance sheet accounts of such subsidiaries 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. At December 31, 2020 and 2019, the Company has classified $45,000 as restricted cash.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation. Depreciation is provided for on a straight-line basis over the estimated useful life of 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, 2020. 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, 2020 and 2019 was $3,484,607 and $1,525,896, respectively. In 2020, this consists of the goodwill of the Company's subsidiaries Jade and Panoptes. In 2019, this solely consists of the goodwill of the Company's subsidiary 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, 2020 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, 2020 and 2019 there is $9,536,414 and $3,912,314, respectively, 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, 2020 and 2019 there is $193,750 and $218,750, 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 the Company's 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 two geographic segments.

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, 2020 and 2019, all of the Company's net deferred income tax assets were subject to a full valuation allowance. As of December 31, 2020 and 2019, the Company has a net deferred tax liability of $728,926 and $365,364, 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, 2020, the Company had no unrecognized uncertain income tax positions.

Refunds for Research and Development

EyeGate, through its Panoptes subsidiary, is entitled to receive certain refunds associated with its research and development expenses in Austria. These refunds are realized in the form of a cash payment in the year following the incurred research & development expenses. The Company records the refundable payment as a reduction in expense 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 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 the weighted-average unvested restricted common stock that has been issued but is subject to forfeiture of 77,262 shares for year ended December 31, 2020 and 50,187 shares for the year ended December 31, 2019.

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. All shares of Common Stock that may potentially be issued in the future are as follows:

	Year Ended December 31,	
	2020	**2019**
Common Stock Warrants	2,726,700	2,875,006
Employee Stock Options	246,893	174,175
Preferred Stock	865,500	852,500
Total Shares of Common Stock Issuable	3,839,093	3,901,681

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, seven 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 manufacturing services to one vendor in the amount of approximately $502,000 during the year ended December 31, 2020. Payments to this vendor were approximately $192,000 for the year ended December 31, 2019. During the year ended December 31, 2019, the Company also made payments to one vendor related to clinical trial services for approximately $978,000. 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 the Company's board of directors, are affiliates of Armistice Capital, LLC, and Mr. Boyd holds voting and investment power over such entity. The total net proceeds from the private placement were approximately $1.8 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

As of December 31, 2020 and 2019, the fair value of the Company's contingent consideration was $5,342,950 and $1,710,000, respectively. During the year ended December 31, 2020, the Company recorded earn-out payments of $9,500,000 at their estimated fair value of $3,632,950 as a result of the Panoptes acquisition. During the year ended December 31, 2016, the Company recorded earn-out payments of $2,164,451 as a result of the Jade acquisition in connection with three products in development, contingent upon FDA marketing approval, at an estimated fair value of $1,210,000. The Company evaluates the fair value of these earn-out payments on a quarterly basis and there were no changes recorded during the year ended December 31, 2020. During the year ended December 31, 2019, taking into consideration discount factors and the probability of FDA approval of the OBG product, the Company recorded an increase of $500,000 to the fair value of contingent consideration.

At December 31, 2020 and 2019, 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 performance obligations 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.

2. Summary of Significant Accounting Policies - (continued)

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.

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 the revenue to be recognized, 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. 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.

	Year 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 U.S. and/or foreign government grant funds for specified 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 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 the Company on January 1, 2020 and is required to be applied prospectively. The Company adopted ASU No. 2017-04 effective January 1, 2020 and the adoption of this standard did 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 the Company's Consolidated Financial Statements and related disclosures.

3. Property and Equipment

Property and equipment at December 31, 2020 and 2019 consists of the following:

	Estimated Useful Life (Years)	2020	2019
Laboratory Equipment	3	$ 82,653	$ 62,576
Office Equipment	3	3,888	-
Office Furniture	5	14,430	14,430
Leasehold Improvements	2	22,569	22,569
Total Property and Equipment, Gross		123,540	99,575
Less Accumulated Depreciation		92,974	82,729
Total Property and Equipment, Net		$ 30,566	$ 16,846

Depreciation expense was $8,399 and $26,672 for the years ended December 31, 2020 and 2019, respectively.

4. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2020	December 31, 2019
Payroll and Benefits	$ 629,465	$ 598,327
Professional Fees	328,420	259,606
Clinical Trials	203,646	254,144
Consulting	125,913	8,403
Interest	1,817	-
Total Accrued Expenses	$ 1,289,261	$ 1,120,480

5. Debt

In May 2020, the Company received loan funds (the "Loan") from the Paycheck Protection Program ("PPP") of approximately $0.278 million. If the Loan is not forgiven, it will mature in May 2022 and bear interest at a rate of 1.0% per annum from the date of the loan, payable monthly commencing in September 2021. Subject to preliminary guidance received from the Small Business Administration on loan forgiveness, the Company believes that the entire loan balance will be forgiven. Until such loan is officially forgiven, the Company will maintain the loan balance on the financial statements.

Other than described above, the Company had no additional indebtedness at December 31, 2020 and 2019.

6. Intangible Assets and In-Process R&D

Intangible assets at December 31, 2020 consist of the rights to trade secrets and know-how related to the manufacturing of OBG. During 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 the 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, 2020 and 2019 consists of projects acquired from the acquisitions of Jade and Panoptes 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, 2020 and 2019 consists of the following:

	Estimated Useful Life (Years)	2020	2019
Trade Secrets	10	$ 250,000	$ 250,000
Less: Accumulated Amortization		(56,250)	(31,250)
Intangible Assets, Net		193,750	218,750
In-Process R&D		9,536,414	3,912,314
Total Intangible Assets and In-Process R&D, Net		$ 9,730,164	$ 4,131,064

Amortization expense on intangible assets was $25,000 for each of the years ended December 31, 2020 and 2019.

7. Capital 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. 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. As of December 31, 2020, 2,444.4 shares of Series C Preferred Stock have been converted into an aggregate of 509,250 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 was 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 net proceeds to the Company from the offering were approximately $1.8 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.

On January 3, 2020, the Company completed a registered direct offering with institutional investors for 500,000 shares of Common Stock with a purchase price of $10.00 per share. The total gross proceeds to the Company from the offering were $5.0 million, and total net proceeds, after deducting the placement agent fees and offering expenses, were approximately $4.5 million.

On June 25, 2020, following the Company’s 2020 Annual Meeting of Stockholders, the Company filed a Certificate of Amendment to its Restated Certificate of Incorporation that decreased the number of authorized shares of the Company’s common stock from 120,000,000 to 50,000,000.

In connection with the Panoptes acquisition, on December 18, 2020, the Company filed a Certificate of Designation of Preferences, Rights and Limitations for up to 20,000 shares of Series D Convertible Preferred Stock with the Delaware Secretary of State. The Series D Convertible Preferred Stock has a stated value of $1,000 per share and a conversion price of $3.5321 per share, but may not be converted until stockholder approval is obtained. The Series D Preferred Stock is only entitled to dividends in the event dividends are paid on the Company’s shares of common stock and does not have any preferences over the Company's shares of common stock or any voting rights, except in limited circumstances.

8. Warrants

At December 31, 2020 and 2019, the following warrants were outstanding:

	Number of Awards		Weighted Average Exercise Price	Weighted Average Remaining Term in Years
Outstanding at December 31, 2018	2,722,967	$	15.00	4.05
Issued	600,000[1]		3.13[3]	4.76
Exercised	(447,961)		4.80	3.30
Outstanding at December 31, 2019	2,875,006	$	14.14	3.37
Issued	25,000[2]		12.50[3]	4.01
Exercised	(45,417)		4.80	2.29
Expired	(127,889)		139.28	-
Outstanding at December 31, 2020	2,726,700	$	8.41	2.45

1 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.

2 Consists of 25,000 warrants to purchase 25,000 shares of Common Stock issued to the placement agent in connection with the Company's registered direct offering on January 3, 2020.

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 2021 through 2025.

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, 2020, the maximum number of shares of Common Stock that may be issued pursuant to the 2014 Plan and the ESPP was 582,672 and 11,371 shares, respectively.

In January 2020, 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 582,672 shares issuable under the 2014 Plan.

The following is a summary of stock option activity for the years ended December 31, 2020 and 2019:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (In Years)
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
Granted	93,165	6.31	
Expired	(17,114)	10.59	
Forfeited	(3,333)	7.20	
Outstanding at December 31, 2020	246,893	$ 20.90	7.20
Exercisable at December 31, 2020	142,061	$ 31.58	5.85
Vested and Expected to Vest at December 31, 2020	246,893	$ 20.90	7.20

During the years ended December 31, 2020 and 2019, the Board approved the grant of options to purchase 93,165 and 49,994 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 years ended December 31, 2020 and 2019, 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:

	2020	2019
Risk-Free Interest Rate	1.82%	1.82%
Expected Life	5.00 years	5.00 years
Expected Volatility	153%	152%
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 years ended December 31, 2020 and 2019 was $6.26 and $7.11, respectively.

The following is a summary of restricted stock activity for the years ended December 31, 2020 and 2019:

	Number of Shares	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Recognition Period
Non-vested Outstanding at December 31, 2018	121,478	$ 8.84	
Vested	(63,632)	9.00	
Forfeited	(7,659)	8.86	
Non-vested Outstanding at December 31, 2019	50,187	8.64	1.49
Awarded	49,000	6.55	
Vested	(31,767)	8.69	
Non-vested Outstanding at December 31, 2020	67,420	$ 7.10	1.66

During the year ended December 31, 2020, the Board approved the grant of 49,000 shares of EyeGate's restricted Common Stock. 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, 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,	
	2020	2019
Research and Development	$ 197,806	$ 203,512
General and Administrative	526,050	648,718
Total Stock-Based Compensation Expense	$ 723,856	$ 852,230

The fair value of options granted for the years ended December 31, 2020 and 2019 was approximately $580,000 and $355,000, respectively. The fair value of restricted stock granted for the year ended December 31, 2020 was approximately $321,000. As of December 31, 2020 and 2019, there was approximately $780,000 and $627,000 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 1.95 and 1.62 years, respectively. The aggregate intrinsic value of stock options outstanding at December 31, 2020 and 2019 was approximately $0 and $32,000, respectively.

As of December 31, 2020, there were 176,524 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,	
	2020	2019
Domestic	$ (7,996,327)	$ (7,523,695)
Foreign	(83,558)	522,395
Total Loss Before Income Taxes	$ (8,079,885)	$ (7,001,300)

The components of income tax expense are as follows:

	Year Ended December 31,	
	2020	2019
Deferred Taxes:		
Federal	$ (529)	$ (4,182)
State	12,584	99,578
Total Deferred Taxes	$ 12,055	$ 95,396
Income Tax Expense	$ 12,055	$ 95,396

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,	
	2020	2019
United States Federal Income Tax Rate	21.00%	21.00%
State Taxes, Net of Federal Benefit	(1.59)	13.82
Permanent Differences	(15.00)	(4.18)
Change in Valuation Allowance	17.53	(37.40)
Research and Development Credits	1.65	6.53
Tax Rate Differential	(2.12)	(1.15)
Stock-Based Compensation	(1.32)	0.45
Gain on Dissolution of Foreign Subsidiary	(15.81)	-
Other	(4.49)	(0.43)
Effective Tax Rate Expense	(0.15)%	(1.36)%

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

	Year Ended December 31,	
	2020	2019
Net Deferred Tax Liability:		
Net Operating Loss Carryforwards	$ 17,042,422	$ 15,230,646
Research and Development Credit Carryforwards	2,695,773	2,594,055
Capitalized Research and Development	6,251,945	6,521,705
Stock-Based Compensation	781,252	814,438
Depreciation and Amortization	-	170
Cash Versus Accrual Adjustments	223,674	1,738,482
Total Deferred Tax Assets	26,995,066	26,899,496
Valuation Allowance	(25,320,159)	(26,278,147)
Net Deferred Tax Asset	1,674,907	621,349
Depreciation and Amortization	(1,083)	-
In-Process Research and Development	(2,402,750)	(986,713)
Net Deferred Tax Liability	$ (728,926)	$ (365,364)

10. Income Taxes - (continued)

As of December 31, 2020, the Company has federal and state net operating loss carryforwards of approximately $62.148 million and $43.212 million, 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, 2020, 2019 and 2018 totaling $16.093 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 $6.081 million as of December 31, 2020, which can be carried forward indefinitely. As of December 31, 2020, the Company also has federal and state research and development tax credit carryforwards of approximately $2.304 million and $0.495 million, respectively, to offset future income taxes, which expire at various times through 2040. 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.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act (the "CARES" Act) was enacted. The CARES Act included several income tax provisions including NOL carryback provisions and other tax benefits. The Company does not expect that the CARES Act will have a material impact on its income tax provision.

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 Austria. The Company will file all foreign tax returns for its former French subsidiary EyeGate Pharma S.A.S., which dissolved December 31, 2020. 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, 2020, and 2019 because the Company's management believes that it is more likely than not that these assets will not be realized. The valuation allowance (decreased) increased by approximately $(0.958) million and $2.618 million during the years ended December 31, 2020 and 2019, respectively, primarily as a result of the increase in net operating losses and credits, adjustments for accrual to cash basis items, and capitalized research and development expenses.

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, 2020 and 2019.

As of December 31, 2020 and 2019, the Company had no unrecognized tax benefits or related interest and penalties accrued. The Company will recognize interest and penalties related to income taxes 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 three real property operating leases for the rental of office or lab space. The Company has office space in Waltham, Massachusetts of up to 4,516 square feet that is used for its corporate headquarters with a term through March 31, 2022. The Company also had office and laboratory space of approximately 2,300 square feet in Salt Lake City, Utah, with its term expiring on February 28, 2021. During the fourth quarter of 2020, the Company entered into a real property operating lease for new office and laboratory space of approximately 3,540 square feet in Salt Lake City, Utah, with a term through November 30, 2023. The Company has office space in Vienna, Austria of approximately 1,555 square feet with a term through October 31, 2023 as a result of the Panoptes acquisition effective December 18, 2020.

Additional right-of-use assets and lease liabilities were recorded upon the new lease agreements or extensions that were effective as of December 31, 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. Operating lease expense, consisting of the reduction of the right-of-use asset and the imputed interest on the lease liability, totaled $0.174 million and $0.171 million for the years ended December 31, 2020 and 2019, respectively.

Maturities of lease liabilities were as follows as of December 31, 2020:

	Operating Leases
2021	$ 51,564
2022	22,209
2023	18,508
Less: Imputed Interest	(8,353)
Lease Liabilities	$ 83,928

License Agreements

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

On July 2, 2013, Panoptes entered into a patent and know-how assignment agreement with 4SC Discovery GmbH ("4SC") transferring to Panoptes all patent rights and know-how to the compound PP-001. The Company (through its Panoptes subsidiary) is responsible for paying royalties based on a specified percentage of net sales of PP-001.

On July 2, 2013, Panoptes entered into an out-license agreement with 4SC Discovery GmbH ("4SC") granting 4SC the exclusive worldwide right to commercialize the compound PP-001 for rheumatoid arthritis and inflammatory bowel disease, including Crohn's Disease and Ulcerative Colitis. The Company (through its Panoptes subsidiary) is eligible to receive milestone payments totaling up to 155 million euros, upon and subject to the achievement of certain specified developmental and commercial milestones. In addition, the Company (through its Panoptes subsidiary) is eligible to receive royalties based on a specified percentage of net sales of PP-001.

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 ("modified HA") for ophthalmic treatments in humans. The agreement provides 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 modified HA technology. The agreement expires when patent protection for the modified HA 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 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 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.

The Company was previously a party to an exclusive worldwide license agreement with the University of Miami School of Medicine to license technology relating to the Company's former EyeGate® II Delivery System. This agreement, which was amended in December 2005, required the Company to pay to the University of Miami an annual license fee of $12,500. This license also required payments to the University of Miami upon the Company's achievement of certain milestones. On July 9, 2020, the Company provided written notice to terminate this agreement effective 90 days from the written notice. Effective October 7, 2020, the Company's agreement with University of Miami School of Medicine terminated.

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 the written notice. Effective February 5, 2020, the Company's agreement with the University of Utah Research Foundation terminated.

The Company was previously a party to 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 percentage 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.

The Company was previously a party to 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 percentage 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.

COVID-19

The continued spread of the COVID-19 pandemic could adversely impact the Company's clinical studies. In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, and business shutdowns. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which could negatively affect the Company's ability to raise additional capital on attractive terms or at all. The extent to which COVID-19 may impact the Company's business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the emergence of new variants, and the effectiveness of actions to contain and treat COVID-19. The Company cannot presently predict the scope and severity of any potential disruptions to its business, including to ongoing and planned clinical studies. Any such shutdowns or other business interruptions could result in material and negative effects to the Company's ability to conduct its business in the manner and on the timelines presently planned, which could have a material adverse impact on its business, results of operation, and financial condition. As of the date of this report, there have been no material adverse effects to the Company's ongoing business operations from COVID-19.

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, 2019, the Company contributed approximately $37,000 to eligible employees during the year ended December 31, 2020. The Company has accrued an estimate of approximately $26,000 for contributions likely due as a result of the 401(k) plan compliance review for the year ended December 31, 2020. The Company made no matching contributions in the years ended December 31, 2020 and 2019.

13. Acquisitions

Panoptes Pharma Ges.m.b.H. Acquisition

Effective December 18, 2020, the Company acquired all of the capital stock of Panoptes Pharma Ges.m.b.H. ("Panoptes"), a privately held clinical stage biotech company focused on developing a novel proprietary small molecule for the treatment of severe eye diseases with a high unmet medical need, as well as for conditions outside the ocular space. With the Panoptes Acquisition, Panoptes became a wholly owned subsidiary of EyeGate. The acquisition has been accounted for in accordance with FASB's Accounting Standards Codification ("ASC") 805, "Business Combinations", with the assets acquired and liabilities assumed recorded at fair value on the date of the acquisition. The excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill, which is not expected to be deductible for tax purposes.

Under the terms of the Panoptes Acquisition agreement, in consideration for 100% of the outstanding equity interests in Panoptes, the Company paid cash in the amount of $444,504 to certain founders and creditors, issued 884,222 shares of EyeGate common stock, and issued 45.8923 shares (convertible into 13,000 shares of common stock) of EyeGate Series D Convertible Preferred Stock. An additional cash payment is due to a creditor in December 2021 and is recorded at a fair value of $212,281 at the acquisition date.

Additionally, up to 1,500 shares of Series D Convertible Preferred Stock (convertible into 424,685 shares of common stock) will be issued after a period of 18 months, subject to post-closing adjustments or indemnification obligations, and are recorded as contingent consideration and fair valued at $1,353,424 at the acquisition date.

The Panoptes Acquisition also includes two cash or stock earn-out provisions providing for an additional cash or stock payment of $4,750,000 per milestone contingent upon (1) the enrollment and randomization of a first patient into the first FDA Phase III pivotal study of a Panoptes product and (2) the FDA approval of the first New Drug Application of a Panoptes product. The cash or stock earn-out payments were recorded as contingent consideration and fair valued at $2,067,245 at the acquisition date.

The fair value of the shares issued in the Panoptes Acquisition was approximately $3.169 million based on the 30-day volume weighted average price of the Company's Common Stock as reported by Bloomberg on the closing date of the acquisition, or $3.5321 per share.

The following table summarizes the preliminary purchase price allocation and the estimated fair value of the net assets acquired and liabilities assumed in the Panoptes Acquisition at the date of acquisition. The purchase price allocation for Panoptes is preliminary pending completion of the fair value analysis of acquired assets and liabilities:

	Panoptes
Current Assets[(1)]	$ 410,863
In-Process R&D	5,624,100
Goodwill	1,958,711
Property, Plant and Equipment	2,042
Accounts Payable and Other Liabilities	(87,777)
Deferred Tax Liability	(351,507)
Contingent Consideration	(3,632,950)
Assumed Liabilities	(312,852)
Total Purchase Price	$ 3,610,630

(1) Current Assets include cash, receivables, and prepaid expenses of $333,860, $73,368, and $3,635, respectively.

Net loss in the Consolidated Statement of Operations for the twelve months ended December 31, 2020 includes net losses of Panoptes from the date of acquisition to December 31, 2020 of $0.034 million. The Company's intangible assets, which consist solely of in-process research and development, will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval, the Intangible assets are then accounted for as finite-lived intangible assets and amortized on a straight-line basis over its estimated useful life.

EyeGate recognized approximately $0.414 million of acquisition-related costs for the Panoptes Acquisition that were expensed in the current period as a component of general and administrative expense.

13. Acquisitions (continued)

Pro forma disclosure for Panoptes acquisition

The following table includes the pro forma results for the years ended December 31, 2020 and 2019 of the combined companies as though the Panoptes Acquisition had been completed as of the beginning of the period presented.

	Year Ended December 31, 2020 (unaudited)	Year Ended December 31, 2019 (unaudited)
Revenues	$ 558,063	$ 2,799,475
Operating Expenses	9,842,685	11,206,998
Net Loss	$ (9,172,201)	$ (8,762,314)

The pro forma financial information is presented for information purposes only. The unaudited pro forma financial information may not necessarily reflect the Company's future results of operations or what the results of operations would have been had the Company owned and operated Panoptes as of the beginning of the period presented.

14. Subsequent Event

On January 6, 2021, the Company completed a private placement of 1,531,101 shares of Common Stock and warrants to purchase up to 1,531,101 shares of Common Stock to an affiliate of Armistice Capital, LLC, with a combined purchase price per share and warrant of $5.225. The total net proceeds from the private placement were approximately $8.0 million. The warrants have an exercise price of $5.225 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.

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 25, 2021

By: /s/ Franz Obermayr
Acting Chief Executive Officer

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

Signature	Title	Date
/s/ Franz Obermayr Franz Obermayr	Acting Chief Executive Officer (principal executive officer)	March 25, 2021
/s/ Sarah Romano Sarah Romano	Chief Financial Officer (principal financial and accounting officer)	March 25, 2021
/s/ Stephen From Stephen From	Executive Chairman	March 25, 2021
/s/ Paul Chaney Paul Chaney	Director	March 25, 2021
/s/ Morton Goldberg Morton Goldberg	Director	March 25, 2021
/s/ Praveen Tyle Praveen Tyle	Director	March 25, 2021
/s/ Thomas E. Hancock Thomas E. Hancock	Director	March 25, 2021
/s/ Bernard Malfroy-Camine Bernard Malfroy-Camine	Director	March 25, 2021
/s/ Keith Maher Keith Maher	Director	March 25, 2021
/s/ Steven Boyd Steven Boyd	Director	March 25, 2021

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.
2.2[21]	Share Purchase Agreement, dated as of December 18, 2020, 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[22]	Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant, filed June 25, 2020.
3.5[2]	Amended and Restated By-laws of the Registrant.
3.6[7]	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.
3.7[8]	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock.
3.8[13]	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock.
3.9[21]	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock.
4.1[25]	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.
4.8[23]	Form of Common Stock Purchase Warrant, dated January 6, 2021.
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.
10.5[6]	Form of Warrant Agency Agreement, dated August 5, 2015, by and between the Registrant and VStock Transfer, LLC.
10.6[4]	Form of Indemnification Agreement.
10.7[4]	Form of Notice of Stock Option Grant pertaining to the 2014 Equity Incentive Plan.

10.8[4]	Form of Notice of Stock Unit Award pertaining to the 2014 Equity Incentive Plan.
10.9#[4]	Form of Amended and Restated Offer of Employment by and between the Registrant and Michael Manzo.
10.10†[16]	Intellectual Property License Agreement, dated as of September 26, 2018, by and between the Registrant and SentrX Animal Care, Inc.
10.11[18]	Registration Rights Agreement between the Registrant and Armistice Capital Master Fund, Ltd. dated as of September 29, 2019.
10.12[19]	EyeGate Pharmaceuticals, Inc. Amended and Restated Change in Control Severance Plan.
10.13[25]††	Exclusive Sub-License Agreement, dated as of September 12, 2013, by and between Jade Therapeutics, Inc. and Biotime, Inc.
10.14[25]††	Amendment No. 1 to Sub-License Agreement, dated as of September 18, 2015, by and between Jade Therapeutics, Inc. and Biotime, Inc.
10.15[25]††	Amendment No. 2 to Sub-License Agreement, dated as of February 17, 2016, by and between Jade Therapeutics, Inc. and Biotime, Inc.
10.16[21]	Registration Rights Agreement, dated as of December 18, 2020, by and among the Registrant and the Sellers listed therein.
10.17#[26]	Employment Agreement, dated March 23, 2020, by and between the Registrant and Sarah Romano.
10.18[23]	Registration Rights Agreement, dated as of December 18, 2020, by and among the Registrant and the Purchasers listed therein.
10.19#[24]	Managing Director Service Agreement, dated as of December 18, 2020, by and between Panoptes Pharma Ges.m.b.H. and Franz Obermayr.
10.20#[24]	First Amendment to Managing Director Service Agreement, dated as of January 29, 2021, by and among Panoptes Pharma Ges.m.b.H., the Registrant and Franz Obermayr.
10.21#[24]	Fourth Amended and Restated Employment Agreement, dated as of January 29, 2021, by and between the Registrant and Stephen From.
10.22††*	Patent and Know How Assignment Agreement, dated as of July 2, 2013, by and between Panoptes Pharma Ges.m.b.H and 4SC Discovery GmbH.
10.23††*	Patent License Agreement, dated as of July 2, 2013, by and between Panoptes Pharma Ges.m.b.H. and 4SC Discovery GmbH.
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.
21 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed December 21, 2020) and incorporated by reference thereto.
22 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed June 26, 2020) and incorporated by reference thereto.

23 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed January 6, 2021) and incorporated by reference thereto.
24 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed February 1, 2021) and incorporated by reference thereto.
25 Previously filed as an exhibit to the Company's Annual Report on Form 10-K (filed March 4, 2020) and incorporated by reference thereto.
26 Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed March 24, 2020) 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.

Exhibit 10.22

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 [***].

Patent and Know How Assignment Agreement

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by and between

4SC Discovery GmbH

and

Panoptes Pharma Ges. m. b. H. in Gründung

2nd July 2013

THIS Patent and Know How Transfer Agreement is entered into effect as of 2nd July 2013 ("Effective Date") BETWEEN:

(1) 4SC Discovery GmbH, Am Klopferspitz 19a, 82152 Planegg-Martinsried, Germany,

("**ASSIGNOR**");

and

(2) Panoptes Pharma Ges. m. b. H. in Gründung, Dr. Obermayr, Dr. Sperl; Stauraczgasse 7/15, 1050 Vienna, Austria,

("**ASSIGNEE**").

RECITALS:

(A) ASSIGNEE has been founded to develop and commercialize the compound PP-001 (formerly SC53842) for certain eye diseases.

(B) ASSIGNOR is co-founder of ASSIGNEE and owner of the assets relating to PP-001.

(C) ASSIGNOR is willing to assign to ASSIGNEE certain know-how and patent rights to enable ASSIGNEE to develop and commercialize PP-001.

(D) NOW, THEREFORE, ASSIGNOR and ASSIGNEE hereby agree as follows:

1. DEFINITIONS

For purposes of this Agreement, the following terms shall have the following meanings:

1.1 "**Affiliate**" shall mean and include in relation to each Party, any person, firm, corporation or other entity: (i) if at least fifty percent (50%) of the voting stock or other equity interest thereof is owned, directly or indirectly, by that Party; (ii) which owns, directly or indirectly, at least fifty percent (50%) of the voting stock or other equity interest of that Party; or (iii) if at least fifty percent (50%) of the voting stock or other equity interest thereof is owned, directly or indirectly, by a person, firm, corporation or other entity that owns, directly or indirectly, at least fifty percent (50%) of the voting stock or other equity interest of that Party provided, however, that [***], a financial investor in ASSIGNOR, and any affiliates of [***] shall not be considered Affiliates for purposes of this Agreement.

1.2 "**Agreement**" shall mean this Assignment Agreement and all Exhibits attached hereto, and the terms "herein", "hereunder", "hereto" and such similar expressions shall refer to this Agreement.

1.3 "**Clinical Proof of Concept**" shall mean the successful completion of a study of a Compound in human patients to determine initial efficacy and dose range finding

1.4 "**Closing Date**" of this Agreement shall mean the date when all of the following conditions have been met:

(i) Foundation of ASIGNEE as evidenced by a notary public and

(ii) signing of a shareholder agreement between the founding shareholders 4SC, Dr. Stefan Sperl, Dr. Franz Obermayr & Dr. Bernd Mühlenweg and

(iii) nomination of Dr. Franz Obermayr and Dr. Stefan Sperl as managing directors of ASSIGNEE and

(iv) approval of this Agreement by the shareholders of ASSIGNEE and

(v) obtaining a written statement by Austria Wirtschaftsservice Gesellschaft mbH that all conditions according to their letter dated March 07, 2013 have been fulfilled and that ASSIGNEE will be funded with [***] € and

(vi) issuance of a letter by ASSIGNEE to ASSIGNOR that all of the conditions according to this Section 1.4 have been met including the Closing Date.

1.5 "**Compound**" shall mean PP-001 and/or any other substance and/or therapeutic product covered by the Transferred Patent Rights.

1.6 "**Confidential Information**" shall mean and include all know how including the Transferred Know How, data and information, not in the public domain, relating to Compound and the business, affairs, research and development activities, products, results of clinical trials, national and multinational regulatory proceedings and affairs, finances, plans, contractual relationships and operations of the Parties. Confidential Information shall also include the existence and terms of this Agreement.

1.7 "**Effective Date**" of this Agreement shall mean the date in the recitals.

1.8 **"Licensee"** shall mean a Third Party to which ASSIGNEE grants a license for further co-development or development or commercialization or co-marketing.

1.9 **"Licensing"** shall mean an agreement with a Third Party to which ASSIGNEE grants a license for further co-development or development or commercialization or co-marketing.

1.10 "**Net Sales**" shall be calculated in accordance with international financial reporting standards (IFRS) and shall mean with respect to any Compound, the gross invoiced sales of such Compound by ASSIGNEE or its Third Party Licensee(s) in the Territory, less the following amounts actually deducted or allowed:

(i) [***];

(ii) [***];

(iii) [***];

(iv) [***]; and

(v) [***].

1.11 "**Party**" or "**Parties**" shall mean ASSIGNOR or ASSIGNEE, or ASSIGNOR and ASSIGNEE, whichever the context admits.

1.12 "**PP-001**" shall mean the chemical compound 3-(2,3,5,6-Tetrafluoro-3`-(trifluoromethoxy) biphenyl-4-ylcarbamoyl)thiophene-2-carboxylic acid which was formerly developed by ASSIGNOR under the name of SC53842.

1.13 **"Royalty Term"** shall mean, on a country-by-country and Compound-by-Compound basis, the period of time beginning upon the date of first commercial sale of a Compound in that country, and ending upon the later to occur of (i) the expiration of the last Valid Claim of a Transferred Patent Right covering such Compound in such country, or (ii) ten (10) years from the first commercial sale of the Compound in such country.

1.14 "**Territory**" shall mean the entire world.

1.15 "**Third Party**" shall mean any other party that is independent from ASSIGNOR and its Affiliates and ASSIGNEE and its Affiliates.

1.16 "**Transferred Know How**" shall include all specifications, results and reports of clinical studies and all other documentation containing or embodying any data, including pre-clinical, clinical and CMC data relating to the application for regulatory approval for the Compound and its use for any therapeutic indications, and registration dossiers to the extent owned by ASSIGNOR as of the Closing Date. Transferred Know How shall further include all proprietary information, inventions, documents and materials (whether patentable or unpatentable), which relate to the Compound, their formulations and dosage forms. Without limiting the generality of the definition set forth in this Section 1.16, the Transferred Know How as of the Effective Date is described in more detail in Exhibit 1.16 hereto.

1.17 "**Transferred Patent Rights**" shall mean any and all rights, as of the Closing Date and in future, in (i) the patent applications listed in Exhibit 1.17 hereto, (ii) any and all patent applications which claim priority of the patent applications listed in Exhibit 1.17 hereto, (iii) any and all patents granted pursuant to the patent applications referred to in (i) and (ii) above, (iv) any and all reissues, substitutions, continuations, divisions, continuation-in-part applications, as well as patents granted on the aforementioned, based on and including any subject matter claimed in any of the aforementioned patent applications and/ or patents, and (v) any and all extensions of term of the patents referred to in (iii) and (iv) above (including but not limited to supplementary protection certificates). Hereunder, “patent” shall be inclusive of intellectual rights assets conferring similar rights as a patent, such as utility models.

1.18 **"Valid Claim"** shall mean any claim of an issued and unexpired Transferred Patent Right, which has not been held unenforceable or invalid by a court or other governmental agency of competent jurisdiction in a decision that is not appealed or cannot be appealed, and which has not been disclaimed or admitted to be invalid or unenforceable through reissue or otherwise; as well as any pending claim in a pending patent application within the Transferred Patent Rights.

2. Assignment and Transfer of the Transferred Patent Rights and the Transferred Know How

2.1 Effective as of the Closing Date and subject to the fulfillment of the Parties' obligations set forth in Section 3.1 below, ASSIGNOR hereby assigns and transfers to ASSIGNEE, and ASSIGNEE hereby accepts the assignment and transfer of the whole property, right, title and interest in and to the Transferred Patent Rights and the Transferred Know How, such assignment and transfer becoming effective on the Closing Date. ASSIGNOR hereby acknowledges and agrees that ASSIGNEE is free to use all Transferred Patent Rights and Transferred Know How for any purpose whatsoever, to exploit such Patent Rights and Know How by any means whatsoever and to disclose such Know How to Third Parties without restrictions. Notwithstanding the foregoing assignment, in the event that the Closing is not consummated within [***] calendar days from the Effective Date, ASSIGNOR shall have the right, in its sole discretion, to terminate this Agreement including all obligations of ASSIGNOR and all rights of ASSIGNEE set forth in this Agreement.

2.2 The assignment and transfer also includes any current and future claims vis-à-vis Third Parties arising from the permitted or unpermitted use or exploitation or the violation of the Transferred Patent Rights, in particular including any license fees, milestone payments, damage claims, claims for injunction, claims for destruction, claims for information, and claims on account of unjust enrichment in case of violation of Transferred Patent Rights.

2.3 ASSIGNOR hereby undertakes to, and to ensure that its employees, assist and execute all such further documents, forms and authorisations as may be required to vest the whole property, right, title and interest in and to the Transferred Patent Rights in ASSIGNEE or any Third Party transferee designated by ASSIGNEE upon the Closing Date, including but not limited to registration of ASSIGNEE's or such Third Party's title as proprietor at the relevant patent offices anywhere in the world and to assist in the resolution of any question concerning ownership of the Transferred Patent Rights. ASSIGNOR will provide to ASSIGNEE such assistance as ASSIGNEE may reasonably require, including but not limited to executing all such further documents, forms and authorisations as may be required, to enable ASSIGNEE to prosecute and maintain the Transferred Patent Rights during the period when the assignment of the Transferred Patent Rights to ASSIGNEE or a Third Party pursuant to Section 2.1 is being registered at the relevant patent offices.

2.4 Within [***] days of the Closing Date, ASSIGNOR will deliver to ASSIGNEE all documents in its possession relating to the Transferred Patent Rights, including but not limited to copies of all correspondence to which ASSIGNOR is a party in relation to the prosecution and/ or maintenance of the Transferred Patent Rights. Upon the Closing Date, ASSIGNOR will instruct its patent agents and foreign correspondents as well as any other parties retained in connection with the prosecution and/ or maintenance of the Transferred Patent Rights that all records and correspondence, including such with the patent offices, ASSIGNOR or any patent agent and any foreign correspondent relating to the Transferred Patent Rights are, as from the Closing Date, to be held to the order of ASSIGNEE. ASSIGNEE will bear all costs and fees invoiced by the relevant patent offices associated with the assignment and transfer of the Transferred Patent Rights. ASSIGNEE further agrees to reimburse ASSIGNOR all reasonable expenses ASSIGNOR incurs with external patent agent and foreign correspondents relating to the Transferred Patent Rights up to a maximum amount of [***] € ([***] Euros).

2.5 If ASSIGNEE reasonably believes that the data in its possession is incomplete, it shall provide written notice thereof to ASSIGNOR, and ASSIGNOR shall furnish additional copies of the Transferred Know How to ASSIGNEE within [***] days after receipt of ASSIGNEE's written notice. ASSIGNOR shall use its best efforts to answer all questions regarding the Transferred Know How received from ASSIGNEE or any Third Party owner of the Transferred Know How. ASSIGNEE is the unrestricted owner of all Transferred Know How and is free to use and disclose such Transferred Know How in its sole discretion.

2.6 Approximately [***] of PP-001 are held by ASSIGNOR upon the Effective Date. ASSIGNOR will transfer this amount of PP-001 to ASSIGNEE at [***] after the Closing Date.

3. PAYMENTS

3.1 In consideration for the assignment and the transfer of Transferred Know How and the Transferred Patent Rights under this Agreement, ASSIGNEE agrees to pay to ASSIGNOR net as follows:

(i) On any lump sum or other consideration received by ASSIGNEE which is derived from the Licensing of Transferred Patent Rights including, but not limited to, sublicense fees, development milestones, commercial milestones or other payments (for the avoidance of doubts excluding research funding or other type of reimbursement for research activities and royalties)

(y) where such license has been executed before a Clinical Proof of Concept: [***]% and

(z) where such license has been executed after a Clinical Proof of Concept: [***]%

whereas the total aggregated amount payable to ASSIGNOR by ASSIGNEE according to sections 3.1(i)(y) and 3.1(i)(z) shall not exceed [***] € ([***] Euro), and

(ii) Independently from the license payments as set forth under 3.1, ASSIGNEE shall pay to ASSIGNOR a running royalty rate of [***]% ([***] percent) on Net Sales (including for the avoidance of doubt those of Licensee(s)) during the applicable Royalty Term.

In the event that in a country in the Territory, as documented by an independent Third Party market research firm, one or more generic products with respect to Compound are sold by any person or entity other than ASSIGNEE and/or its Licensee(s) and the sales of such generic product in such country during a calendar year are in the aggregate (on a unit equivalent basis) more than [***]percent ([***]%) of the entire combined market for such Compound and such generic product in such country during such calendar year, then the applicable royalty rate set forth in this section (ii) shall be reduced by [***] percent ([***]%) for that particular country; provided however that royalties already paid by ASSIGNEE shall not be reimbursed by ASSIGNOR.

Upon the expiration of the applicable Royalty Term, the assignment under Section 2.1 in the applicable country will become fully-paid for the applicable Compound. These financial terms are explicit and exclude any future cost sharing.

The Parties have evaluated the payments set out above before entering into this Agreement and have considered such payments to be at arm's length and in conformity with Austrian capital maintenance rules. The Parties will evaluate the amount of these payments from time to time and reduce the amount of any payments which, in future, turn out not to be at arm's length for whatever reason. The Parties agree that this Agreement and the payments from ASSIGNEE to ASSIGNOR hereunder shall at any time be interpreted in view to fulfil the arm's length principle and therefore, if required to be considered at arm's length, the amount of the payments shall be deemed to be reduced accordingly.

3.2 ASSIGNEE will inform ASSIGNOR within [***] days after it has received any income that triggers a payment under section 3.1(i) and will pay the resulting amount to ASSIGNOR within [***] days after collection of such income.

3.3 Running royalties payable by ASSIGNEE under Section 3.1(ii) shall be payable on a [***]basis, within [***] days after the end of each [***], based upon the aggregate Net Sales during such [***]. Only one royalty payment shall be due on Net Sales even though the sale or use of the Compound may be covered by more than one Transferred Patent Rights or item of Transferred Know How in a country.

3.4 At the request of either Party, the Parties shall meet and confer in good faith with respect to which, if any, invoices shall be issued by ASSIGNOR to ASSIGNEE in connection with payments owed by the paying party to the payment receiving party under this Section 3.

3.5 Each royalty payment hereunder shall be accompanied by a statement in sufficient detail to allow for the calculation of royalties due hereunder, including by showing, to the extent possible, country-by country and broken out by month (v) invoiced sales and Net Sales, (w) the number of units of Compound sold in such country during such calendar quarter and the country(ies) in which such Compound was manufactured, (x) a detailed breakdown of any deductions from the invoiced sales to obtain Net Sales (y) the amount of royalties due on such Net Sales, and (z) for the entire applicable territory, the aggregated annual Net Sales to date.

3.6 All payments to be made by ASSIGNEE under this Section 3 are fully-earned, non-refundable, non-creditable and non-cancelable upon expiry or termination of this Agreement for any reason whatsoever. Nothing in this Section 3.6 shall be deemed to limit either Party's right to claim damages against the other Party in case of breach of this Agreement or for other causes of action or inaction.

3.7 Payment Terms.

(a) All payments by ASSIGNEE to ASSIGNOR under this Section 3 shall be made in Euros to the following account, unless indicated otherwise after the Effective Date or in an applicable invoice – free of bank charges, transfer fees or similar charges:
Owner: [***]
Bank Institute: [***]
BIC Code: [***]
IBAN: [***]

(b) All payments by one Party to the other shall be made in full, without any deductions (subject to section 3.7(e) below), and are exclusive of value added taxes, which shall, if applicable, be invoiced separately.

(c) If any Net Sale are received in any currency other than Euro, for purposes of calculating the payment payable to ASSIGNOR, such Net Sales shall be converted into Euros at the conversion rate as quoted by the European Central Bank on the last business day of the calendar month in which such Net Sales were received by ASSIGNEE.

(d) If ASSIGNEE fails to make a timely payment pursuant to the terms of this Agreement, ASSIGNOR shall provide written notice of such failure to ASSIGNEE and interest shall accrue on the past due amount starting on the date of such notice at the [***] rate, plus [***] percent per annum, computed for the actual number of days after the date of such notice that the payment was past due and calculated on a daily basis.

(e) For all payments to be made under this section 3, ASSIGNEE shall withhold taxes and other duties payable under applicable Laws and Regulations and shall forward such retained payments to the competent tax authorities, however, only if all of the following conditions are met:

(i) the respective tax is an income tax and no use tax, franchise tax, sales tax or other tax; and

(ii) ASSIGNOR is the debtor of such income taxes under applicable laws and regulations; and

(iii) ASSIGNEE is required by laws and regulations to withhold the tax and to forward such tax to the competent tax authorities; and

(iv) ASSIGNEE provides ASSIGNOR a tax certificate of withheld and paid taxes.

ASSIGNEE shall reasonably assist ASSIGNOR in obtaining relief or exemption from any tax on all of the amounts and royalties under any applicable tax treaty.

(f) All other taxes and duties payable hereunder shall be paid by ASSIGNEE.

3.8 Book Keeping and Auditing. Until the expiration of ASSIGNEE's obligations to make payments under this Agreement and for a term of [***] years thereafter, ASSIGNEE shall maintain complete and accurate books and records of account, in accordance with generally accepted account principles, of all transactions and other business activities under this Agreement, sufficient to confirm the accuracy of all reports and payments furnished by ASSIGNEE to ASSIGNOR under this Section 3. Upon ASSIGNOR's reasonable written notice to ASSIGNEE, during normal business hours and not more than once every calendar year, a certified public accountant designated by ASSIGNOR and reasonably acceptable to ASSIGNEE shall have the right to audit such books and records of account of ASSIGNEE (provided always that such certified public accountant enters into an appropriate confidentiality agreement with ASSIGNEE), in order to confirm the accuracy and completeness of all such reports and all such payments; provided that, the ASSIGNOR may only audit transactions that occurred within the [***] years immediately prior to the date of the audit. Such certified public accountant may disclose to ASSIGNOR only whether such reports and payments are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to ASSIGNOR. ASSIGNOR shall bear all costs and expenses incurred in connection with any such audit; *provided, however,* that if any such audit reveals a variance of [***]percent ([***]%) or more between the amount of payments actually due and the amount of payments made to ASSIGNOR in any calendar quarter, then, in addition to paying the full amount of such underpayment, plus accrued interest, ASSIGNEE shall reimburse ASSIGNOR's reasonable out-of-pocket costs and expenses incurred in conducting such audit.

4. Prosecution, Maintenance and Defense of the Transferred Patent Rights

4.1 As of the Closing Date, ASSIGNEE shall take over all costs of and be solely responsible for prosecuting and maintaining the Transferred Patent Rights. ASSIGNOR hereby acknowledges that ASSIGNEE will be the owner of the Transferred Patent Rights and ASSIGNOR shall retain no rights, title or interest whatsoever in or to any of the Transferred Patent Rights. For the avoidance of doubt, ASSIGNEE is entitled to abandon any or all Transferred Patent Right in its sole discretion. Without limiting the generality of this Section 4.1, ASSIGNOR shall not utilize any of the Transferred Patent Rights for any purpose whatsoever, shall not register or attempt to register, any of the Transferred Patent Rights, or otherwise assert any ownership rights with respect to any of the Transferred Patent Rights.

4.2 The Parties explicitly agree that ASSIGNEE does not assume any obligation under the German Act on Employee Inventions (Gesetz über Arbeitnehmererfindungen) regarding the Transferred Patent Rights. ASSIGNOR shall indemnify ASSIGNEE against any claim brought by a Third Party under such Act, including but not limited to claims for employee compensation.

5. Confidential Information

5.1 All Confidential Information disclosed, revealed or otherwise made available by one Party ("**Disclosing Party**") to the other Party ("**Receiving Party**") under, or as a result of, this Agreement is furnished to the Receiving Party solely to permit the Receiving Party to exercise its rights, and perform its obligations, under this Agreement. The Receiving Party shall not use any of the Disclosing Party's Confidential Information for any other purpose, and shall not disclose, reveal or otherwise make any of the Disclosing Party's Confidential Information available to any other person, firm, corporation or other entity, without the prior written authorization of the Disclosing Party. For the avoidance of doubt, this provision shall not restrict ASSIGNEE'S right to use, exploit and disclose the Transferred Know How as stipulated in above section 2.1.

5.2 In furtherance of the Receiving Party's obligations under Section 5.1 hereof, the Receiving Party shall take all appropriate steps, and shall implement all appropriate safeguards, to prevent the unauthorized use or disclosure of any of the Disclosing Party's Confidential Information. Without limiting the generality of this Section 5.2, the Receiving Party shall disclose any of the Disclosing Party's Confidential Information only to those of its officers, employees, directors, consultants, Licensees, (sub)licensees, other representatives and financial investors that have a need to know the Disclosing Party's Confidential Information, in order for the Receiving Party to exercise its rights and perform its obligations under this Agreement, and only if such officers, employees, directors, consultants, Licensees, (sub)licensees, other representatives and financial investors have executed appropriate non-disclosure agreements containing substantially similar terms regarding confidentiality as those set out in this Agreement or are otherwise bound by obligations of confidentiality effectively prohibiting the unauthorized use or disclosure of the Disclosing Party's Confidential Information. The Receiving Party shall furnish the Disclosing Party with immediate written notice of any unauthorized use or disclosure of any of the Disclosing Party's Confidential Information by any officers, employees, directors, consultants, Licensees, (sub)licensees, other representatives and financial investors of the Receiving Party, and shall take all actions that the Disclosing Party reasonably requests in order to prevent any further unauthorized use or disclosure of the Disclosing Party's Confidential Information.

5.3 The Receiving Party's obligations under Sections 5.1 and 5.2 hereof shall not apply to the extent that any of the Disclosing Party's Confidential Information:

(a) passes into the public domain, or becomes generally available to the public through no fault of the Receiving Party;

(b) was known to the Receiving Party prior to disclosure hereunder by the Disclosing Party;

(c) is disclosed, revealed or otherwise made available to the Receiving Party by a Third Party that is under no obligation of non-disclosure and/or non-use to the Disclosing Party; or

(d) is required to be disclosed under applicable law; provided, however, that the Receiving Party shall furnish the Disclosing Party's with as much prior written notice of such disclosure requirement as reasonably practicable, so as to permit the Disclosing Party, in its sole discretion, to take appropriate action, including seeking a protective order, in order to prevent the Disclosing Party's Confidential Information from passing into the public domain or becoming generally available to the public.

5.4 The obligation of confidentiality with respect to any Confidential Information other than Transferred Know How shall remain in effect for a term of [***] years after the Effective Date, provided that ASSIGNEE is entitled to limit such term to a minimum term of [***] years if ASSIGNEE is unable to agree on a [***] years term with a potential licensee of the Transferred Patent Rights and the Transferred Know How. ASSIGNOR's obligation of confidentiality with respect to Transferred Know How is not limited in time and is subject only to Section 5.3 above.

6. CONTRACTS EXISTING BEFORE THE EFFECTIVE DATE

6.1 Exhibit 6.1 contains a list of contracts that were signed by ASSIGNOR and which relate to the Compounds. It is explicitly understood by the Parties that Exhibit 6.1 does not include contracts with service providers that were contracted by ASSIGNOR to perform services in relation to the Compounds. ASSIGNOR will – to the extend legally possible – assign ASSIGNEE with the active contracts, i.e. the agreements with

(i) [***], and

(ii) [***] and

(iii) [***].

In case an assignment is not possible for whatever, then ASSIGNOR will terminate these contracts and reasonably support ASSIGNEE in arranging the discussions to enter into new contractual relationships with these parties.

6.2 ASSIGNOR agrees to provide ASSIGNEE copies of the contracts listed in Section 6.1.

6.3 ASSIGNOR agrees not to actively terminate the collaboration with NIAID that is disclosed in Exhibit 6.1. In case ASSIGNOR receives further data from NIAID then ASSIGNOR will make available such data to ASSIGNEE without undue delay and such data will be considered as Transferred Know How.

6.4 After the Effective Date ASSIGNOR will not enter into new contracts with Third Parties which relate to the Compounds.

7. WARRANTIES AND LIABILITIES

7.1 ASSIGNOR warrants and represents to ASSIGNEE that in all cases as of the Effective Date:

(a) it owns the entire right, title and interest in the Transferred Patent Rights and the Transferred Know How, and has the full power, right and authority to enter into this Agreement, to assign the Transferred Patent Rights and the Transferred Know How to ASSIGNEE pursuant to Section 2.1;

(b) to the best of its knowledge the Transferred Patent Rights and the Transferred Know How are free of any encumbrances;

(c) to the best of its knowledge it has not granted licenses or similar rights for co-development or development or commercialization or co-marketing or other exploitation to Third Parties;

(d) subject only to Exhibit 7.1 hereto, it has no knowledge from which it can be inferred that the Transferred Patent Rights are invalid or that the use of the Transferred Patent Rights and the Transferred Know How would infringe any patent rights or other intellectual property rights of Third Parties or that the Transferred Patent Rights and the Transferred Know How do not infringe any patent rights of ASSIGNOR or its Affiliates; and

(e) all fees payable in respect of the Transferred Patent Rights, including but not limited to the application and renewal fees, have been duly paid in time and ASSIGNOR has done everything necessary to prosecute such patent applications, and subject only to Exhibit 7.1 hereto so far as ASSIGNOR is aware, there are no facts which could undermine or reduce the scope of protection of any patents arising from such patent applications.

7.2 Any new knowledge of ASSIGNOR between the Effective Date and the Closing Date relating to the warranties and representations by ASSIGNOR in accordance to Section 7.1 shall be disclosed to ASSIGNEE without undue delay. In the event that this new knowledge materially adversely affects the warranties and representations by ASSIGNOR in accordance to Section 7.1 ASSIGNEE shall have the right, in its sole discretion, to terminate this Agreement including all obligations of ASSIGNOR and all rights of ASSIGNEE set forth in this Agreement.

7.3 ASSIGNOR makes no representation or warranty and specifically disclaims any guarantee that the development of Contract Products will be successful, in whole or in part, or that the Transferred Patent Rights and the Transferred Know How will be suitable for commercialization. Other than as set out in Section 7.1, ASSIGNOR expressly disclaims any warranties or conditions, express, implied, statutory or otherwise with respect to the Transferred Patent Rights and the Transferred Know How, including without limitation, any warranty or merchantability of fitness for a particular purpose.

7.4 ASSIGNEE warrants and represents to ASSIGNOR that in all cases as of the Closing Date:

(a) it is a corporation or entity duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation or formation;

(b) the execution, delivery and performance of this Agreement does not conflict with any other agreement by which it is bound, and has been duly authorized by all requisite corporate or shareholder action and approval and does not require any third party consent or authorization in connections with the execution and consummation of this Agreement;

(c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and

(d) its activities under this Agreement do not violate in a material way or with material consequences any applicable laws and shall continue to do so throughout the term of this Agreement.

8. MISCELLANEOUS

8.1 All notices, reports and other communications between the Parties under this Agreement shall be sent by registered air mail, postage prepaid and return receipt requested, by international air courier, or by facsimile, with a confirmation copy sent by registered air mail or international air courier, addressed as follows:

To: ASSIGNOR
4SC Discovery GmbH
Attention: Managing Director
Am Klopferspitz 19a
82152 Martinsried
Germany

To: ASSIGNEE
Panoptes Pharma Ges. m. b. H.
Attention: Dr. Obermayr, Dr. Sperl
Stauraczgasse 7/15,
1050 Vienna
Austria

8.2 This Agreement shall be governed by, and interpreted in accordance with the laws of Germany. The validity of the intellectual property rights shall be subject to an evaluation under the law of the country in which the intellectual property rights were applied for or have been issued.

8.3 Any dispute relating to the validity, performance, construction or interpretation of this Agreement which cannot be resolved amicably between the Parties shall be submitted to binding arbitration, to be held in Munich, Germany, in accordance Arbitration Rules of the Deutsche Institution fur Schiedsgerichtsbarkeit e.V. The decision of the arbitrators in any arbitration proceeding between the Parties under this Section 8.3 shall be: (i) in writing, stating the reasons therefor; (ii) based solely on the terms and conditions of this Agreement, as interpreted in accordance with the laws of the Federal Republic of Germany; (iii) final and binding upon the Parties; and (iv) enforceable in any court of competent jurisdiction. The Parties agree that this Agreement shall be construed and interpreted in its English version only. Any translation of this Agreement into another language shall be for convenience only and shall not be used to construe and interpret this Agreement.

8.4 If any provision of this Agreement is determined by any court or administrative tribunal of competent jurisdiction to be invalid or unenforceable under applicable law, the Parties shall negotiate in good faith a replacement provision that is commercially equivalent, to the maximum extent permitted by applicable law, to such invalid or unenforceable provision. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of the other provisions of this Agreement.

8.5 This Agreement, together with all Exhibits attached hereto, constitutes the entire agreement between the Parties, and supersedes all prior agreements, understandings and communications between the Parties, with respect to the subject matter hereof. No modification or amendment of this Agreement shall be binding upon the Parties unless in writing and executed by the duly authorized representative of each of the Parties. This provision shall also apply to any change of this Section 8.5.

8.6 The failure by either Party to assert any of its rights hereunder shall not be deemed to constitute a waiver by that Party of its right thereafter to enforce each and every provision of this Agreement in accordance with its terms.

Exhibits:

Exhibit 1.16 Transferred Know How

Exhibit 1.17 List of Transferred Patent Rights

Exhibit 6.1 List of contracts with Third Parties

Exhibit 7.1 List of objections and third party rights to the Transferred Patent Rights

***** signature page follows *****

4SC Discovery GmbH

/s/ Dr. Stefan Strobl
By: Dr. Stefan Strobl
Title: Managing Director

/s/ Dr. Daniel Vitt
By: Dr. Daniel Vitt
Title: Managing Director

Panoptes Pharma Ges. m. b. H. in Gründung

/s/ Dr. Franz Obermayr
By: Dr. Franz Obermayr
Title: CEO

/s/ Dr. Stefan Sperl
By: Dr. Stefan Sperl
Title: COO

Exhibit 1.16 Transferred Know How

[***]

[***]

[***]

[***]

Exhibit 1.17 List of Transferred Patent Rights

[***]

Country	Application No.	Patent No.	4SC Ref	Boehmert Ref
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[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

[***]

Country	Application No.	Patent No.	4SC Ref	Boehmert Ref
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
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[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

Exhibit 6.1 List of contracts with Third Parties

Partner	Research topic	Active	Comment
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

[***]

Exhibit 7.1 List of objections and third party rights to the Transferred Patent Rights

[***]

[***]
[***]
[***]
[***]
[***]
[***]

Exhibit 10.23

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 [***].

Patent License Agreement

by and between

Panoptes Pharma Ges. m. b. H. in Gründung

and

4SC Discovery GmbH

2nd July 2013

THIS License Agreement is entered into effect as of 2nd July 2013 ("Effective Date") BETWEEN:

(1) Panoptes Pharma Ges. m. b. H. in Gründung, Dr. Obermayr, Dr. Sperl; Stauraczgasse 7/15, 1050 Vienna, Austria,

("**LICENSOR**");

and

(2) 4SC Discovery GmbH, Am Klopferspitz 19a, 82152 Planegg-Martinsried, Germany,

("**LICENSEE**").

RECITALS:

(A) LICENSOR has been founded to develop and commercialize the compound PP-001 (formerly SC53842) for certain eye diseases.

(B) LICENSEE is co-founder of LICENSOR.

(C) LICENSEE has assigned to LICENSOR certain know-how and patent rights to enable LICENSOR to develop and commercialize PP-001 in a separate Assignment Agreement.

(D) LICENSOR is willing to grant LICENSEE a defined license to that certain know-how and patent rights that have been assigned to LICENSOR by LICENSEE in accordance with the Assignment Agreement (as defined below) to protect certain of LICENSEE's business interests.

(E) NOW, THEREFORE, LICENSEE and LICENSOR hereby agree as follows:

1. DEFINITIONS

For purposes of this Agreement, the following terms shall have the following meanings:

1.1 "**Affiliate**" shall mean and include in relation to each Party, any person, firm, corporation or other entity: (i) if at least fifty percent (50%) of the voting stock or other equity interest thereof is owned, directly or indirectly, by that Party; (ii) which owns, directly or indirectly, at least fifty percent (50%) of the voting stock or other equity interest of that Party; or (iii) if at least fifty percent (50%) of the voting stock or other equity interest thereof is owned, directly or indirectly, by a person, firm, corporation or other entity that owns, directly or indirectly, at least fifty percent (50%) of the voting stock or other equity interest of that Party provided, however, that Santo Holding (Deutschland) GmbH, a financial investor in LICENSOR, and any affiliates of Santo Holding (Deutschland) GmbH shall not be considered Affiliates for purposes of this Agreement.

1.2 "**Agreement**" shall mean this License Agreement and all Exhibits attached hereto, and the terms "herein", "hereunder", "hereto" and such similar expressions shall refer to this Agreement.

1.3 "**Assignment Agreement**" shall mean the Patent and Know How Assignment Agreement between the Parties that came into effect on 2nd July 2013.

1.4 "**Closing Date**" of this Agreement shall mean the date when all of the following conditions have been met:

(a) Foundation of LICENSOR as evidenced by a notary public and

(b) signing of a shareholder agreement between the founding shareholders 4SC, Dr. Stefan Sperl, Dr. Franz Obermayr and Dr. Bernd Mühlenweg and

(c) nomination of Dr. Franz Obermayr and Dr. Stefan Sperl as managing directors of LICENSOR and

(d) closing of the Assignment Agreement as described therein and

(e) approval of this Agreement by the shareholders of LICENSOR and

(f) obtaining a written statement by [***] that all conditions according to their letter dated March 07, 2013 have been fulfilled and that LICENSOR will be funded with [***] € and

(g) issuance of a letter by LICENSOR to LICENSEE indicating that all of the conditions according to this Section 1.4 have been met, and also indicating the Closing Date.

1.5 "**Compound**" shall mean PP-001 and/or any other substance and/or therapeutic product covered by the Licensed Patent Rights.

1.6 "**Confidential Information**" shall mean and include all know how including the Licensed Know How, data and information, not in the public domain, relating to Compound and the business, affairs, research and development activities, products, results of clinical trials, national and multinational regulatory proceedings and affairs, finances, plans, contractual relationships and operations of the Parties. Confidential Information shall also include the existence and terms of this Agreement.

1.7 "**Effective Date**" of this Agreement shall mean the date in the recitals.

1.8 "**Field**" shall mean the indications rheumatoid arthritis (ICD-10: M05 – M06) and inflammatory bowel disease (including Crohn's disease (ICD-10: K50) and ulcerative colitis (ICD-10: K51)).

1.9 "**Licensed Know How**" shall include all specifications, results and reports of clinical studies and all other documentation containing or embodying any data, including pre-clinical, clinical and CMC data relating to the application for regulatory approval for the Compound, and registration dossiers to the extent owned by LICENSOR as of the Closing Date. Licensed Know How shall further include all proprietary information, inventions, documents and materials (whether patentable or unpatentable), which relate to the Compound, their formulations and dosage forms. Without limiting the generality of the definition set forth in this Section 1.9, the Licensed Know How as of the Effective Date is described in more detail in Exhibit 1.9 hereto.

1.10 "**Licensed Patent Rights**" shall mean any and all rights, as of the Closing Date and in future, in (i) the patent applications listed in Exhibit 1.10 hereto, (ii) any and all patent applications which claim priority of the patent applications listed in Exhibit 1.10 hereto, (iii) any and all patents granted pursuant to the patent applications referred to in (i) and (ii) above, (iv) any and all reissues, substitutions, continuations, divisions, continuation-in-part applications, as well as patents granted on the aforementioned, based on and including any subject matter claimed in any of the aforementioned patent applications and/ or patents, and (v) any and all extensions of term of the patents referred to in (iii) and (iv) above (including but not limited to supplementary protection certificates). Hereunder, "patent" shall be inclusive of intellectual rights assets conferring similar rights as a patent, such as utility models.

1.11 "**Net Sales**" shall be calculated in accordance with international financial reporting standards (IFRS) and shall mean with respect to any Compound, the gross invoiced sales of such Compound by LICENSEE in the Field in the Territory, less the following amounts actually deducted or allowed:

(a) [***];

(b) [***];

(c) [***];

(d) [***]; and

(e) [***].

1.12 "**Party**" or "**Parties**" shall mean LICENSOR or LICENSEE, or LICENSOR and LICENSEE, whichever the context admits.

1.13 "**PP-001**" shall mean the chemical compound 3-(2,3,5,6-Tetrafluoro-3`-(trifluoromethoxy) biphenyl-4-ylcarbamoyl)thiophene-2-carboxylic acid which was formerly developed by LICENSEE under the name of SC53842.

1.14 **"Royalty Term"** shall mean, on a country-by-country and Compound-by-Compound basis, the period of time beginning upon the date of first commercial sale of a Compound in that country, and ending upon the later to occur of (i) the expiration of the last Valid Claim of a Licensed Patent Right covering such Compound in such country, or (ii) ten (10) years from the first commercial sale of the Compound in such country.

1.15 "**Territory**" shall mean the entire world.

1.16 "**Third Party**" shall mean any other party that is independent from LICENSOR and its Affiliates and LICENSEE and its Affiliates.

1.17 **"Valid Claim"** shall mean any claim of an issued and unexpired Licensed Patent Right, which has not been held unenforceable or invalid by a court or other governmental agency of competent jurisdiction in a decision that is not appealed or cannot be appealed, and which has not been disclaimed or admitted to be invalid or unenforceable through reissue or otherwise; as well as any pending claim in a pending patent application within the Licensed Patent Rights.

2. Licensing of the Licensed Patent Rights and the Licensed Know How

2.1 Subject to the terms of this Agreement, LICENSOR hereby grants to LICENSEE as of the Closing Date and LICENSEE hereby accepts, the exclusive (even as to Licensor), perpetual and irrevocable (subject to Sections 2.4 and 3.1) license under and to the Licensed Know How and Licensed Patent Rights in order to develop and/or commercialize the Compounds within the Field in the Territory

2.2 LICENSOR shall execute all documents, give all declarations regarding the licenses granted hereunder and reasonably cooperate with LICENSEE at the costs of LICENSEE to the extent such documents, declarations and/or cooperation are required for the recordation or registration of the license granted hereunder at competent patent offices in the Territory.

2.3 Except as expressly set forth therein, LICENSOR grants no other right or license under, and reserves all right, title and interest in and to the Licensed Know How and Licensed Patent Rights. LICENSOR reserves all rights not explicitly granted herein.

2.4 LICENSOR may at any time, but in no case earlier than [***] years after the Closing Date, request in writing that LICENSOR may buy back from LICENSEE the license granted under this Agreement to LICENSEE. If LICENSOR makes such request to LICENSEE then LICENSEE agrees to consider such request in good faith and to enter into appropriate negotiations with LICENSOR about the price to buy back the license contemplated under this Agreement.

2.5 Future improvements, technology or proprietary information relating to the Licensed Know How and Licensed Patent Rights reduced to practice by either Party shall be exchanged between the Parties if requested by any Party (but not more than twice per year).

3. Payments

3.1 In consideration for the license to the Licensed Know How and Licensed Patent Rights under this Agreement, LICENSEE agrees to pay to LICENSOR net as follows:

i. Milestone payment for reaching the following development events within the Field

Milestone	**Amount in € (million)**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

ii. Independently from the milestone payments as set forth under 3.1(i), LICENSEE shall pay to LICENSOR a running royalty rate of [***] % ([***] percent) on Net Sales during the applicable Royalty Term.

In the event that in a country in the Field in the Territory, as documented by an independent Third Party market research firm, one or more generic products with respect to Compound are sold by any person or entity other than LICENSEE and the sales of such generic product in such country during a calendar year are in the aggregate (on a unit equivalent basis) more than [***] percent ([***] %) of the entire combined market for such Compound and such generic product in such country during such calendar year, then the applicable royalty rate set forth in this section 3.1(ii) shall be reduced by [***] percent ([***] %) for that particular country; provided however that royalties already paid by LICENSEE shall not be reimbursed by LICENSOR.

Upon the expiration of the applicable Royalty Term, the license under Section 2.1 in the applicable country will become fully-paid for the applicable Compound. These financial terms are explicit and exclude any future cost sharing.

3.2 LICENSEE will inform LICENSOR within [***] days after it has met any milestone that triggers a payment under Section 3.1(i) and will pay the resulting amount to LICENSOR within [***] days after meeting such milestone.

3.3 Running royalties payable by LICENSEE under Section 3.1(ii) shall be payable on a [***] basis, within [***] days after the end of each [***], based upon the aggregate Net Sales during such [***]. Only one royalty payment shall be due on Net Sales even though the sale or use of the Compound may be covered by more than one Licensed Patent Rights or item of Licensed Know How in a country.

3.4 At the request of either Party, the Parties shall meet and confer in good faith with respect to which, if any, invoices shall be issued by LICENSOR to LICENSEE in connection with payments owed by the paying party to the payment receiving party under this Section 3.

3.5 Each royalty payment hereunder shall be accompanied by a statement in sufficient detail to allow for the calculation of royalties due hereunder, including by showing, to the extent possible, country-by-country and broken out by month (v) invoiced sales and Net Sales, (w) the number of units of Compound sold in such country during such calendar quarter and the country(ies) in which such Compound was manufactured, (x) a detailed breakdown of any deductions from the invoiced sales to obtain Net Sales (y) the amount of royalties due on such Net Sales, and (z) for the entire applicable territory, the aggregated annual Net Sales to date.

3.6 All payments to be made by LICENSEE under this Section 3 are fully-earned, non-refundable, non-creditable and non-cancelable upon expiry or termination of this Agreement for any reason whatsoever. Nothing in this Section 3.6 shall be deemed to limit either Party's right to claim damages against the other Party in case of breach of this Agreement or for other causes of action or inaction.

3.7 Payment Terms.

(a) All payments by LICENSEE to LICENSOR under this Section 3 shall be made in Euros, free of bank charges, transfer fees or similar charges. LICENSOR will inform LICENSEE about its account details in sufficient time to allow a timely payment by LICENSEE. In case LICENSOR does not inform LICENSEE in a timely manner then LICENSEE shall not be obliged to pay interest according to Section 3.7(d) until [***] days after receipt of the bank account of LICENSOR.

(b) All payments by one Party to the other shall be made in full, without any deductions (subject to section 3.7(e) below), and are exclusive of value added taxes, which shall, if applicable, be invoiced separately.

(c) If any Net Sale are received in any currency other than Euro, for purposes of calculating the payment payable to LICENSOR, such Net Sales shall be converted into Euros at the conversion rate as quoted by the European Central Bank on the last business day of the calendar month in which such Net Sales were received by LICENSEE.

(d) If LICENSEE fails to make a timely payment pursuant to the terms of this Agreement, LICENSOR shall provide written notice of such failure to LICENSEE and interest shall accrue on the past due amount starting on the date of such notice at the [***] rate, plus [***] percent per annum, computed for the actual number of days after the date of such notice that the payment was past due and calculated on a daily basis.

(e) For all payments to be made under this section 3, LICENSEE shall withhold taxes and other duties payable under applicable Laws and Regulations and shall forward such retained payments to the competent tax authorities, however, only if all of the following conditions are met:

(i) the respective tax is an income tax and no use tax, franchise tax, sales tax or other tax; and

(ii) LICENSOR is the debtor of such income taxes under applicable laws and regulations; and

(iii) LICENSEE is required by laws and regulations to withhold the tax and to forward such tax to the competent tax authorities; and

(iv) LICENSEE provides LICENSOR a tax certificate of withheld and paid taxes.

LICENSEE shall reasonably assist LICENSOR in obtaining relief or exemption from any tax on all of the amounts and royalties under any applicable tax treaty.

(f) All other taxes and duties payable hereunder shall be paid by LICENSEE.

3.8 Book Keeping and Auditing. Until the expiration of LICENSEE's obligations to make payments under this Agreement and for a term of [***] years thereafter, LICENSEE shall maintain complete and accurate books and records of account, in accordance with generally accepted account principles, of all transactions and other business activities under this Agreement, sufficient to confirm the accuracy of all reports and payments furnished by LICENSEE to LICENSOR under this Section 3. Upon LICENSOR's reasonable written notice to LICENSEE, during normal business hours and not more than once every calendar year, a certified public accountant designated by LICENSOR and reasonably acceptable to LICENSEE shall have the right to audit such books and records of account of LICENSEE (provided always that such certified public accountant enters into an appropriate confidentiality agreement with LICENSEE), in order to confirm the accuracy and completeness of all such reports and all such payments; provided that, the LICENSOR may only audit transactions that occurred within the [***] years immediately prior to the date of the audit. Such certified public accountant may disclose to LICENSOR only whether such reports and payments are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to LICENSOR. LICENSOR shall bear all costs and expenses incurred in connection with any such audit; *provided, however,* that if any such audit reveals a variance of [***] percent ([***]%) or more between the amount of payments actually due and the amount of payments made to LICENSOR in any calendar quarter, then, in addition to paying the full amount of such underpayment, plus accrued interest, LICENSEE shall reimburse LICENSOR's reasonable out-of-pocket costs and expenses incurred in conducting such audit.

4. Prosecution, Maintenance and Defence of the Licensed Patent Rights

4.1 LICENSOR shall be responsible to prosecute and maintain the Licensed Patent Rights.

4.2 If either LICENSOR or LICENSEE becomes aware of any infringement of any issued patent within the Licensed Patent Rights in the Territory in the Field, it will promptly notify the other Party to that effect. LICENSOR shall at its costs have the first right to take actions, in the courts, administrative agencies, or otherwise, including a settlement, to prevent or enjoin any and all such infringements and other unauthorized uses of the Licensed Patent Rights in the Field in the Territory.

4.3 LICENSEE shall take no action with respect to any such infringement or unauthorized use of Licensed Patent Rights, without the prior written authorization of LICENSOR; provided, however, that Licensee shall provide at the reasonable request and at LICENSOR's cost such assistance as LICENSOR shall reasonably request in connection with any action to prevent or enjoin any such infringement or unauthorized use of any of Licensed Patent Rights in the Field in the Territory. In the event Licensor is unable or unwilling to sue the alleged infringer in the Territory within (i) [***] days of the date of notice of such infringement, or (ii) [***] days before the time limit, if any, set forth in applicable laws and regulations for the filing of such actions, whichever comes first, LICENSEE may, but shall not be obligated to, take such action as LICENSEE may deem appropriate to prevent, enjoin or otherwise address the alleged infringement or threatened infringement of a Licensed Patent Right in the Field in the Territory. In such event, LICENSEE shall act at its own expense, and LICENSOR shall co-operate reasonably with LICENSEE, at the expense of LICENSEE in prosecuting such action. Any recovery obtained as a result of any proceeding against a Third Party infringer in the Field in the Territory shall be allocated as follows:

(a) the recovery shall first be used to reimburse each Party for all litigation costs in connection with such litigation paid by that Party; and

(b) each Party shall receive [***] percent ([***]%) of any recovery remaining after payment of the amounts specified in clause (i) above; provided that, if LICENSOR is unwilling or unable to prosecute such action and LICENSEE elects to prosecute such action, LICENSEE shall receive [***] percent ([***]%) of any recovery remaining after payment of the amounts specified in clause (i) above.

(c) For the avoidance of doubt, any right for LICENSEE to take action under this Section 4.3 is limited to the Field in the Territory.

4.4 Each Party shall promptly notify the other in writing (i) of any suspected or threatened infringement of a Licensed Patent Rights by a Third Party in the Field in the Territory, (ii) of any known or suspected unauthorized use or misappropriation by a Third Party of any Licensed Patent Rights in the Field in the Territory, and (iii) of any assertion or claim of alleged patent infringement by LICENSEE with respect to the exploitation of the Compounds in the Field in the Territory, and shall provide the other Party with all evidence in its possession that tends to prove the Third Party infringement or unauthorized use or misappropriation described in clauses (i) or (ii); or that tends to negate the alleged infringement described in clause (iii); in the case of each of clauses (i), (ii) and (iii), to the extent such Party becomes aware of it. The Parties shall promptly advise the other Party of any events outside the Field in the Territory of which it becomes aware that may have a material bearing on the validity or enforceability of the Licensed Patent Rights in the Field in the Territory.

4.5 If the development, commercialization or other exploitation of the Licensed Patent Rights is alleged by a Third Party to infringe a Third Party's patent right in the Field in the Territory or in a certain country of the Territory, the Party becoming aware of such allegation shall promptly notify the other Party.

5. CONFIDENTIAL INFORMATION

5.1 All Confidential Information disclosed, revealed or otherwise made available by one Party ("**Disclosing Party**") to the other Party ("**Receiving Party**") under, or as a result of, this Agreement is furnished to the Receiving Party solely to permit the Receiving Party to exercise its rights, and perform its obligations, under this Agreement. The Receiving Party shall not use any of the Disclosing Party's Confidential Information for any other purpose, and shall not disclose, reveal or otherwise make any of the Disclosing Party's Confidential Information available to any other person, firm, corporation or other entity, without the prior written authorization of the Disclosing Party. For the avoidance of doubt, this provision shall not restrict LICENSEE's right to use, exploit and disclose the Licensed Know How as stipulated in above section 2.1.

5.2 In furtherance of the Receiving Party's obligations under Section 5.1 hereof, the Receiving Party shall take all appropriate steps, and shall implement all appropriate safeguards, to prevent the unauthorized use or disclosure of any of the Disclosing Party's Confidential Information. Without limiting the generality of this Section 5.2, the Receiving Party shall disclose any of the Disclosing Party's Confidential Information only to those of its officers, employees, directors, consultants, Licensees, (sub)licensees, other representatives and financial investors that have a need to know the Disclosing Party's Confidential Information, in order for the Receiving Party to exercise its rights and perform its obligations under this Agreement, and only if such officers, employees, directors, consultants, Licensees, (sub)licensees, other representatives and financial investors have executed appropriate non-disclosure agreements containing substantially similar terms regarding confidentiality as those set out in this Agreement or are otherwise bound by obligations of confidentiality effectively prohibiting the unauthorized use or disclosure of the Disclosing Party's Confidential Information. The Receiving Party shall furnish the Disclosing Party with immediate written notice of any unauthorized use or disclosure of any of the Disclosing Party's Confidential Information by any officers, employees, directors, consultants, Licensees, (sub)licensees, other representatives and financial investors of the Receiving Party, and shall take all actions that the Disclosing Party reasonably requests in order to prevent any further unauthorized use or disclosure of the Disclosing Party's Confidential Information.

5.3 The Receiving Party's obligations under Sections 5.1 and 5.2 hereof shall not apply to the extent that any of the Disclosing Party's Confidential Information:

(a) passes into the public domain, or becomes generally available to the public through no fault of the Receiving Party;

(b) was known to the Receiving Party prior to disclosure hereunder by the Disclosing Party;

(c) is disclosed, revealed or otherwise made available to the Receiving Party by a Third Party that is under no obligation of non-disclosure and/or non-use to the Disclosing Party; or

(d) is required to be disclosed under applicable law; provided, however, that the Receiving Party shall furnish the Disclosing Party's with as much prior written notice of such disclosure requirement as reasonably practicable, so as to permit the Disclosing Party, in its sole discretion, to take appropriate action, including seeking a protective order, in order to prevent the Disclosing Party's Confidential Information from passing into the public domain or becoming generally available to the public.

5.4 The obligation of confidentiality with respect to any Confidential Information other than Licensed Know How shall remain in effect for a term of [***] years after the Effective Date, provided that LICENSEE is entitled to limit such term to a minimum term of [***] years if LICENSEE is unable to agree on a [***] years term with a potential licensee of the Licensed Patent Rights and the Licensed Know How. LICENSOR's obligation of confidentiality with respect to Licensed Know How is not limited in time and is subject only to Section 5.3 above.

6. WARRANTIES AND LIABILITIES

6.1 LICENSOR warrants and represents to LICENSEE that in all cases as of the Closing Date:

(a) it owns the entire right, title and interest in the Licensed Patent Rights and the Licensed Know How, and has the full power, right and authority to enter into this Agreement, to license the Licensed Patent Rights and the Licensed Know How to LICENSEE pursuant to Section 2.1;

(b) to the best of its knowledge the Licensed Patent Rights and the Licensed Know How are free of any encumbrances;

(c) to the best of its knowledge it has not granted licenses or similar rights for co-development or development or commercialization or co-marketing or other exploitation to Third Parties;

(d) subject only to Exhibit 6.1 hereto, it has no knowledge from which it can be inferred that the Licensed Patent Rights are invalid or that the use of the Licensed Patent Rights and the Licensed Know How would infringe any patent rights or other intellectual property rights of Third Parties or that the Licensed Patent Rights and the Licensed Know How do not infringe any patent rights of LICENSOR or its Affiliates.

6.2 Any new knowledge of LICENSOR between the Effective Date and the Closing Date relating to the warranties and representations by LICENSOR in accordance to Section 6.1 shall be disclosed to LICENSEE without undue delay. In the event that this new knowledge materially adversely affects the warranties and representations by LICENSOR in accordance to Section 6.1 LICENSEE shall have the right, in its sole discretion, to terminate this Agreement including all obligations of LICENSOR and all rights of LICENSEE set forth in this Agreement.

6.3 LICENSOR makes no representation or warranty and specifically disclaims any guarantee that the development of Compounds will be successful, in whole or in part, or that the Licensed Patent Rights and the Licensed Know How will be suitable for commercialization. Other than as set out in Section 6.1, LICENSOR expressly disclaims any warranties or conditions, express, implied, statutory or otherwise with respect to the Licensed Patent Rights and the Licensed Know How, including without limitation, any warranty or merchantability of fitness for a particular purpose.

6.4 LICENSEE warrants and represents to LICENSOR that in all cases as of the Closing Date:

(a) it is a corporation or entity duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation or formation;

(b) the execution, delivery and performance of this Agreement does not conflict with any other agreement by which it is bound, and has been duly authorized by all requisite corporate or shareholder action and approval and does not require any third party consent or authorization in connections with the execution and consummation of this Agreement;

(c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and

(d) its activities under this Agreement do not violate in a material way or with material consequences any applicable laws and shall continue to do so throughout the term of this Agreement.

7. TERM AND TERMINATION

7.1 This Agreement will become effective on the Effective Date and will expire on a country by country basis with the expiry of the royalty payments obligations under Section 3.1(ii) above (the "**Term**"). Upon its expiration in accordance with this Section, the rights granted under Section 2.1 shall in the respective country become irrevocable, perpetual and fully paid up, unless this Agreement is terminated prematurely pursuant to Sections 6.2 or under this Section 7.

7.2 **Ordinary Termination by LICENSEE.** LICENSEE shall be entitled to terminate this License Agreement at any time for any and no reason upon [***] days prior written notice.

7.3 **Extraordinary Termination for Breach.** In the event that either Party (the "**Breaching Party**") commits a material breach or default of any of its obligations hereunder, the other Party hereto (the "**Non-Breaching Party**") may give the Breaching Party written notice of such material breach or default, and shall request that such material breach or default be cured as soon as reasonably practicable. In the event that the Breaching Party fails to cure such breach or default within [***] days after the date of the Non-Breaching Party's notice thereof (in the event of default of payment within [***] days after the date of the Non-Breaching Party's notice), the Non-Breaching Party may submit the matter to arbitration in accordance with Section 8.3. If the Breaching Party fails to cure such non-fulfilment as determined by the arbitration award within the time period set forth in the arbitration award, or if no such time period is stated within [***] days following the arbitration award, the Non-Breaching Party may terminate this Agreement with immediate effect. Termination of this Agreement in accordance with this Section 7.3 shall not affect or impair the Non-Breaching Party's right to pursue any legal remedy, including, but not limited to, the right to recover damages, for any harm suffered or incurred by the Non-Breaching Party as a result of such breach or default.

7.4 Upon termination under Section 7.3:

(a) LICENSEE's license shall immediately lapse with respect to the Field in the Territory;

(b) Immediately upon the termination of this Agreement, LICENSEE shall cease all development, commercialization and sale of the Compounds under the license granted hereunder in the Field in the Territory provided, however, that LICENSEE shall have the right to distribute and sell its existing inventory of the Compounds in the Field and in the Territory subject to LICENSEE's continuing obligation to pay royalties with respect to the Net Sales derived from the distribution and sale of such existing inventory of the Compounds.

7.5 Expiry or termination of this Agreement for any reason whatsoever shall not relieve LICENSEE of its obligations to pay all royalties and other amounts payable to LICENSOR which have accrued prior to, but remain unpaid as of, the date of expiry or termination hereof, or which accrue thereafter, in accordance with Section 7.4(b).

7.6 Sections 5, 6, 7 and 8 shall survive any termination of this Agreement. In addition, Section 3 shall survive to the extent necessary for LICENSEE to fulfil its obligations under Section 7.4(b).

8. MISCELLANEOUS

8.1 All notices, reports and other communications between the Parties under this Agreement shall be sent by registered air mail, postage prepaid and return receipt requested, by international air courier, or by facsimile, with a confirmation copy sent by registered air mail or international air courier, addressed as follows:

To LICENSOR
Panoptes Pharma Ges. m. b. H. in Gründung
Attention: Dr. Obermayr, Dr. Sperl
Stauraczgasse 7/15,
1050 Vienna
Austria

To LICENSEE
4SC Discovery GmbH
Attention: Managing Director
Am Klopferspitz 19a
82152 Martinsried
Germany

8.2 This Agreement shall be governed by, and interpreted in accordance with the laws of Germany. The validity of the intellectual property rights shall be subject to an evaluation under the law of the country in which the intellectual property rights were applied for or have been issued.

8.3 Any dispute relating to the validity, performance, construction or interpretation of this Agreement which cannot be resolved amicably between the Parties shall be submitted to binding arbitration, to be held in Munich, Germany, in accordance with the Arbitration Rules of the *Deutsche Institution für Schiedsgerichtsbarkeit e.V.* The decision of the arbitrators in any arbitration proceeding between the Parties under this Section 8.3 shall be: (i) in writing, stating the reasons therefor; (ii) based solely on the terms and conditions of this Agreement, as interpreted in accordance with the laws of the Federal Republic of Germany; (iii) final and binding upon the Parties; and (iv) enforceable in any court of competent jurisdiction. The Parties agree that this Agreement shall be construed and interpreted in its English version only. Any translation of this Agreement into another language shall be for convenience only and shall not be used to construe and interpret this Agreement.

8.4 If any provision of this Agreement is determined by any court or administrative tribunal of competent jurisdiction to be invalid or unenforceable under applicable law, the Parties shall negotiate in good faith a replacement provision that is commercially equivalent, to the maximum extent permitted by applicable law, to such invalid or unenforceable provision. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of the other provisions of this Agreement.

8.5 This Agreement, together with all Exhibits attached hereto, constitutes the entire agreement between the Parties, and supersedes all prior agreements, understandings and communications between the Parties, with respect to the subject matter hereof. No modification or amendment of this Agreement shall be binding upon the Parties unless in writing and executed by the duly authorized representative of each of the Parties. This provision shall also apply to any change of this Section 8.5.

8.6 The failure by either Party to assert any of its rights hereunder shall not be deemed to constitute a waiver by that Party of its right thereafter to enforce each and every provision of this Agreement in accordance with its terms.

8.7 Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment or transfer without the other Party's consent (i) to the assigning Party's Affiliates or (ii) to the successor to all or substantially all of the business or assets of such Party to which this Agreement relates (whether by merger, sale of stock, sale of assets or other transaction). Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 8.7 will be null and void.

Exhibits:

Exhibit 1.9 Licensed Know How

Exhibit 1.10 List of Licensed Patent Rights

Exhibit 6.1 List of objections and third party rights to the Licensed Patent Rights

***** signature page follows *****

Panoptes Pharma Ges. m. b. H. in Gründung

/s/ Dr. Franz Obermayr
By: Dr. Franz Obermayr
Title: CEO

/s/ Dr. Stefan Sperl
By: Dr. Stefan Sperl
Title: COO

4SC Discovery GmbH

/s/ Dr. Stefan Strobl
By: Dr. Stefan Strobl
Title: Managing Director

/s/ Dr. Daniel Vitt
By: Dr. Daniel Vitt
Title: Managing Director

Exhibit 1.9: Licensed Know How

[***]

[***]

[***]

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Exhibit 1.10 List of Licensed Patent Rights

[***]

Country	Application No.	Patent No.	4SC Ref	Boehmert Ref
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Country	Application No.	Patent No.	4SC Ref	Boehmert Ref
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Exhibit 6.1 List of objections and third party rights to the Licensed Patent Rights

[***][***][***][***][***][***][***]

Exhibit 21.1

Subsidiaries of the Registrant

Jade Therapeutics, Inc.	**(United States - Delaware)**
Panoptes Pharma Ges.m.b.H.	**(Austria)**

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement of EyeGate Pharmaceuticals, Inc. on Form S-8 (Nos. 333-241657, 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 25, 2021, on our audits of the consolidated financial statements as of December 31, 2020 and 2019 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 25, 2021. 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 25, 2021

Exhibit 31.1

Certification

I, Franz Obermayr, 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 25, 2021

/s/ Franz Obermayr
Franz Obermayr
Acting 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 25, 2021

/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, 2020 (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 25, 2021

/s/ Franz Obermayr
Franz Obermayr
Acting 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, 2020 (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 25, 2021

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