UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

or

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

For the transition period from to

Commission File Number 000-51122

EyePoint Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2774444**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
480 Pleasant Street Watertown, MA	**02472**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 926-5000

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, par value $0.001	EYPT	The Nasdaq Stock Market LLC (Nasdaq Global 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 (§ 232.405 of this chapter) 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, 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 any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

The aggregate market value of the common stock held by non-affiliates of the registrant, computed by reference to the closing price of the common stock on the Nasdaq Global Market on June 28, 2019, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately $100,752,272.

There were 124,741,832 shares of the registrant's common stock, $0.001 par value, outstanding as of March 5, 2020.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates certain information by reference from the registrant's proxy statement for the 2020 annual meeting of stockholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2019.

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For the Fiscal Year Ended December 31, 2019
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Preliminary Note Regarding Forward-Looking Statements

Various statements made in this Annual Report on Form 10-K are forward-looking and involve risks and uncertainties. All statements that address activities, events or developments that we intend, expect or believe may occur in the future 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. Such statements give our current expectations or forecasts of future events and are not statements of historical or current facts. These statements include, among others, statements about:

- the potential advantages of DEXYCU® and YUTIQ® for the treatment of eye diseases;
- our ability to manufacture DEXYCU and YUTIQ, or any future products or product candidates, in sufficient quantities and quality;
- our commercial sales of DEXYCU and YUTIQ;
- our expectations regarding the timing and clinical development of our product candidates, including EYP-1901 and YUTIQ50;
- our expectations to avoid the toxicity seen in the prior clinical studies of orally delivered vorolanib, a tyrosine kinase inhibitor (“TKI”) by delivering vorolanib locally using bioerodible Durasert technology as EYP-1901 at a significantly lower total dose;
- the potential for EYP-1901, as a new six-month treatment for serious eye diseases including wet age-related macular degeneration (“wAMD”), diabetic retinopathy (“DR”) and retinal vein occlusion (“RVO”).
- our ability to further develop sales and marketing capabilities, whether alone or with potential future collaborators;
- the sufficiency of our cash, cash equivalents and current year financing availability to fund our operations one year from the issuance of these financial statements;
- our belief that our cash and cash equivalents of $22.2 million at December 31, 2019, incremental financing cash flows of approximately $20.3 million from our February 2019 stock offering, excluding approximately $300,000 of additional unpaid share issue costs and expected cash inflows under our product sales and royalty agreements will enable us to fund our current and planned operations into 2021;
- our ability to obtain additional capital in sufficient amounts and on terms acceptable to us, and the consequences of failing to do so;
- future expenses and capital expenditures;
- our expectations regarding the timing and design of our future clinical development plans;
- our expectations regarding the timing and outcome of Good Laboratory Practices (“GLP”) toxicology studies for EYP-1901 to support the filing of an Investigational New Drug (“IND”), application with the FDA;
- our ability to establish or maintain collaborations and obtain milestone, royalty and/or other payments from any such collaborators;
- the ability of Alimera Sciences, Inc. (“Alimera”), to commercialize ILUVIEN® for the treatment of non-infectious uveitis affecting the posterior segment of the eye in Europe, the Middle East and Africa (the “EMEA”);
- the implications of results from pre-clinical and clinical trials and our other research activities;
- our intentions regarding our research into other uses and applications of our Durasert® and Verisome® technology platforms;
- our expected participation in the Tricare Retail Pharmacy program;
- our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for DEXYCU, YUTIQ, EYP-1901 and YUTIQ50 and any future products or product candidates, and to avoid claims of infringement of third-party intellectual property rights;
- the scope and duration of intellectual property protection;
- our expectation that we will continue to incur significant expenses and that our operating losses and our net cash outflows to fund operations will continue for the foreseeable future;
- the extent to which our business could be adversely impacted by the effects of the COVID-19 coronavirus pandemic or by other pandemics, epidemics or outbreaks; and
- the effect of legal and regulatory developments.

Forward-looking statements also include statements other than statements of current or historical fact, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as “likely”, “expect”, “intend”, “anticipate”, “believe”, “estimate”, “plan”, “project”, “forecast” and “outlook”.

The following are some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements: uncertainties with respect to: the effectiveness and timeliness of our preclinical studies and clinical trials, and the usefulness of the data; the timeliness of regulatory approval; our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; our ability to successfully produce sufficient commercial quantities of YUTIQ and DEXYCU and to successfully commercialize YUTIQ and DEXYCU in the U.S.; our ability to sustain and enhance an effective commercial infrastructure and enter into and maintain commercial agreements for YUTIQ and DEXYCU; potential off-label sales of ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye; consequences of fluocinolone acetonide side effects for YUTIQ; consequences of dexamethasone side effects for DEXYCU; successful commercialization of, and receipt of revenues from, ILUVIEN for diabetic macular edema; Alimera's ability to obtain additional marketing approvals and the effect of pricing and reimbursement decisions on sales of ILUVIEN for diabetic macular edema; Alimera's ability to commercialize ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye in the territories in which Alimera is licensed to do so; our ability to market and sell products; the success of current and future license agreements, including our agreement with Equinox Science, LLC; termination or breach of current license agreements, including our agreement with Equinox Science, LLC; our dependence on contract research organizations, contract sales organizations, vendors and investigators; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; volatility of our stock price; possible dilution; absence of dividends; the impact of the COVID-19 pandemic on our business; and other factors described in our filings with the Securities and Exchange Commission, or SEC. We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. The risks set forth under Item 1A of this Annual Report on Form 10-K describe major risks to our business, and you should read and interpret any forward-looking statements together with these risks. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements.

Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

DEXYCU®, YUTIQ®, and Durasert® are our trademarks. Retisert® and Vitrasert® are Bausch & Lomb's trademarks. ILUVIEN® is Alimera's trademark. Verisome® is a trademark owned by Ramscor, Inc. and exclusively licensed to us. The reports we file or furnish with the Securities and Exchange Commission (the "SEC"), including this Annual Report on Form 10-K, also contain trademarks, trade names and service marks of other companies, which are the property of their respective owners.

ITEM 1. BUSINESS

Change in Fiscal Year

As previously reported, we changed our fiscal year end to December 31 from June 30, effective January 1, 2019. This Annual report on Form 10-K is for the twelve month period from January 1, 2019 through December 31, 2019. References in this Annual Report to "fiscal 2019" refer to the year ended December 31, 2019. References in this report to "transition period" refer to the six month period ended December 31, 2018. References in this report to "fiscal 2018" refer to the year ended June 30, 2018 and "fiscal 2017" refer to the year ended June 30, 2017. For comparison purposes, unaudited data is shown for the twelve months ended December 31, 2018 and the six months ended December 31, 2017.

Overview

We are a pharmaceutical company committed to developing and commercializing innovative ophthalmic products for the treatment of serious eye diseases. We have two products that were approved by the United States ("U.S.") Food and Drug Administration ("FDA") in 2018 and commercially launched in the U.S. during the first quarter of 2019.

DEXYCU® (dexamethasone intraocular suspension) 9%, for intraocular administration, was approved by the FDA in February 2018 for the treatment of post-operative ocular inflammation and commercially launched in the U.S. in March 2019 with a primary focus on its use immediately following cataract surgery. DEXYCU is administered as a single dose directly into the surgical site at the end of ocular surgery and is the first long-acting intraocular product approved by the FDA for the treatment of post-operative inflammation. DEXYCU utilizes our proprietary Verisome® drug-delivery technology, which allows for a single intraocular injection that releases dexamethasone, a corticosteroid, for up to 22 days. In 2018, there were approximately 3.8 million cataract surgeries performed in the U.S.

Prior to the launch of DEXYCU, the standard of care for post-operative treatment of cataract surgery for the reduction of inflammation and pain had been a combination of steroid, antibiotic and non-steroidal eye drops administered multiple times each day over a period of several weeks. Effective October 2018, DEXYCU was granted "pass through status" by the Centers for Medicare & Medicaid Services ("CMS") that provides for reimbursement of DEXYCU separate from the cataract procedure payment bundle for a 3-year period. The 3-year period commenced in April 2019, the quarter that the first claim for reimbursement for DEXYCU was made with CMS and will expire in March 2022. In addition, in November 2018, CMS assigned a specific and permanent J-code for DEXYCU, effective January 1, 2019, that enables reimbursement across all types of payers. Thirty-three Key Account Managers ("KAMs"), through a contract sales organization, are dedicated to calling on cataract surgeons and ambulatory surgical centers ("ASCs") and are supported by our market access, marketing and commercial sales management teams.

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg for intravitreal injection, was approved by the FDA in October 2018 and we commercially launched YUTIQ in the U.S. in February 2019. YUTIQ is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, which affects between 60,000 to 100,000 people each year in the U.S., causes approximately 30,000 new cases of blindness every year and is the third leading cause of blindness. YUTIQ is a non-erodible intravitreal implant containing 0.18 mg fluocinolone acetonide ("FA"), designed to release FA at an initial rate of 0.25 mcg/day, and lasting for up to 36 months. Injected into the eye during a physician office visit, YUTIQ delivers a micro-dose of a corticosteroid to the back of the eye on a sustained nearly constant (zero order release) basis. YUTIQ utilizes our proprietary Durasert® sustained-release drug delivery technology platform, which can deliver drugs for predetermined periods of time ranging from months to years.

Chronic non-infectious uveitis affecting the posterior segment of the eye is typically treated by uveitis and retina specialists. The standard of care treatment for this disease involves the use of corticosteroids to reduce uveitic flares followed by additional treatments of sustained release, lower dose steroids to reduce the risk of further flares. Prior to the launch of YUTIQ, the sustained release treatment period covered only 3 to 4 months. In contrast, YUTIQ is designed to release FA continuously, for up to 36 months. Twelve KAMs are dedicated to calling predominantly uveitis specialists across the U.S. Effective October 1, 2019, YUTIQ was granted a permanent and specific J-code by the CMS.

We own the worldwide rights to all indications for DEXYCU and in January 2020 we out-licensed clinical development, regulatory, reimbursement and distribution rights for the product in Mainland China, Hong Kong, Macau and Taiwan. We own the rights for YUTIQ in the U.S. and all foreign jurisdictions and have licensed these rights in EMEA and Mainland China, Hong Kong, Macau and Taiwan. We have patent rights for DEXYCU in the U.S. through at least June 2034 and internationally through dates ranging from April 2032 to May 2034. We have patent rights for YUTIQ in the U.S. through at least August 2027 and internationally through dates ranging from October 2024 to May 2027.

We seek to enhance our longer-term commercial potential by identifying and advancing additional product candidates through clinical development and regulatory approval. This may be accomplished through our internal discovery efforts, entry into potential research collaborations and/or in-licensing arrangements or our acquisition of additional ophthalmic products, product candidates or technologies that complement our current product portfolio.

EYP-1901, a 6-Month bioerodible Durasert® Vorolanib -Tyrosine Kinase Inhibitor ("TKI") is being advanced as a potential treatment for wet age-related macular degeneration ("wAMD"), diabetic retinopathy ("DR") and retinal vein occlusion ("RVO"). We have completed initial animal pharmacokinetic and toxicology studies and expect to initiate formal GLP toxicology studies in the first quarter of 2020 to support the filing of an Investigational New Drug application with the FDA.

YUTIQ50 is being developed as a 6-month dosing option for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. We have consulted with the FDA and identified a clinical pathway for an sNDA filing that involves a clinical trial of approximately 60 patients, randomized 2:1. We are currently evaluating the timeline and investment requirements for the initiation of this trial.

We are entitled to royalties pursuant to license and collaboration agreements utilizing our Durasert technology platform. These include (i) ILUVIEN® for the treatment of diabetic macular edema ("DME"), and pursuant to EMEA regulatory approval received in March 2019 and subject to its commercialization plans, ILUVIEN for uveitis indication, licensed to Alimera Sciences, Inc. ("Alimera") and (ii) Retisert® for the treatment of posterior segment uveitis licensed to Bausch & Lomb, which concluded at the end of March 2019 following the expiration of the U.S. patent with which Retisert was marketed.

We also earn collaborative research and development revenues from other arrangements, including upfront fees, research funding and development, regulatory and/or sales milestones and royalties. These include license agreements and, from time to time, funded feasibility study agreements. Such license agreements include (i) an exclusive license with OncoSil Medical Ltd for the development and commercialization of a product candidate for the treatment of pancreatic cancer and (ii) exclusive license agreements with Ocumension Therapeutics ("Ocumension") for the development and commercialization in Mainland China, Hong Kong, Macau and Taiwan of our Durasert three-year treatment of non-infectious uveitis affecting the posterior segment of the eye. We also undertake research study agreements which generally include formulation and other pre-clinical studies designed to evaluate the use of our Durasert technology platform, or potentially in the future our Verisome technology platform, for the delivery of third-party proprietary compounds for various eye diseases.

The Unmet Need in the Treatment of Eye Disease

The human eye is an organ which reacts to light to provide sight. The eye has two principal anatomical segments: the anterior segment and the posterior segment. The anterior segment consists of the cornea, iris, pupil, lens and aqueous humor, while the posterior segment consists of the retina, choroid, vitreous humor and the optic nerve.

The tissues and structures in the anterior and posterior segment of the eye work in concert to produce sight. Light from an object or scene enters the eye through the anterior chamber, beginning with the cornea. The cornea bends the light such that it passes freely through the pupil, which is the opening in the center of the iris. The iris works like a shutter in a camera, enlarging or shrinking depending on how much light is entering the eye. After passing through the iris, the light rays pass through the eye's natural crystalline lens. This clear, flexible structure works like the lens in a camera, shortening and lengthening its width in order to focus light rays properly. Light rays then pass from the anterior segment into the posterior segment of the eye starting with a dense, transparent gel-like substance, called the vitreous. The vitreous fills the globe of the eyeball, which bathes the eye in nutrients and helps the eye hold its spherical shape. In a normal eye, the light rays come to a sharp focusing point on the retina. The retina functions much like the film in a camera, capturing the light rays, processing them into light impulses through millions of tiny nerve endings and then sending these light impulses through over a million nerve fibers to the optic nerve. Because the process of producing sight requires the precise coordination of the tissues and structures in both the anterior and posterior segments of the eye, if disease affects any one of these components, vision can be impaired or potentially render a person blind.

Diseases of the anterior chamber of the eye include ocular inflammation, cataracts, dry eye, infection, and refractive disorders. Glaucoma, which is a disease that damages the optic nerve, can also be caused by inflammation in the anterior chamber (inflammatory or uveitic glaucoma). Because the anterior segment is readily accessible, physicians typically treat these diseases with topically-applied eye drops. However, there are several limitations of eye drops. First, the eye often eliminates topically applied medications via tear elimination, limiting the penetration of drugs into the ocular tissue. Second, eye drops are often administered by patients themselves, which often leads to misuse or non-compliance by patients due to complicated and arduous eye drop regimens.

Diseases of the posterior segment of the eye include conditions such as age-related macular degeneration ("AMD"), DR, RVO, DME and chronic non-infectious uveitis affecting the posterior segment of the eye. These diseases frequently result in damage to the vasculature of the eye, leading to poor visual function, and often to proliferation of new, abnormal and leaky blood vessels in the back of the eye. These conditions can lead to retinal damage, scarring and irreversible loss of vision. Because the posterior segment is not readily accessible, physicians typically treat these diseases with intravitreal injections. However, there are several limitations of frequent intravitreal injections. First, these injections can be painful and often cause swelling or bleeding. Second, repeated intravitreal injections can cause scarring of the eye sclera. The sclera, also known as the white of the eye, is the opaque, fibrous, protective, outer layer of the human eye containing mainly collagen and some elastic fiber. Many patients with retinal diseases require lifelong treatment and over time, these chronic intravitreal injections can cause significant sclera scarring, increased risk of intraocular infection and vitreous hemorrhage. Further, most ocular drugs are delivered via a bolus injection that requires monthly or bi-monthly re-injections. Each time the patient or the physician lengthens the treatment interval due to either missed appointments, cost to the patient, or lack of reimbursement, the patient's disease can reactivate, which leads to incremental and cumulative damage to the retina. Over time this may lead to permanent loss of vision. Thus, monthly or bi-monthly injections are not an effective means of delivering a steady state dose to the site of disease. Finally, the risk of patient non-compliance increases when treatment involves multiple products or complex or painful dosing regimens, as patients age or suffer cognitive impairment or serious illness, or when the treatment is lengthy or expensive.

Drug delivery for treating ophthalmic diseases in both the anterior and posterior segments of the eye is a significant challenge. Due to the effectiveness of the blood-eye barrier, it is difficult for systemically (orally or intravenously) administered drugs to reach the retina in sufficient quantities to have a beneficial effect without causing adverse side effects to other parts of the body.

Due to the drawbacks of eye drops, frequent intravitreal injections, and oral or systemic injectable delivery, we believe the development of methods to deliver drugs to patients in a more precise, micro dose zero order release, controlled fashion over sustained periods of time with Durasert, and over shorter periods of time with a tapered release mechanism with Verisome satisfies a large unmet medical need. In addition, with less frequent injections, or daily eye drops, we believe patients will comply better with their prescribed treatment regimen. Our commercial product, YUTIQ addresses this treatment need for posterior segment uveitis, and we

believe our pre-clinical product, EYP-1901 for wAMD, if approved, can also address this need by using our proprietary Durasert drug delivery technology to provide long-acting, zero order release, sustained micro dosing. DEXYCU utilizes our proprietary Verisome drug delivery suspension that provides sustained delivery over 22 days for conditions that need ocular inflammation control after eye surgery over a shorter period of time and potentially eliminating the need for daily steroid eye drops.

Strategy

Our strategy is to become a leading pharmaceutical company committed to developing and commercializing ophthalmic products for the treatment of serious eye diseases. The key elements of our strategy include:

- **Grow commercial product revenues and gain market share** for both DEXYCU and YUTIQ in the U.S.
- **Advance EYP-1901,** a 6-Month bioerodible Durasert® Vorolanib - TKI, into clinical development as a potential six-month treatment for wAMD, DR and RVO.
- **Advance YUTIQ50** into clinical development for a potential sNDA filing as a six-month treatment for chronic non-infectious uveitis affecting the posterior segment of the eye.
- **Identify and in-license, co-market or partner** ophthalmology products or product candidates that can leverage our existing sales organizations that are in place for YUTIQ and DEXYCU.
- **Identify and in-license, partner or acquire** additional transformative ophthalmology products to build long-term shareholder value including programs that can utilize our Durasert and Verisome technologies.
- **Leverage our Durasert and Verisome technologies** through collaborations and out-licenses with other pharmaceutical and biopharmaceutical companies, institutions and other organizations. We believe our technologies can provide sustained, targeted delivery of therapeutic agents, resulting in improved therapeutic effectiveness, safer administration and better patient compliance and convenience, with reduced product development risk and cost.

Our Products and Product Candidates

The following table describes the stage of each of our programs:

FDA Approved Products	Disease	Status	Commercial Partner
DEXYCU	Ocular post-surgical inflammation	U.S. commercial launch - March 2019	Ocumension for Mainland China, Hong Kong, Macau and Taiwan
YUTIQ	Chronic non-infectious uveitis affecting the posterior segment of the eye	U.S. commercial launch - February 2019	Ocumension (as Durasert FA) for Mainland China, Hong Kong, Macau and Taiwan Alimera (out-license) (marketed as ILUVIEN) in 17 EU countries; direct commercialization in the U.K., Germany, Portugal, Ireland and Austria; distribution rights through sublicense partners in Belgium, France, Italy, Luxembourg, the Netherlands, Spain, Australia, New Zealand, Canada and various countries in the Middle East
ILUVIEN	DME	Commercial	Alimera (out-license) in 17 EU countries; direct commercialization in the U.S., U.K., Germany, Portugal, Ireland and Austria; distribution rights through sublicense partners in Belgium, France, Italy, Luxembourg, the Netherlands, Spain, Australia, New Zealand, Canada and various countries in the Middle East

FDA Approved Products	Disease	Status	Commercial Partner
RETISERT	Chronic non-infectious uveitis affecting the posterior segment of the eye	Commercialized in the U.S. from 2005 through 2019 patent expiration	Bausch & Lomb (out-license)

Product Candidates	Disease	Stage of Development	Commercial Partner
EYP-1901–6-Month bioerodible Durasert® Vorolanib -TKI	wAMD, RVO, DR	Pre-clinical– GLP Toxicology Studies	None
YUTIQ50	Chronic non-infectious uveitis affecting the posterior segment of the eye	Clinical	None

DEXYCU

DEXYCU was approved by the FDA in February 2018 and commercially launched in March 2019.

DEXYCU is the first long-acting intraocular product approved by the FDA for the treatment of post-operative ocular inflammation, including treatment following cataract surgery. Cataract surgery is one of the most frequent surgical procedures performed in the U.S., with approximately 3.8 million procedures performed in 2018 in the U.S. Prior to the commercial launch of DEXYCU, the standard of care for inflammation associated with cataract surgery required patients, many of whom are elderly, to self-administer medicated eye drops multiple times a day over several weeks. DEXYCU, administered as a single intraocular injection at the conclusion of cataract surgery, utilizes our bioerodible Verisome technology to deliver an extended-release dosage of dexamethasone, a corticosteroid, in the chamber of the anterior segment, directly behind the iris. We believe that a single administration of DEXYCU at the surgical site will benefit patients by removing non-compliance and dosing errors associated with the current practice of self-administering repeated daily eye drops over a period of several weeks.

In January 2020, we licensed clinical development, regulatory, reimbursement and distribution rights for the product to Ocumension in Mainland China, Hong Kong, Macau and Taiwan.

DEXYCU Phase 3 Clinical Trial

The efficacy of DEXYCU has been demonstrated in a double-masked randomized Phase 3 clinical trial of 394 patients. In the clinical trial, patients received an intraocular dose of 517 micrograms (“mcg”) of DEXYCU, 342 mcg of DEXYCU, or placebo administered by a physician at the end of cataract surgery. The primary efficacy endpoint in the clinical trial was anterior chamber cell clearing in the study eye on the eighth day following surgery. The percentage of patients meeting the primary efficacy endpoint was 20% in the placebo group while 57% and 60% met the primary efficacy outcome in the 342 and 517 mcg DEXYCU treatment groups, respectively (statistically significant with $p<0.001$). In addition, the percentage of patients receiving rescue medication of ocular steroid or a nonsteroidal anti-inflammatory drug was significantly lower at day one, three, eight, 15 and 30 in the 342 and 517 mcg treatment groups versus placebo. The most common adverse reactions (5 – 15%) reported with DEXYCU were increased intraocular pressure (“IOP”), corneal edema and iritis. Other adverse reactions occurring in 1 – 5% of patients included corneal endothelial cell loss, blepharitis, eye pain, cystoid macular edema, dry eye, ocular inflammation, posterior capsule opacification, blurred vision, reduced visual acuity, vitreous floaters, foreign body sensation, photophobia and vitreous detachment. Warnings and precautions included on the label for DEXYCU include increases in IOP, delayed healing, exacerbation of infection and cataract progression which are side effects generally associated with intraocular steroids. There are no adequate and well-controlled studies of DEXYCU in pregnant women. Safety and effectiveness of DEXYCU in pediatric patients have not been established.

Positive retrospective case study data supporting DEXYCU were highlighted in an oral presentation at the 2020 Caribbean Eye Meeting in an oral session entitled, “Drug Delivery: Real-World Experience With Dexamethasone Intraocular Suspension”. The ongoing retrospective study is designed to provide large-scale, real-world data on early experiences with DEXYCU from surgeons. Interim results presented are from 154 patients administered DEXYCU with each time point of data based on patient chart data and frequency of measurement by participating physicians. The proportion of patients with complete anterior chamber cell clearing (cell score=0) was 47.5%, 50.0%, 84.1% and 87.5% at postoperative day 1, 8, 14 and 30, respectively. The proportion of patients with no anterior chamber flares (flare score=0), another measurement of inflammation, was 77.7%, 98.5%, 98.8% and 99.1% at postoperative day 1, 8, 14 and 30, respectively. Mean intraocular pressure at postoperative day 1 was 17.6 mmHg, with levels decreasing through to postoperative day 30.

The FDA-approved dosage of DEXYCU is 0.005 milliliters (“mL”), of dexamethasone 9% (equivalent to 517 mcg), administered as a single dose intraocularly in the posterior chamber of the anterior segment, directly behind the iris, at the end of surgery. DEXYCU is available as a 9% intraocular suspension equivalent to dexamethasone 103.4 mg/mL in a single-dose vial

provided in a kit. The drug utilizes our Verisome technology to provide an extended release of dexamethasone for up to 22 days post-injection.

DEXYCU Market Opportunity

DEXYCU is approved for ocular post-surgical inflammation. The initial market we have focused on for DEXYCU is post-operative inflammation associated with cataract surgery as there were approximately 3.8 million cataract surgeries performed in 2018 in the U.S. Prior to the commercial launch of DEXYCU, the standard of care in the U.S. for treating post-operative inflammation was primarily a combination of steroid, antibiotic and non-steroidal eye drops. This eye drop regimen can result in up to 100 eye drops being administered over several weeks. Steroid eye drops are the most complicated medication to administer in this regimen, requiring up to 70 eye drops over 3-4 weeks on a tapered dosing schedule. A further complication is that many patients schedule cataract surgery in their second eye within a few weeks after the initial surgery resulting in an additional dosing regimen. Further, cataract surgery patients are often elderly and can have compromised cognitive function, osteoarthritis in their hands and poor eyesight due to the cataract surgery. These complexities can lead to poor compliance due to failure to administer eye drops according to the prescribed schedule, eye drops failing to go into the eye, and/or not finishing the full treatment regimen. As a result, patients often call their physician's office multiple times to have them re-explain the treatment regimen or they return with pain and inflammation from non-compliance. We believe DEXYCU addresses many of these issues and potentially eliminates the need for post-surgical steroid eye drops by being provided immediately after surgery into the same incision site as the new intraocular lens.

Claims data suggest that approximately 60% of patients who undergo cataract surgery are covered by Medicare Part B. New drugs approved by the FDA that are part of cataract surgery performed in a hospital outpatient department or ASC, may receive an additional transitional pass-through payment under Medicare, provided it meets certain criteria, including a "not insignificant" cost criterion. This pass-through payment consists of Medicare reimbursement for the drug based on a defined formula for calculating the minimum fee that a manufacturer may charge for the drug. Reimbursement via the pass-through payment is initially granted for three years.

Effective October 2018, DEXYCU was granted "pass through status" by the CMS that provides for reimbursement of DEXYCU separate from the cataract procedure payment bundle for a 3-year period. The 3-year period commenced in April 2019, the quarter that the first claim for reimbursement for DEXYCU was made with CMS and will expire in March 2022. In addition, in November 2018, CMS assigned a specific and permanent J-code for DEXYCU, effective January 1, 2019, that enables reimbursement across all types of payers.

Based upon our current pricing and the number of cataract surgeries performed each year, we believe the total addressable market for DEXYCU is in excess of $2.0 billion.

DEXYCU Intellectual Property

Our DEXYCU U.S. patent portfolio includes two patent families under an exclusive license from Ramscor, Inc. for all ophthalmic conditions. These two issued patents contain composition claims for delivering biologically active substances using citric acid esters. We have also filed our own U.S. patent applications pertaining to DEXYCU, three of which became issued patents in 2018. These patents, one with method of use claims and the other with device claims, will provide further protection for DEXYCU through May 2034.

The drug delivery technology used in DEXYCU is called Verisome. The basic technology can be formulated into numerous products, as a biodegradable solid, gel, or liquid substance that provides drug release in a controlled manner over a period of weeks to several months for ocular, systemic, or topical applications. Ophthalmic applications are focused on the ability of this system to create an injectable liquid or slightly viscous gel. Verisome-based products can be injected into the aqueous or vitreous humor as a liquid via a small gauge needle. When the drug is injected into an ocular chamber, it coalesces into a single spherical dose that settles in the lower portion of the chamber. The system is biodegradable and versatile for administering different drugs; furthermore, duration of use can be tailored. Shrinkage of the Verisome sphere over time reflects simultaneous degradation of the delivery system and release of the active agent. In ophthalmology, this mode of delivery offers advantages because the physician can easily assess the status of therapy by observing the drug-containing system within the eye. When the sphere is no longer visible, the entire drug has been released, and no inactive ingredient remains in the eye. Potential applications could include intraocular products to treat inflammation, ocular hypertension and glaucoma.

YUTIQ

YUTIQ was approved by the FDA in October 2018 and commercially launched in February 2019.

YUTIQ is a non-erodible intravitreal implant containing 0.18 mg FA designed to release FA at an initial rate of 0.25 mcg/day, and lasting for up to 36 months. Injected into the eye during a physician office visit, YUTIQ is a micro-insert that delivers a micro-dose of a corticosteroid to the back of the eye on a sustained nearly constant (zero order release) basis. It is injected with our proprietary inserter using a 25-gauge needle. In addition to direct commercialization of YUTIQ in the U.S., (i) we have licensed regulatory, reimbursement and distribution rights to the product to Alimera for EMEA under its ILUVIEN tradename and (ii) in November 2018 we licensed clinical development, regulatory, reimbursement and distribution rights to Durasert FA to Ocumension

for Mainland China, Hong Kong, Macau and Taiwan. YUTIQ utilizes our proprietary Durasert® sustained-release drug delivery technology platform, which can deliver drugs for predetermined periods of time ranging from months to years.

Chronic non-infectious uveitis is an inflammatory disease affecting the posterior segment of the eye, often involving the retina, and is a leading cause of blindness in developed countries. It afflicts people of all ages, producing swelling and destroying eye tissues, which can lead to severe vision loss and blindness. In the U.S., chronic non-infectious uveitis affecting the posterior segment of the eye is estimated to affect approximately 60,000–100,000 people, resulting in approximately 30,000 cases of blindness and making it the third leading cause of blindness in the U.S. Patients with chronic non-infectious uveitis affecting the posterior segment of the eye are typically treated with ocular injected steroids and systemic steroids, but frequently develop serious side effects from systemic steroids over time that can limit effective dosing. Patients who do not tolerate systemic steroids then are offered – as the last line of treatment – therapy with systemic immunosuppressants or biologics, which themselves can cause severe side effects.

YUTIQ Market Opportunity

In February 2019, we commenced the commercial launch of YUTIQ with a direct sales force in the U.S. We believe that the chronic non-infectious uveitis affecting the posterior segment of the eye market in the U.S. is relatively modest in size, with an estimated patient prevalence for chronic non-infectious uveitis affecting the posterior segment of the eye of approximately 60,000 to 100,000 patients. Consequently, the number of uveitis and retinal physicians who treat the majority of this patient population is relatively small. As a result, we believe the commercial footprint and cost to market for YUTIQ will be less than a typical pharmaceutical product launch that requires a larger physician call population. Members of our leadership team have extensive commercialization experience and we believe that commercializing YUTIQ ourselves in the U.S. will maximize the value of YUTIQ to us. YUTIQ was reimbursed using a permanent J Code, established October 1, 2019. The total market size of disease prevalence is approximately $500 million. Of those patients currently being treated, the addressable market size is approximately $250 million.

Outside of the U.S., we expanded our existing license agreement with Alimera to include uveitis in EMEA. This additional license right was part of the July 10, 2017 amended and restated collaboration agreement with Alimera, or the Amended Alimera Agreement. Alimera has commercialized the chronic non-infectious uveitis affecting the posterior segment of the eye EMEA indication under its ILUVIEN trademark.

In November 2018, we licensed to Ocumension the clinical development, regulatory, reimbursement and distribution rights for Durasert FA in Mainland China, Hong Kong, Macau and Taiwan. Ocumension does not have rights to the YUTIQ trade name.

Durasert Technology Platform

Our Durasert technology platform uses proprietary sustained polymer technology to deliver drugs to treat chronic diseases, affecting the difficult to access posterior segment of the eye. To date, four products utilizing successive generations of the Durasert technology have been approved by the FDA. In addition to YUTIQ, these products include ILUVIEN (FA intravitreal implant) 0.19 mg, licensed to Alimera, and Retisert (FA intravitreal implant) 0.59 mg and Vitrasert® (ganciclovir) 4.5 mg, both licensed to Bausch & Lomb. Although the earlier ophthalmic products that utilize the Durasert technology, Retisert and Vitrasert, are surgically implanted, ILUVIEN, and YUTIQ were designed to be injected during a physician office visit. The Durasert technology platform utilizes a miniaturized, injectable, sustained release insert for small molecules that can deliver a drug for up to three years. For YUTIQ and ILUVIEN, the insert is 3.5 mm in length with an external diameter of 0.37 mm. The insert is administered in an office setting using a 25-gauge needle. In these products and product candidates, the drug core is surrounded with one or more polymer layers, and the permeability of those layers and other design aspects control the rate and duration of drug release. By changing elements of the design, we can alter both the rate and duration of release to meet different therapeutic needs.

EYP-1901, a 6-Month bioerodible Durasert® Vorolanib - TKI is being advanced as a potential treatment for wAMD, DR, and RVO. This program utilizes a bioerodible version of the Durasert technology.

Our Durasert technology platform is designed to provide sustained delivery for ophthalmic diseases and conditions, featuring:

- *Extended Delivery*. The delivery of drugs for predetermined periods of time ranging from months to years. We believe that uninterrupted, sustained delivery offers the opportunity to develop products that reduce the need for repeated applications, thereby reducing the risks of patient noncompliance and adverse effects from repeated administrations.
- *Controlled Release Rate*. The release of therapeutics at a controlled rate. We believe that this feature allows us to develop products that deliver optimal concentrations of therapeutics over time and eliminate excessive variability in dosing during treatment.
- *Localized Delivery*. The delivery of therapeutics directly to a target site. We believe this administration can allow the natural barriers of the body to isolate and assist in maintaining appropriate concentrations at the target site in an effort to achieve the maximum therapeutic effect while minimizing unwanted systemic effects.

YUTIQ Phase 3 Clinical Trials

In our two Phase 3 clinical trials to assess the safety and efficacy of YUTIQ, we achieved the primary efficacy endpoint of prevention of recurrence of uveitis through six months with statistical significance (p value of < 0.001 in each trial). These Phase 3 clinical trials were randomized, sham injection-controlled, double-masked trials with the primary endpoint of both trials defined as recurrence of uveitis at six months, with patients followed for three years. Our first Phase 3 trial enrolled 129 patients in 16 centers in the U.S. and 17 centers outside the U.S, with 87 eyes treated with YUTIQ and 42 eyes receiving sham injections. Our second Phase 3 trial enrolled 153 patients in 15 centers in India with 101 eyes treated with YUTIQ and 52 eyes receiving sham injections. The 36-month patient follow-up was completed in the first Phase 3 trial in March 2018 and the second Phase 3 trial in October 2019.

Our first Phase 3 trial met its primary efficacy endpoint of prevention of recurrence of disease at 6 months with statistical significance ($p < 0.001$, intent to treat analysis; recurrence of 18.4% for YUTIQ versus 78.6% for control). The trial yielded similar efficacy through 36 months of follow up ($p < 0.001$, intent to treat analysis; recurrence of 56.3% for YUTIQ versus 92.9% for control). YUTIQ was generally well tolerated through 36 months of follow-up. 19.5% of YUTIQ treated eyes needed the assistance of adjunctive intraocular / periocular injection medication for uveitic inflammation compared to 69.0% for sham treated eyes. IOP lowering drops were used in 42.5% of YUTIQ treated eyes and 33.3% of sham treated eyes, with IOP lowering surgeries performed in 5.7% of YUTIQ treated eyes and 11.9% of sham treated eyes. Cataracts were extracted from 73.8% of patients administered YUTIQ with phakic eyes (42) and 23.8% of patients administered sham with phakic eyes (21). Cataracts are both a side effect of treatment with steroids and a natural consequence of uveitis.

Our second Phase 3 trial also met its primary efficacy endpoint of prevention of recurrence of disease at 6 months with statistical significance ($p < 0.001$, intent to treat analysis; recurrence of 21.8% for YUTIQ versus 53.8% for control). This second double-masked, randomized Phase 3 trial of YUTIQ enrolled 153 patients in 15 clinical centers in India, with 101 eyes treated with YUTIQ and 52 eyes receiving sham injections. In March 2020, we announced positive topline 36-month follow-up data from the second Phase 3 trial of YUTIQ for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. At 36-months, the recurrence rate in YUTIQ randomized eyes was significantly lower than in sham treated eyes (46.5% vs. 75.0%, respectively; $p=0.001$). Visual acuity gains or losses of 3-lines or more were both similar between treatment groups. Safety data showed no unanticipated side effects at each follow-up timepoint at 12, 24 and 36-months. These positive results were consistent with the findings from the first Phase 3 study of YUTIQ and provide further validation of its long-term ability to reduce uveitic flares.

We also conducted a multi-center, randomized, controlled, single-masked study of the safety and utilization of two different inserters for YUTIQ for a study period of one year. We enrolled 26 subjects (38 eyes) in this study in 6 centers in the U.S. The utilization and safety results of this study were included in our NDA filing for YUTIQ.

Adequate and well-controlled studies of YUTIQ have not been conducted in pregnant women to inform drug-associated risk. Safety and efficacy of YUTIQ in pediatric patients have not been established.

We have out-licensed the rights for Durasert FA for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye to Alimera for the EMEA as an extension of our original license agreement with Alimera. Pursuant to the original agreement, we granted worldwide license rights to ILUVIEN for DME and other potential back-of-the-eye diseases (other than uveitis) utilizing a corticosteroid with our Durasert technology. In the European Economic Area, or EEA, Alimera has submitted our previously-filed YUTIQ data as a Type II variation in each of the 17 countries in which it previously obtained regulatory approval for ILUVIEN for DME. According to Alimera's public filings, Alimera submitted follow-up data supporting its Type II variation application in October 2018 and obtained approval for its application in March 2019.

Manufacturing

Manufacturing of pharmaceutical products is subject to extensive FDA regulations that impose strict procedural and documentation requirements, which govern record-keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among other activities. Incoming raw materials and components from suppliers are inspected upon arrival according to pre-specified criteria prior to use in a commercial product. During product manufacture, in-process tests are conducted on intermediate products according to pre-specified criteria; testing is finally conducted on the finished product prior to its release. Our systems and our contractors are required to comply with regulatory GMP requirements, and we assess compliance regularly through performance monitoring and audits.

YUTIQ

We source the active pharmaceutical ingredient ("API") and various raw materials and components for YUTIQ from third-party vendors. Our agreements with these third parties include confidentiality and intellectual property provisions to protect our proprietary rights related to YUTIQ. We require our contract manufacturers to operate in accordance with current Good Manufacturing Practice, or cGMP, and all other applicable laws and regulations. Production, assembly and packaging of YUTIQ is done in the Class 10,000 clean room located at our Watertown, MA facility.

DEXYCU

We currently use a contract manufacturer for the commercial supply of DEXYCU. A separate contract manufacturer provides kitting and packaging of the finished product, and other vendors provide sterilization, testing and storage services. Our agreements with these third parties include confidentiality and intellectual property provisions to protect our proprietary rights related to DEXYCU. We require our contract manufacturers to operate in accordance with current cGMPs and all other applicable laws and regulations. We employ personnel with extensive technical, manufacturing, analytical and quality experience to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions.

Clinical and Pre-Clinical Supply

All pre-clinical study and clinical trial supplies for products and product candidates that utilize our Durasert technology platform have been, and will continue to be, manufactured by ourselves. Raw materials and components are obtained from third-party vendors.

U.S. Sales and Marketing

We launched YUTIQ and DEXYCU in the U.S. during the first quarter of 2019 utilizing a contract sales organization ("CSO") model. This model involved the hiring of sales and marketing leadership professionals providing oversight and leadership to the CSO teams. We believe this flexible sales model provided less execution risk as CSOs leverage costs across multiple clients allowing us to cost-effectively build the necessary infrastructure to support sales activities. In addition, we are able to utilize CSO installed systems and processes for, *inter alia*, regulatory filings, data tracking, field incentive compensation, training, hiring of KAMS, territory sizing / alignment, sample tracking, and customer relationship management systems.

Members of our sales and marketing leadership team have extensive commercialization experience with ophthalmic products at previous companies. We have twelve KAMS for YUTIQ with plans to expand that sales force with continued success of the product. We have thirty-three KAMS selling DEXYCU supported by a contract specialist team. The KAMs have an average of 18 years of sales experience, with most having prior ophthalmological or pharmaceutical sales experience. The KAMs for YUTIQ and DEXYCU were deployed in February 2019 and in March 2019, respectively, in geographies where we expect to have greater than 80% coverage of the potential patient population in the U.S.

In January 2020, the YUTIQ KAMs were converted to full-time employees from our CSO.

U.S. Market Access and Payer Reimbursement

In 2018 we recruited a team of highly experienced personnel to form our market access team. The team is comprised of our VP of Market Access, VP of Government Affairs and Reimbursement, Director of Patient Access, national account directors ("NADs") and field reimbursement managers ("FRMs") who handle the reimbursement for both YUTIQ and DEXYCU. Their roles include the discussions with payers regarding the costs and benefits of our products for their members; assisting with the addition of our products to the medical policy of payers; and providing the market with assistance regarding reimbursement queries.

We have initiated a patient assistance platform called EyePoint Assist℠ to provide co-pay and coinsurance relief for eligible commercial patients.

Reimbursement for YUTIQ is obtained using a permanent J code, established October 1, 2019, which enables reimbursement from both Medicare and commercial payers. DEXYCU has three-year pass through status with Medicare whereby it is routinely reimbursed for Medicare Part B patients. The issuance of a specific and permanent J code for DEXYCU in November 2018 has enabled our market access team to work with non-Medicare payers with regard to adding DEXYCU to their medical policies. We believe that products that are reimbursable using a specific J code (as opposed to a C code or miscellaneous J code) are simpler for payers to process and therefore have a greater likelihood of reimbursement.

U.S. Product Distribution Channel

We have established a distribution channel in the United States for the commercialization of YUTIQ and DEXYCU that provides physicians with several options for ordering our products. This includes agreements with a nationally recognized third-party logistics provider ("3PL"), several distributors and a specialty pharmacy provider for physicians who prefer to use a traditional buy-and-bill model. The 3PL will provide fee-based services related to logistics, warehousing, order fulfilment, invoicing, returns and accounts receivable management.

Approved Products Licensed to Others

ILUVIEN for DME

ILUVIEN is an injectable, sustained-release micro-insert based on our Durasert technology platform and delivers 0.19 mg of FA to the back of the eye for treatment of DME. ILUVIEN is injected in an office visit using a 25-gauge inserter, and delivers up to 36 months of continuous, low-dose corticosteroid therapy with a single injection. ILUVIEN is approved in the U.S. for the treatment of

DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in IOP. In the countries where ILUVIEN has been approved, it is indicated for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. DME is a disease suffered by diabetics where leaking capillaries cause swelling in the macula, the most sensitive part of the retina. DME is a leading cause of blindness in the working-age population in most developed countries. The ILUVIEN micro-insert is substantially the same micro-insert as YUTIQ.

We originally licensed our Durasert proprietary insert technology to Alimera for use in ILUVIEN for the treatment of all ocular diseases (excluding uveitis). Alimera has sold ILUVIEN for DME in the U.K. and Germany since 2013, in Portugal and the U.S. since 2015 and in Austria and Ireland since 2017. ILUVIEN also has marketing approvals in 12 other European countries. In addition, Alimera has entered into various agreements under which distributors will provide regulatory, reimbursement and/or sales and marketing support for commercialization or future commercialization of ILUVIEN in several countries in the Middle East, as well as in France, Italy, Spain, Australia, New Zealand and Canada.

On July 10, 2017, we entered into the Amended Alimera Agreement, pursuant to which we (i) expanded the license to Alimera to our proprietary Durasert sustained-release drug delivery technology platform to include uveitis, including chronic non-infectious uveitis affecting the posterior segment of the eye, in the EMEA and (ii) converted the net profit share arrangement for each licensed product (including ILUVIEN) under the original collaboration agreement with Alimera, or the Prior Alimera Agreement, to a sales-based royalty on a calendar quarter basis commencing July 1, 2017, with payments from Alimera due 60 days following the end of each calendar quarter.

Sales-based royalties started at the rate of 2% and increased, commencing December 12, 2018, to 6% on aggregate calendar year net sales up to $75 million and 8% in excess of $75 million. Alimera's share of contingently recoverable accumulated ILUVIEN commercialization losses under the Prior Alimera Agreement, capped at $25 million, are to be reduced as follows: (i) $10.0 million was cancelled in lieu of an upfront license fee on the effective date of the Amended Alimera Agreement; (ii) for calendar years 2019 and 2020, 50% of earned sales-based royalties in excess of 2% will be offset against the quarterly royalty payments otherwise due from Alimera; (iii) in March 2020, another $5 million was cancelled upon Alimera's receipt of regulatory approval for ILUVIEN for the uveitis indication; and (iv) commencing in calendar year 2021, 20% of earned sales-based royalties in excess of 2% will be offset against the quarterly royalty payments due from Alimera until such time as the balance of the original $25 million of recoverable commercialization losses has been fully recouped.

Following the completion of the Amended Alimera Agreement, we withdrew our previously filed EU marketing approval application and our EU orphan drug designation for YUTIQ, and Alimera was responsible for filing a Type II variation for ILUVIEN for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. In January 2018, Alimera received validation of a Type II variation submitted in December 2017 in all seventeen European countries in which it previously received regulatory approval for ILUVIEN for DME. According to Alimera's public filings, in October 2018 Alimera submitted follow-up data in support of its Type II variation application and obtained approval for its application in March 2019. Alimera has reported that it plans to commercialize the three-year uveitis indication under its ILUVIEN trademark.

Information with respect to ILUVIEN, including regulatory and marketing information, and Alimera's plans and intentions, reflects information publicly disclosed by Alimera.

Retisert for chronic non-infectious uveitis affecting the posterior segment of the eye

Retisert is a sustained-release implant based on our Durasert technology platform for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Surgically implanted, it delivers 0.59 mg of FA to the back of the eye for approximately 30 months. Retisert is licensed to Bausch & Lomb, with which we co-developed the product. Retisert is approved in the U.S., Bausch & Lomb sells the product and paid sales-based royalties to us. The patent with which Retisert is marketed expired in March 2019. As such, pursuant to our agreement with Bausch & Lomb, payment of sales-based royalties concluded at the end of March 2019 following patent expiration.

Development Product Candidates

EYP-1901* 6-Month bioerodible Durasert® Vorolanib - TKI *for wAMD, DR and RVO

We are developing EYP-1901, a 6-Month bioerodible Durasert® Vorolanib TKI, as an injectable, bioerodible, sustained-release Durasert insert delivering vorolanib, for the treatment of wAMD, DR and RVO.

wAMD, the leading cause of vision loss in people over 65, DR and RVO are most commonly treated with intravitreal injections of biologics that block vascular endothelial growth factor, ("VEGF").

Vorolanib, the active drug candidate in EYP-1901, is a small molecule VEGF inhibitor that has been previously studied in phase 1 and 2 trials as an orally dosed therapy for the treatment of wAMD. Data from these trials demonstrated a positive efficacy signal, however these trials were discontinued due to systemic toxicity due to the oral delivery. By delivering vorolanib locally, as EYP-1901, in our non-erodible Durasert technology at a significantly lower total dose, we expect to avoid the toxicity seen in the prior

clinical trials of vorolanib and other orally delivered TKIs. This has been supported by initial pharmacokinetic and safety studies completed for EYP-1901 and will be further evaluated in GLP toxicology studies planned in 2020.

EYP-1901 is being designed to provide sustained release of vorolanib at a controlled rate directly to the back of the eye for six-months from a single administration.

YUTIQ50

YUTIQ50 is a potential six-month duration treatment for chronic non-infectious uveitis affecting the posterior segment of the eye, using the same bioerodible Durasert technology and steroid (FA) as in YUTIQ. This program is designed to offer an intravitreal micro insert with a shorter delivery period, thus providing physicians with flexibility for multiple dosing intervals. Our market research has indicated a strong preference amongst those physicians surveyed for a six to nine-month drug delivery product in addition to the three-year drug delivery option provided by YUTIQ. Although we believe many patients would likely opt for a longer-acting treatment option, some doctors may prefer to initially treat their uveitis patients over shorter time periods. We have consulted with the FDA and identified a potential clinical pathway for an sNDA filing that involves a clinical trial of approximately 60 patients, randomized 2:1. We are currently evaluating the timeline and investment requirements for the initiation of this trial.

Research Agreements

From time to time we have entered into research (feasibility study) agreements funded by third parties to evaluate our Durasert technology platform for the treatment of ophthalmic and other diseases. We intend to continue this activity with partner compounds that could be successfully delivered with our Durasert and Verisome technology platforms on a fee-for-service basis with the potential for future clinical and commercial milestones and royalties.

Strategic Collaborations

We have entered into a number of collaboration/license agreements to develop and commercialize our product candidates and technologies. In all of these agreements, we have retained the right to use and develop the underlying technologies outside of the scope of the exclusive licenses granted. The license and collaboration arrangements typically include, among other terms and conditions, non-refundable upfront license fees, milestone payments and royalty and/or profit sharing obligations. See Note 4, "License and Collaboration Agreements" to the Consolidated Financial Statements included under Item 15, "Exhibits and Financial Statement Schedules."

Intellectual Property

We own or license patents in the U.S. and other countries. Our patents generally cover the design, formulation, manufacturing methods and use of our sustained release therapeutics, devices and technologies. Patents for individual products extend for varying periods according to the date of patent filing or grant and legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends upon the type of patent, the scope of its coverage and the availability of legal remedies in the country. Patent term extension may be available in various countries to compensate for a patent office delay or a regulatory delay in approval of the product.

The U.S. patent with which Retisert is marketed expired in March 2019. The latest expiring patent covering ILUVIEN and YUTIQ expires in August 2027 in the U.S. and in October 2024 in the EU, although extensions have been obtained or applied for through May 2027 in various EU countries.

The last of the previously issued patents covering DEXYCU expire in July 2023, but additional patents have issued in the U.S. that will cover DEXYCU until at least 2034.

The last expiring patent covering the vorolanib compound licensed to us by Equinox Science and used in EYP-1901 expires in September 2027, but additional patents have been applied for which, if issued, will extend coverage of EYP-1901 until at least 2037.

The following table provides general details relating to our owned and licensed patents (including both patents that have been issued and applications that have been accepted for issuance) and patent applications as of February 29, 2020:

Technology	United States Patents	United States Applications	Foreign Patents	Foreign Applications	Patent Families
Durasert	14	3	141	20	8
Verisome (Ocular)	5	2	116	43	4
Other	22	7	101	51	14
Total	41	12	358	114	26

Employees

We had 84 employees on February 28, 2020. None of our employees is covered by a collective bargaining agreement.

Competition

The market for products treating eye diseases is highly competitive and is characterized by extensive research efforts and rapid technological progress. We face substantial competition for our FDA-approved products and our product candidates. Pharmaceutical, drug delivery and biotechnology companies, as well as research organizations, governmental entities, universities, hospitals, other nonprofit organizations and individual scientists, have developed and are seeking to develop drugs, therapies and novel delivery methods to treat diseases targeted by our products and product candidates. Most of our competitors and potential competitors are larger, better established, more experienced and have substantially more resources than we or our partners have. Competitors may reach the market earlier, may have obtained or could obtain patent protection that dominates or adversely affects our products and potential products, and may offer products with greater efficacy, lesser or fewer side effects and/or other competitive advantages. We believe that competition for treatments of eye diseases is based upon the effectiveness of the treatment, side effects, time to market, reimbursement and price, reliability, ease of administration, dosing or injection frequency, patent position and other factors.

Many companies have or are pursuing products to treat eye diseases that are or would be competitive with DEXYCU, ILUVIEN for DME, ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye, YUTIQ, YUTIQ50 and EYP-1901. Some of these products and product candidates include the following:

Inflammation following cataract surgery.

There is a high unmet medical need among patients who undergo cataract surgery as the current standard of care to treat inflammation post-surgery includes a schedule of up to 70 steroid eye drops over a period of 3 - 4 weeks.

In August 2018, Kala Pharmaceuticals, Inc. (“Kala”) announced that the FDA approved INVELTYS™ (loteprednol etabonate ophthalmic suspension) 1% for the topical treatment of post-operative inflammation and pain following ocular surgery. INVELTYS is the first twice-daily ocular corticosteroid approved for this indication while all other available ocular steroid eyedrops are only approved for four-times-a-day dosing. This product is expected to improve compliance and allow for less burdensome self-dosing with eyedrops for patients. On January 7, 2019, Kala announced the launch of INVELTYS in the U.S. In addition, there are various formulations of steroids that are produced by compounding pharmacies and that are in drop form or are injected into the eye following ocular surgery.

Ocular Therapeutix™ Inc. (“Ocular”) has developed DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg, which is a corticosteroid intracanalicular insert placed through the punctum, a natural opening in the eye lid, into the canaliculus, and is designed to deliver dexamethasone to the ocular surface for up to 30 days. Following treatment, DEXTENZA is intended to resorb and exit the nasolacrimal system without the need for removal. On December 3, 2018, Ocular announced FDA approval of DEXTENZA for the treatment of ocular pain following ophthalmic surgery. On June 21, 2019, Ocular announced FDA approval of its supplemental New Drug Application (“sNDA”) for DEXTENZA to include the treatment of ocular inflammation following ophthalmic surgery. On July 1, 2019, Ocular announced the launch of DEXTENZA for both approved indications in the U.S.

Both INVELTYS and DEXTENZA deliver a steroid on the surface of the eye and therefore are dependent on penetration through the cornea to reach the intended target of the anti-inflammatory effect. Comparatively, as DEXYCU is delivered directly into the posterior chamber of the anterior segment and bypasses that anatomical barrier, we believe that it can exert its anti-inflammatory effect upon dosing.

On February 25, 2019, Bausch + Lomb announced the approval of LOTEMAX®SM (loteprednol etabonate ophthalmic gel) 0.38%, a new gel formulation for the treatment of postoperative inflammation and pain following ocular surgery. Compared to LOTEMAX® GEL (loteprednol etabonate ophthalmic gel) 0.5%, already available on the market, LOTEMAX SM delivers a submicron particle size for faster drug dissolution in tears. LOTEMAX SM also provides two times greater penetration to the aqueous humor compared to LOTEMAX GEL. The FDA approval of LOTEMAX SM was based on data from two randomized, multicenter, double-masked, parallel-group, vehicle-controlled studies in patients with postoperative inflammation following cataract surgery. In those studies, LOTEMAX SM was administered three times daily.

Posterior Segment Uveitis

Periocular and intravitreal steroid injections, and systemic delivery of corticosteroids are routinely used to treat posterior segment uveitis, which is a chronic, inflammatory condition of the eye. It is treated both aggressively and frequently by physicians in order to minimize the disease "flares", which are the main cause of vision deterioration and potential blindness.

OZURDEX®, marketed by Allergan, is approved in the U.S. and EU for posterior segment uveitis through an intravitreal bioerodible implant that provides treatment which lasts for several months. This limited duration effectiveness of OZURDEX can result in frequent intravitreal injections of the implant.

AbbVie, Inc. has FDA approval for HUMIRA® (adalimumab) for the treatment of all types of non-infectious uveitis (intermediate, posterior and panuveitis) and it is administered subcutaneously every other week for systemic delivery. HUMIRA is a biologic that blocks tumor necrosis factor alpha, a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Humira's retail price in the U.S. is approximately $50,000 per year.

Other companies have ongoing trials of posterior segment uveitis treatments, including Santen Pharmaceutical Co. Ltd., which received a Complete Response Letter, or CRL, in December 2017 from the FDA for its filed NDA for sirolimus, which is administered through intravitreal injection every two months. Sirolimus is a mammalian target of rapamycin inhibitor and modulator of the immune system and is being developed for chronic non-infectious uveitis affecting the posterior segment of the eye. Santen has since initiated a Phase 3 clinical trial of sirolimus in December 2018 in the U.S. Clearside Biomedical Inc.'s ("Clearside") CLS-TA (triamcinolone acetonide, a steroid) for macular edema associated with non-infectious uveitis has been accepted by the FDA for review and it is administered through a suprachoroidal injection administered every 12 weeks. Preliminary clinical data indicated that the suprachoroidal route may reduce the risk of increased IOP that is typically associated with intraocular injection of steroids. The results of the Phase 3 trial, presented in September 2018, indicated that while about 50% of patients experienced significant improvements in visual acuity through 24 weeks, adverse events of IOP increase were reported in about 12% of patients. On December 19, 2018, Clearside submitted an NDA for XIPERE™ (CLS-TA) to the U.S. FDA for the treatment of macular edema associated with uveitis. On October 18, 2019, Clearside received a CRL from the FDA regarding its NDA for XIPERE. The CRL included the FDA's request for additional stability data, reinspection of the drug product manufacturer and additional data on clinical use of the final to-be-marketed SCS Microinjector™ delivery system. Clearside indicated that it expects to resubmit its New Drug Application for XIPERE to FDA for review in the first quarter of 2020. On October 23, 2019, Bausch Health Companies Inc. acquired an exclusive license for the commercialization and development of XIPERE in the United States and Canada.

Diabetic Macula Edema (DME)

Genentech USA Inc.'s LUCENTIS (ranibizumab) and Regeneron Pharmaceutical Inc.'s EYLEA (aflibercept) are approved in the U.S. and the EU for the treatment of DME. Roche's lower-cost AVASTIN is approved to treat various cancers, but is used off-label for the treatment of DR. These products are VEGF inhibitors, which are considered first line therapy for DME due to their ability to block the VEGF protein, which at high levels can cause abnormal blood vessels to grow in the eye and leak fluid. Genentech is a wholly-owned member of the Roche Group. Novartis AG, or Novartis, has the right to market and sell LUCENTIS outside of the U.S. Regeneron maintains exclusive rights to EYLEA in the U.S., and Bayer HealthCare Pharmaceuticals LLC owns the exclusive marketing rights outside the U.S. LUCENTIS, EYLEA and AVASTIN are all injected into the back of the eye on a monthly or bi-monthly basis.

Allergan, Inc.'s, or Allergan's, OZURDEX (dexamethasone intravitreal implant), a bioerodible intravitreal implant, has been approved for the treatment of DME, RVO and NIPU, and has a therapeutic duration of several months. As with ILUVIEN, OZURDEX delivers a corticosteroid (dexamethasone) to the back of the eye through an intravitreal injection. However, it only lasts for up to several months, resulting in frequent injections compared to ILUVIEN (or YUTIQ) which can last for up to three years. Other companies, including Roche, are working on the development of product candidates and extended delivery systems for the potential treatment of DME. RG7716, being developed by Roche, is a bispecific antibody that simultaneously binds to and inactivates vascular endothelial growth factor A, or VEGF-A, and angiopoietin-2. In a Phase 2 clinical trial, RG7716 demonstrated clinically meaningful visual acuity gains from baseline, and statistically significant improvements in visual acuity compared with ranibizumab. Roche's two Phase 3 clinical trials of RG7716 in DME started in September and October 2018, respectively.

Wet Age-Related Macular Degeneration

wAMD, the leading cause of vision loss in people over 65, is most commonly treated with intravitreal injections of biologics that block VEGF.

FDA-approved LUCENTIS and EYLEA and off-label use of the anti-cancer AVASTIN® are the leading treatments for wAMD. These biologics must be injected into the eye frequently and typically can lose efficacy over time, resulting in vision loss and return of the disease. However, EYLEA was approved in August 2018 by the FDA for dosing every 12 weeks after one year of effective

therapy. As a result, the label now indicates that, although not as effective as the recommended every 8 week dosing regimen, patients may also be treated with one dose every 12 weeks after one year of effective therapy.

Novartis announced FDA approval and launch of Beovu® brolucizumab injection on October 8, 2019 for a three-month dosing interval immediately after a three-month loading phase .BEOVU is an antibody fragment with high affinity to all VEGF-A isoforms. In May 2018, Novartis announced that treatment with brolucizumab, which could be given every 12 weeks, showed non-inferiority compared with EYLEA given every 8 weeks when assessed for improvements over baseline in best corrected visual acuity (BCVA) in two Phase 3 trials.

Abicipar pegol is a monoDARPin (Designed Ankyrin Repeat Protein) that blocks all isoforms of VEGF-A and is currently being developed by Allergan. Smaller molecular size (34 kDa) may lead to longer duration (12 weeks) than the currently available anti-VEGF-A agents. Allergan is conducting Phase 3 trials to compare treatment arms of abicipar every 8 weeks, abicipar every 12 weeks and ranibizumab every four weeks. In July 2018, Allergan announced positive results from two clinical trials, SEQUOIA and CEDAR for abicipar, demonstrating that both the 8-week and 12-week treatment regimens met the pre-specified primary endpoint of non-inferiority to ranibizumab. On September 9, 2019, Allergan announced acceptance of its Biologics License Application by the FDA and validation of its Marketing Authorization Application (MAA) by the European Medicines Agency (EMA) for abicipar pegol. Regulatory decisions on both applications are expected in 2020.

Genentech is developing a refillable reservoir port delivery system (PDS) designed to gradually release LUCENTIS (ranibizumab) using a diffusion-control mechanism. The port is placed under the conjunctiva, fixed to the pars plana, and no sutures are needed. The port is then refilled as an in-office procedure with the help of a refill needle system that simultaneously introduces the drug into the reservoir and removes any remaining contents. In July 2018, Roche announced positive Phase 2 results: the majority of PDS patients went 6 months or longer between the implant of the device and first required refill, and patients in the high dose PDS group achieved similar vision outcomes as monthly ranibizumab eye injections. Two Phase 3 clinical trials to evaluate PDS in wet AMD were initiated in September 2018.

Kodiak Sciences is developing KSI-301, an anti-VEGF antibody biopolymer conjugate being developed for treatment-naïve wet age-related macular degeneration, diabetic macular edema and retinal vein occlusion. In October 2019, Kodiak Sciences presented data demonstrating 87% of wAMD patients extending beyond three months after the last loading dose without receiving retreatment and 82% of DME patients were extended beyond three months without receiving retreatment following only three initial loading doses. Kodiak initiated a pivotal study of KSI-301 in wAMD in October 2019.

Graybug Vision, Inc.'s, or Graybug lead product, GB-102, is an intravitreal injectable depot formulation of sunitinib malate, an anti-VEGF TKI, that blocks multiple angiogenesis pathways. In 2017, Graybug launched the first clinical trial of GB-102 given every 6 months in patients with wAMD. This Phase 1/2 clinical trial is designed to evaluate patients being treated with available intravitreal anti-VEGF agents who are later switched over to just GB-102. Preliminary data from this study were presented in January 2019: GB-102 was well-tolerated with no dose limiting toxicities, drug-related serious adverse events or inflammation. In addition, 88% and 68% percent of evaluable patients were maintained only on a single dose of GB-102 at 3- and 6-months, respectively. Graybug Vision's Phase 2b trial of GB-102, initiated in October 2019.

Ocular Therapeutix, Inc. is developing OTX-TKI, a bioresorbable hydrogel formulated with TKI particles in an injectable fiber that can be delivered through a small-gauge, sterile injection needle to the back of the eye. OTX-TKI is designed to deliver drug to the target tissues for a period of up to nine months, thereby potentially extending the dosing interval from the one-to-two month frequency needed with the current standard of care. On February 20, 2019, Ocular Therapeutix announced the dosing of the first patient in a Phase 1 trial of OTX-TKI in patients with wAMD. The trial is a multi-center, open-label study testing the safety, durability, and tolerability of OTX-TKI delivered by intravitreal injection.

REGENXBIO Inc. and Adverum Biotechnologies, Inc. are developing gene therapy treatments for wAMD. REGENXBIO is developing RGX-314, a gene therapy utilizing its NAV AAV8 vector containing a gene encoding for a monoclonal antibody fragment which inhibits VEGF. Adverum is developing ADVM-022, a gene therapy utilizing an AAV.7m8 vector containing a gene encoding for a protein that expresses aflibercept.

Diabetic Retinopathy

The central retina area that is located between the main branches (superior and inferior arcades) of the central retinal vessels in the eye is known as the "macular area". The retina beyond this is considered "peripheral retina". The central retinal area can develop abnormal findings in DR. These findings can be present in the non-proliferative or the proliferative forms of the disease. These changes in the macula include the presence of abnormally dilated small vessel outpouchings (called microaneurysms), retinal bleeding (retinal hemorrhages) and yellow lipid and protein deposits (hard exudates). The macula can get thicker than normal- referred to as macular edema (DME).

Non-proliferative retinopathy (NPDR) can be classified into mild, moderate or severe stages based upon the presence or absence of retinal bleeding, abnormal venous beading of the vessel wall (venous beading) or abnormal vascular findings (intraretinal microvascular anomalies or IRMA). No treatment is usually done at this stage. Proliferative retinopathy (PDR) is progressive and requires treatment to prevent bleeding and scar tissue formation. Macular edema is a complication of DR and is a major cause of vision loss in a diabetic eye.

Treatment of macular edema is usually needed in order to prevent loss of vision or to try to improve vision. Treatment includes the use of lasers or injection of anti-VEGF drugs that cause the retinal swelling/macular edema (from leaking blood vessels) to resolve. Patients are seen monthly if being injected or every 3 months post-laser for macular edema. Several studies indicate that anti-VEGF drugs are more effective than focal laser (DRCR, READ2, RIDE, RISE, DAVINCI). A recent study by the DRCR network has shown all three drugs – Avastin (bevacizumab), Lucentis (ranibizumab) and Eylea (aflibercept) are effective for macular edema therapy.

Treatment of PDR is laser photocoagulation of the peripheral retina/panretinal photocoagulation (PRP). The laser is used to create scars on the peripheral retina. If successful, vitreous bleeding may be averted. Sometimes the proliferative disease is advanced and there is bleeding filling the eye (and preventing laser to be done) or scar tissue that wrinkles the retina or pulls it off the eyewall surface. In these situations, surgery is necessary (see vitrectomy for more information).

In cases of abnormal blood vessel growth anti-VEGF injections into the eye can also be used. DRCR protocol S showed that anti-VEGF drug ranibizumab was noninferior to PRP in PDR. Anti-VEGF injections are sometimes used in concert with laser when blood vessels grow in the iris and neovascular glaucoma is present. Anti-VEGF are also given prior to vitrectomy surgery in selected cases. Follow-up is crucial for these patients. Thus, in a patient who is for any reason unlikely to return for follow-up, anti-VEGF is not the treatment of choice and PRP should be done.

In addition to their efficacy at treating DME, anti-VEGF drugs such as Avastin, Lucentis and Eylea, have all been shown in a number of studies to have promise for halting and reversing DR. Looking towards the future, the treatment intervals and follow-up required to maintain improvements in DR and PDR will need to be determined, but long-acting anti-VEGF agents and small molecules, such as TKIs, formulated in novel sustained delivery methods have the potential to transform the diabetic retinopathy treatment landscape.

Retinal Vein Occlusion

RVO can cause retinal ischemia, neovascular complications such as glaucoma, vitreous hemorrhage and retinal traction, and macular edema. Patients often present with acute visual acuity loss. They may report a history of cardiovascular risk factors including a history of diabetes mellitus and hypertension. No treatment is available to reverse the retinal vein occlusions. However, the iris or retinal neovascularization or macular edema may be managed with anti-VEGF or steroid injections. Vein occlusion can affect the central retinal vein (CRVO) or a smaller branch (BRVO).

Medical therapy can limit complications from retinal vein occlusions. Anti-VEGF intraocular injections can cause regression of iris neovascularization and macular edema. In addition, the SCORE study demonstrated the benefit of triamcinolone acetonide for macular edema secondary to central retinal vein occlusions but did not demonstrate benefit for branch retinal vein occlusions (vs. focal laser).

The mainstay of therapy is now anti-VEGF therapy for macular edema with either CRVO or BRVO. Both Lucentis (ranibizumab, BRAVO and CRUISE studies) and Eylea (aflibercept, GALILEO/COPERNICUS and VIBRANT studies) have been shown to be efficacious in the treatment of macular edema. Significant gains in visual acuity results and the retinal edema subsides with therapy. Both drugs are recommended to be used monthly for the 6 treatments and then as needed. Avastin (bevacizumab) is also used off-label to treat macular edema. RVO physiopathology is highly dependent on VEGF levels resulting from retina ischemia and requires frequent intravitreal injections of current therapies. Therefore, long-acting anti-VEGF agents and small molecules, such as TKIs, formulated in novel sustained delivery methods and being developed for wAMD and DR have the potential to transform the treatment landscape in this condition as well.

Material Customers

Customers that accounted for greater than 10% of total revenues for the year ended December 31, 2019, for the six months ended December 31, 2018 and for the years ended June 30, 2018 and 2017 are summarized in the following table:

	Year Ended December 31,	Six Months Ended December 31,	Year Ended June 30,	
Customer / Category	**2019**	**2018**	**2018**	**2017**
Third-party Logistics Provider	56%	*	*	*
ASD Specialty Healthcare LLC	15%	*	*	*
Ocumension Therapeutics	*	59%	*	*
Alimera Sciences	10%	21%	24%	*
Bausch & Lomb	*	16%	35%	13%
Feasibility studies	*	*	36%	*
Pfizer	*	*	*	74%

* Less than 10%

Government Regulation

We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug and Cosmetic Act, or the FD&C Act, and FDA's implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record-keeping, reporting, distribution, import, export, advertising and promotion of our products and product candidates. Although the discussion below focuses on regulation in the U.S., we currently out-license certain of our products and may seek approval for, and market, other products in other countries in the future. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope to that imposed in the U.S., although there can be important differences. Additionally, some significant aspects of regulation in the EU are addressed in a centralized way through the EMA, and the European Commission, but country-specific regulation remains essential in many respects. The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and may not be successful.

Development and Approval

Under the FD&C Act, FDA approval of an NDA is required before any new drug can be marketed in the U.S. NDAs require extensive studies and submission of a large amount of data by the applicant.

Pre-clinical Testing. Before testing any compound in human patients in the U.S., a company must generate extensive pre-clinical data. Pre-clinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the toxicity and dosing of the product. Certain animal studies must be performed in compliance with the FDA's GLP, regulations and the U.S. Department of Agriculture's Animal Welfare Act.

IND Application. Human clinical trials in the U.S. cannot commence until an IND, application is submitted and becomes effective. A company must submit pre-clinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA, and the clinical trial proposed in the IND may begin. Once human clinical trials have commenced, the FDA may stop a clinical trial by placing it on "clinical hold" because of concerns about the safety of the product being tested, or for other reasons.

Clinical Trials. Clinical trials involve the administration of a drug to healthy human volunteers or to patients under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice, or GCP, requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an Institutional Review Board, or IRB, for each clinical site. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events, or AEs. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the U.S. Data from a foreign study not conducted under an IND may be submitted in support of an NDA if the study was conducted in accordance with GCP and the FDA is able to validate the data.

A study sponsor is required to publicly post specified details about certain clinical trials and clinical trial results on government or independent websites (e.g., http://clinicaltrials.gov). Human clinical trials typically are conducted in three sequential phases, although the phases may overlap or be combined:

- Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to evaluate the safety, metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population and are designed to develop initial data regarding the product's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential AEs.
- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained and are intended to gather the additional information about dosage, safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile, and to provide a basis for regulatory approval. Generally, Phase 3 clinical development programs consist of expanded, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen.

The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval.

NDA Submission and Review. The FD&C Act provides two pathways for the approval of new drugs through an NDA. An NDA under Section 505(b)(1) of the FD&C Act is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that production methods are adequate to ensure its identity, strength, quality, and purity of the drug, and that proposed labeling is appropriate and contains all necessary information. A 505(b)(1) NDA contains results of the full set of pre-clinical studies and clinical trials conducted by or on behalf of the applicant to characterize and evaluate the product candidate.

Section 505(b)(2) of the FD&C Act provides an alternate regulatory pathway to obtain FDA approval that permits the filing of an NDA 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. The applicant may rely to some extent upon the FDA's findings of safety and effectiveness for an approved product that acts as the reference drug, and submit its own product-specific data — which may include data from pre-clinical studies or clinical trials conducted by or on behalf of the applicant — to address differences between the product candidate and the reference drug.

The submission of an NDA under either Section 505(b)(1) or Section 505(b)(2) generally requires payment of a substantial user fee to the FDA, subject to certain limited deferrals, waivers and reductions. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the agency usually considers such recommendations carefully when making decisions.

The FDA may determine that a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act, or PREA, certain applications for approval must also include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug in relevant pediatric populations.

Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP, requirements and adequate to assure consistent production of the product within required specifications.

Once the FDA accepts an NDA submission for filing — which occurs, if at all, within 60 days after submission of the NDA — the FDA's goal for a non-priority review of an NDA is ten months. The review process can be and often is significantly extended, however, by FDA requests for additional information, studies, or clarification.

After review of an NDA and the facilities where the product candidate is manufactured, the FDA either issues an approval letter or a CRL, outlining the deficiencies in the submission. The CRL may require additional testing or information, including additional pre-clinical or clinical data, for the FDA to reconsider the application. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor. FDA approval of any application may include many delays or never be granted. If FDA grants approval, an approval letter authorizes commercial marketing of the product candidate with specific prescribing information for specific indications.

Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional clinical studies, which often are referred to as "Phase 4" or "post-marketing" studies.

Post-approval modifications to the drug, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional pre-clinical studies or clinical trials, to be submitted in a new or supplemental NDA, which would require FDA approval.

Post-Approval Regulation

Once approved, drug products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met, or if safety or manufacturing problems occur after the product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing studies or clinical trials, changes to a product's approved labeling, including the addition of new warnings and contraindications, or the implementation of other risk management measures, including distribution-related restrictions, if there are new safety information developments.

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable cGMP requirements and product-specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical products prior to approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to take enforcement actions or seek sanctions, including fines,

issuance of warning letters, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor the FDA compliance of our third-party manufacturers, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP and other applicable FDA regulatory requirements.

Advertising and Promotion. The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses — that is, uses not approved by the FDA and not described in the product's labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label use. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug.

Other Requirements. NDA holders must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences, and maintaining certain records.

Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow-on versions of already approved products.

Generic Drugs. A generic version of an approved drug is approved by means of an abbreviated NDA, or ANDA, by which the sponsor demonstrates that the proposed product is the same as the approved, brand-name drug, which is referred to as the reference listed drug, or RLD. Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (i) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. This is instead of independently demonstrating the proposed product's safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective.

505(b)(2) NDAs. As discussed previously, products may also be submitted for approval via an NDA under section 505(b)(2) of the FD&C Act. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on information from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, and must submit its own product-specific data of safety and effectiveness to an extent necessary because of the differences between the products. An NDA approved under 505(b)(2) may in turn serve as an RLD for subsequent applications from other sponsors.

RLD Patents. In an NDA, a sponsor must identify patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the *Orange Book*. The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A "Paragraph I" certification is the sponsor's statement that patent information has not been filed for the RLD. A "Paragraph II" certification is the sponsor's statement that the RLD's patents have expired. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product.

Regulatory Exclusivities. The Hatch-Waxman Act provides periods of regulatory exclusivity for products that would serve as RLDs for an ANDA or 505(b)(2) application. If a product is a "new chemical entity," or NCE — generally meaning that the active moiety has never before been approved in any drug — there is a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification.

A product that is not an NCE may qualify for a three-year period of exclusivity if the NDA contains new clinical data (other than bioavailability studies), derived from studies conducted by or for the sponsor, that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of an ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application has been submitted and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

Patent Term Restoration. A portion of the patent term lost during product development and FDA review of an NDA is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration.

European and Other International Government Regulation

In addition to regulations in the U.S., we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Some countries outside of the U.S. have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In the EU, for example, similar to the FDA a CTA must be submitted for authorization to the competent national authority of each EU Member State in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee, much like the IRB, has issued a favorable opinion. Once the CTA is approved in accordance with the EU Clinical Trials Directive 2001/20/EC and the related national implementing provisions of the relevant individual EU Member States' requirements, clinical trial development may proceed.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014, or Clinical Trials Regulation, was adopted. The Regulation is anticipated to enter into force in 2021 or 2022. The Clinical Trials Regulation will be directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which on-going clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The new Clinical Trials Regulation is intended to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure through a single entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts.

To obtain regulatory approval to commercialize a new drug under EU regulatory systems, we must submit a MAA, to the competent regulatory authority. In the EU, marketing authorization for a medicinal product can be obtained through a centralized, mutual recognition, decentralized procedure, or the national procedure of an individual EU Member State. A marketing authorization, irrespective of its route to authorization, may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all 27 EU Member States and three of the four European Free Trade Association States, Iceland, Liechtenstein and Norway. Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the initial assessment of a product. The maximum timeframe for the evaluation of an MAA is 210 days. This period excludes clock stops during which additional information or written or oral explanation is to be provided by the applicant in response to questions posed by the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest. A major public health interest defined by three cumulative criteria: (i) the seriousness of the disease (for example, heavy disabling or life-threatening diseases) to be treated, (ii) the absence or insufficiency of an appropriate alternative therapeutic approach, and (iii) anticipation of high therapeutic benefit. If the CHMP accepts to review a medicinal product as a major public health interest, the time limit of 210 days will be reduced to 150 days. It is, however, possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Irrespective of the related procedure, at the completion of the review period the CHMP will provide a scientific opinion concerning whether or not a marketing authorization should be granted in relation to a medicinal product. This opinion is based on a review of the quality, safety, and efficacy of the product. Within 15 days of the adoption, the EMA will forward its opinion to the European Commission for its decision. Following the opinion of the EMA, the European Commission makes a final decision to grant a centralized marketing authorization. The centralized procedure is mandatory for certain types of medicinal products, including orphan medicinal products, medicinal products derived from certain biotechnological processes, advanced therapy medicinal products and medicinal products containing a new active substance for the treatment of certain diseases. This route is optional for certain other products, including medicinal products that are of significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public or animal health at EU level.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application process is identical to the application that would be submitted to the EMA for authorization through the centralized procedure and must be completed within 210 days, excluding potential clock-stops, during which the applicant can respond to questions. The reference EU Member State prepares a draft assessment and drafts of the related materials. The concerned EU Member States must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States.

The mutual recognition procedure is similarly based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a medicinal product by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

Marketing authorization holders are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU Member States both before and after grant of marketing authorization. This includes control of compliance by the entities with EU cGMP rules, which govern quality control of the manufacturing process and require documentation policies and procedures.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with GCP, applicable regulatory requirements of each jurisdiction and the medical ethics principles that have their origin in the Declaration of Helsinki.

Compliance

During all phases of development and in the post-market setting, failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the FDA's imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention or refusal to permit the import or export of products, injunctions, fines, civil penalties or criminal prosecution. Third country authorities can impose equivalent penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Other Exclusivities

Pediatric Exclusivity. Section 505A of the FD&C Act provides for six months of additional exclusivity or patent protection if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data does not need to show that the product is effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or *Orange Book* listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. When any product is approved, we will evaluate seeking pediatric exclusivity as appropriate.

In the EU, Regulation No 1901/2006, or the Pediatric Regulation, requires that prior to obtaining a marketing authorization in the EU, applicants demonstrate compliance with all measures included in an EMA, approved Pediatric Investigation Plan, or PIP. This PIP covers all subsets in a pediatric population, unless the EMA has granted either, a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. Where all measures provided in the agreed PIP are completed, a six-month extension period of qualifying Supplementary Protection Certificates is granted.

Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which are diseases or conditions affecting less than 200,000 individuals in the U.S., or a disease or condition affecting

more than 200,000 individuals in the U.S. but there is no reasonable expectation that the cost of developing and making the drug product would be recovered from sales in the U.S. If a sponsor demonstrates that a drug product qualifies for orphan drug designation, the FDA may grant orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication generally is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. The FDA can revoke a product's orphan drug exclusivity under certain circumstances, including when the product sponsor is unable to assure the availability of sufficient quantities of the product to meet patient needs. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same biologic for a different disease or condition.

In the EU, medicinal products: (a) that are used to diagnose, treat or prevent life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the EU; or (b) that are used to treat or prevent life-threatening or chronically debilitating conditions and that, for economic reasons, would be unlikely to be developed without incentives; and (c) where no satisfactory method of diagnosis, prevention or treatment of the condition concerned exists, or, if such a method exists, the medicinal product would be of significant benefit to those affected by the condition, may be granted an orphan designation in the EU. The application for orphan designation must be submitted to the EMA's Committee for Orphan Medicinal Products and approved by the European Commission before an application is made for marketing authorization for the product. Once authorized, orphan medicinal product designation entitles an applicant to financial incentives such as reduction of fees or fee waivers. In addition, orphan medicinal products are entitled to ten years of market exclusivity following authorization. During this ten-year period, with a limited number of exceptions, neither the competent authorities of the EU Member States, the EMA, or the European Commission are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten-year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if this latter product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity

Data Exclusivity. In the EU, if a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities. The product also benefits from 10 years' market exclusivity during which generic products, even if authorized, may not be placed on the market. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

U.S. Healthcare Reform

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, which we refer to together as the Affordable Care Act, or ACA, is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges, and expansion of the Medicaid program. This law substantially changed the way healthcare is financed by both governmental and private insurers and has significantly impacted the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service Act's 340B drug pricing discount program, or 340B program, fraud and abuse, and enforcement. These changes have impacted and will continue to impact existing government healthcare programs and have resulted in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Some states have elected not to expand their Medicaid programs to individuals with an income of up to 133% of the federal poverty level, as is permitted under the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales of products and product candidates for which we receive regulatory approval, and our business and financial condition. Where new patients receive insurance coverage under any of the new Medicaid options made available through the Affordable Care Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues.

Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation and implementation. For example, on December 22, 2017, the U.S. government signed into law comprehensive tax legislation, referred to as the Tax Cuts and Jobs Act, or the Tax Act, which includes a provision repealing,

effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drugs plans, commonly known as the "donut hole," by raising the required manufacturer point-of-sale discount from 50% to 70% off the negotiated price effective as of January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible, but the nature and extent of such potential changes or challenges are uncertain at this time. It is unclear how the Affordable Care Act and its implementation, as well as efforts to repeal or replace, or invalidate, the Affordable Care Act, or portions thereof, will affect our business, financial condition and results of operations. It is possible that the Affordable Care Act, as currently enacted or as it may be amended or replaced in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our products or product candidates for which we receive regulatory approval or to successfully commercialize our products and product candidates.

Coverage and Reimbursement

Sales of any of our products and product candidates, if approved, depend, in part, on the extent to which the costs of the products will be covered by Medicare and Medicaid, and private payors, such as commercial health insurers and managed care organizations. Third-party payors determine which drugs they will cover and the amount of reimbursement they will provide for a covered drug. In the U.S., there is no uniform system among payors for making coverage and reimbursement decisions. In addition, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

In order to secure coverage and reimbursement for our products, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costly studies required to obtain FDA or other comparable regulatory approvals. Even if we conduct pharmacoeconomic studies, our product candidates may not be considered medically necessary or cost-effective by payors. Further, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved because HCPs negotiate their own reimbursement directly with commercial payors.

In the past, payors have implemented reimbursement metrics and periodically revised those metrics as well as the methodologies used as the basis for reimbursement rates, such as ASP, average manufacturer price, or AMP, and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. The CMS surveys and publishes retail pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates.

We participate in the Medicaid Drug Rebate Program. This program requires us to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the "basic" portion of the rebate for each product is set by law as the larger of: (i) 23.1% of quarterly AMP, or (ii) the difference between quarterly AMP and the quarterly best price available from us to any commercial or non-governmental customer, or Best Price. AMP must be reported on a monthly and quarterly basis and Best Price is reported on a quarterly basis only. In addition, the rebate also includes the "additional" portion, which adjusts the overall rebate amount upward as an "inflation penalty" when the drug's latest quarter's AMP exceeds the drug's AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index-Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation-adjusted AMP from the first full quarter of sales. The rebate amount is computed each quarter based on our report to CMS of current quarterly AMP and Best Price for our drug. We are required to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision.

Federal law requires that any manufacturer that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program, which is administered by the Health Resources and Services Administration, or HRSA, requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Any changes to the definition of AMP and the Medicaid rebate amount under the Affordable Care Act or other legislation could affect our 340B ceiling price calculations and negatively impact our results of operations.

HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is

currently unclear how HRSA will apply its enforcement authority under the new regulation. HRSA has also implemented a ceiling price reporting requirement related to the 340B program under which we are required to report 340B ceiling prices to HRSA on a quarterly basis. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report ASP information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the ASP based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. For more information about Medicare Part B, refer to the risk factor entitled “Our products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business” set forth under the section titled “Risk Factors” in this Annual Report on Form 10-K.

In the U.S. Medicare program, outpatient prescription drugs may be covered under Medicare Part D. Medicare Part D is a voluntary prescription drug benefit, through which Medicare beneficiaries may enroll in prescription drug plans offered by private entities for coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans provided for under Medicare Part C.

Coverage and reimbursement for covered outpatient drugs under Part D are not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, they have some flexibility to establish those categories and classes and are not required to cover all of the drugs in each category or class. Medicare Part D prescription drug plans may use formularies to limit the number of drugs that will be covered in any therapeutic class and/or impose differential cost sharing or other utilization management techniques.

Medicare Part D coverage is available for our products and may be available for any future product candidates for which we receive marketing approval. However, in order for the products that we market to be included on the formularies of Part D prescription drug plans, we likely will have to offer pricing that is lower than the prices we might otherwise obtain. Changes to Medicare Part D that give plans more freedom to limit coverage or manage utilization, and other cost reduction initiatives in the program, could decrease the coverage and price that we receive for any approved products and could seriously harm our business.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we must complete an application process with the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under this program, we will be obligated to make our “innovator” drugs available for procurement on an FSS contract and charge a price to four federal agencies — the VA, U.S. Department of Defense, or DoD, Public Health Service and U.S. Coast Guard — that is no higher than the statutory Federal Ceiling Price, or FCP. The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. We also expect to participate in the Tricare Retail Pharmacy program, under which we would pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. We could be held liable for errors associated with our submission of pricing data. In addition to retroactive Medicaid rebates and the potential for issuing 340B program refunds, if we are found to have knowingly submitted false AMP, best price, or Non-FAMP information to the government, we may be liable for significant civil monetary penalties per item of false information. If we are found to have made a misrepresentation in the reporting of our ASP, the Medicare statute provides for significant civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly AMP and best price data on a timely basis could result in a significant civil monetary penalty per day for each day the information is late beyond the due date . Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Significant civil monetary penalties also could apply to late submissions of Non-FAMP information. Civil monetary penalties could also be applied if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. In addition, claims submitted to federally-funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the federal civil False Claims Act.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example,

there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs, and reform government program reimbursement methodologies for drug products.

Beginning April 1, 2013, Medicare payments for all items and services, including drugs, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2027. If Congress does not take action in the future to modify these sequestrations, Medicare Part D plans could seek to reduce their negotiated prices for drugs. Other legislative or regulatory cost containment legislation could have a similar effect.

Further, the Affordable Care Act may reduce the profitability of drug products. It expanded manufacturers' rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well, increased the minimum Medicaid rebate due for most innovator drugs, and capped the total rebate amount at 100% of AMP. The Affordable Care Act and subsequent legislation also changed the definition of AMP. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid drug rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016.

The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each such manufacturer pays a prorated share of the branded prescription drug fee of $2.8 billion in 2019, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The Affordable Care Act also expanded the Public Health Service Act's 340B program to include additional types of covered entities. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners. It appears likely that the Affordable Care Act will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible, as discussed above under the heading "U.S. Healthcare Reform." In addition, there likely will continue to be proposals by legislators at both the federal and state levels, regulators, and third-party payors to contain healthcare costs. Thus, even if we obtain favorable coverage and reimbursement status for our products and any product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Different pricing and reimbursement schemes exist in other countries. In the EU, each EU Member State can restrict the range of medicinal products for which its national health insurance system provides reimbursement and can control the prices of medicinal products for human use marketed on its territory. As a result, following receipt of marketing authorization in an EU Member State, through any application route, the applicant is required to engage in pricing discussions and negotiations with the competent pricing authority in the individual EU Member State. The governments of the EU Member States influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some EU Member States operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other EU Member States allow companies to fix their own prices for medicines, but monitor and control company profits. Others adopt a system of reference pricing, basing the price or reimbursement level in their territories either on the pricing and reimbursement levels in other countries or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Further, some EU Member States approve a specific price for the medicinal product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. The downward pressure on healthcare costs in general, particularly prescription drugs, has become more intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, we may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

Health Technology Assessment, or HTA, of medicinal products, however, is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States. These EU Member States include the U.K., France, Germany, Ireland, Italy and Sweden. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product varies between EU Member States.

In addition, pursuant to Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, a voluntary network of national authorities or bodies responsible for HTA in the individual EU Member States was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This may lead to harmonization of the criteria taken into account in the conduct of HTAs between EU Member States and in pricing and reimbursement decisions and may negatively affect price in at least some EU Member States.

Healthcare Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, our business is subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These laws include, but are not limited to the following:

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A violation of the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. The government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceuticals, including certain discounts, or engaging such individuals as consultants, speakers or advisors, may be subject to scrutiny if they do not fit squarely within the exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance programs. Arrangements that implicate the Anti-Kickback Statute and do not fit within an exception or safe harbor are reviewed on a case-by-case basis to determine whether, based on the facts and circumstances, they violate the statute.

The federal civil False Claims Act prohibits any person from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Actions under the False Claims Act may be brought by private individuals known as qui tam relators in the name of the government. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the False Claims Act for, among other things, providing free product to customers with the expectation that the customers would bill federal programs for the product, , and other interactions with prescribers and other customers including interactions that may have affected customers' billing or coding practices on claims submitted to the federal government. Other companies have faced enforcement actions for causing false claims to be submitted because of the company's marketing the product for unapproved, and thus non-reimbursable, uses. Federal enforcement agencies also have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements.

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which we refer to collectively as HIPAA prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. We may obtain health information from third parties that are subject to privacy and security requirements under HIPAA and we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

The majority of states also have statutes or regulations similar to the federal anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities including the provision of gifts, meals, or other items to certain health care providers. Other states have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co-pay

assistance that pharmaceutical companies can offer to patients. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives.

Compliance with such laws and regulations will require substantial resources. Because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity.

Healthcare Privacy Laws

We may be subject to federal, state and foreign laws and regulations governing data privacy and security of health information, and the collection, use, disclosure, and protection of health-related and other personal information, including state data breach notification laws, state health information and/or genetic privacy laws, and federal and state consumer protection laws, such as Section 5 of the FTC Act, many of which differ from each other in significant ways, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming, and companies that do not comply with these laws may face civil penalties. Many of these state laws enable a state attorney general to bring actions and provide private rights of action to consumers as enforcement mechanisms. There is also heightened sensitivity around certain types of health information, such as sensitive condition information or the health information of minors, which may be subject to additional protections. Federal regulators, state attorneys general, and plaintiffs' attorneys have been and will likely continue to be active in this space.

The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Failure to comply with these laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our business. Healthcare providers who prescribe our products and research institutions we collaborate with are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we or our affiliates or agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA.

In California, the California Consumer Privacy Act ("CCPA") took effect on January 1, 2020. The CCPA establishes certain requirements for data use and sharing transparency and creates new data privacy rights for consumers. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. Similarly, there are a number of legislative proposals in the EU, the United States, at both the federal and state level, as well as other jurisdictions that could impose new obligations or limitations in areas affecting our business. In addition, some countries are considering or have passed legislation implementing data protection requirements or requiring local storage and processing of data or similar requirements that could increase the cost and complexity of delivering our services and research activities. These laws and regulations, as well as any associated claims, inquiries, or investigations or any other government actions may lead to unfavorable outcomes including increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, and remedies that harm our business, including fines or demands or orders that we modify or cease existing business practices.

In the EU, the General Data Protection Regulation ("GDPR") regulates the processing of personal data. The GDPR imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data from the EU to the US, including health data from clinical trials.

Foreign Corrupt Practices Act

In addition, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any official of another country, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in that capacity.

Corporate Information

We were incorporated under the laws of the state of Delaware on March 19, 2008 under the name New pSivida, Inc.; our predecessor, pSivida Limited, was formed in December 2000 as an Australian company incorporated in Western Australia. We subsequently changed our name to pSivida Corp. in May 2008 and again to EyePoint Pharmaceuticals, Inc. in March 2018. Our principal executive office is located at 480 Pleasant Street, Suite B300, Watertown, Massachusetts 02472 and our telephone number is (617) 926-5000.

Additional Information

Our website address is http://www.eyepointpharma.com. Information contained on, or connected to, our website is not incorporated by reference into this Annual Report on Form 10-K. Copies of this Annual Report on Form 10-K, and our annual reports on Form 10-K, proxy statements, quarterly reports on Form 10-Q, current reports on Form 8-K and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website under “Investors – Financial Information – SEC Filings” as soon as reasonably practicable after we electronically file these materials with, or otherwise furnish them to, the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

ITEM 1A. RISK FACTORS

RISKS RELATED TO OUR FINANCIAL POSITION AND OUR CAPITAL RESOURCES

We will likely need additional capital to fund our operations and continue as a going concern. If we are unable to obtain sufficient capital, we will need to curtail and reduce our operations and costs and modify our business strategy.

Our operations have consumed substantial amounts of cash. To date, we have financed our operations primarily through the sale of capital stock, proceeds from term loan agreements and the receipt of license fees, milestone payments, research and development funding and royalty payments from our collaboration partners. In the first quarter of 2019, we commenced the U.S. launch of our first two commercial products, YUTIQ and DEXYCU. However, we have no history of direct commercialization of our products and therefore no sufficient historical evidence to assert that it is probable that we will receive sufficient revenues from our product sales to fund operations. As of December 31, 2019, our cash and cash equivalents totaled $22.2 million. We believe that our existing capital resources, together with the net proceeds of $20.3 million received on February 25, 2020 from the issuance of shares of our common stock, excluding approximately $300,000 of additional unpaid share issue costs (see Note 18), expected amounts to be received from revenue of YUTIQ and DEXYCU product sales, licensing arrangements, additional capital raise or other arrangement should enable us to fund our operations as currently planned for the next 12 months from the issuance of these financial statements. Although we believe such plans, if executed, should provide us sufficient financing to meet our needs, there is no assurance that additional funding will be achieved and that we will succeed in our future operations. Actual cash requirements could differ from our projections due to many factors, including the success of commercialization for YUTIQ and DEXYCU, the actual costs of these commercialization efforts, additional investments in research and development programs, competing technological and market developments and the costs of any strategic acquisitions and/or development of complementary business opportunities. These factors raise substantial doubt about our ability to continue as a going concern for at least one year following the issuance of these financial statements. As a result, our independent registered public accounting firm has included an explanatory paragraph in its report on our audited consolidated financial statements for the year ended December 31, 2019 related to our ability to continue as a going concern.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will need to curtail and reduce our operations and costs, and modify our business strategy, which may require us to, among other things:

- significantly delay, scale back or discontinue the commercialization or development of one or more of our products or product candidates or one or more of our other research and development initiatives;
- seek partners or collaborators for one or more of our products or product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- sell or license on unfavorable terms our rights to one or more of our technologies, products or product candidates that we otherwise would seek to develop or commercialize ourselves; and/or
- seek to sell our company at an earlier stage than would otherwise be desirable or on terms that are less favorable than might otherwise be available.

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

We have incurred significant losses since our inception, have not generated significant revenue from commercial sales of our products and, with the exception of fiscal year 2010 and fiscal year 2015, we have never been profitable. Investment in drug development is highly speculative because it entails substantial upfront operating expenses and significant risk that a product candidate will fail to successfully complete clinical trials, gain regulatory approval or become commercially viable. We continue to incur significant operating expenses due primarily to investments in sales and marketing infrastructure, research and development, and other expenses related to our ongoing operations. For the year ended December 31, 2019 and the six months ended December 31, 2018, we had losses from operations of $47.9 million and $24.6 million, respectively, and net losses of $56.8 million and $44.7 million, respectively, and we had a total accumulated deficit of $465.3 million at December 31, 2019.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will continue to be significant if, and as, we:

- continue to commercialize sales of DEXYCU and YUTIQ and further scale up our manufacturing and distribution capabilities to commercial sales of both DEXYCU and YUTIQ or any other product candidate for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed drugs;
- add operational, financial and management information systems and personnel, including personnel to support our commercialization efforts;
- hire additional commercial, clinical, manufacturing and scientific personnel and engage third party commercial, clinical and manufacturing organizations;
- continue the research and pre-clinical and clinical development of our product candidates;
- initiate additional pre-clinical, clinical or other studies or trials for our product candidates;
- further develop the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- seek to identify and validate additional product candidates;
- acquire or in-license other products, product candidates and technologies;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our product development and planned future commercial sale efforts; and
- experience any delays or encounter issues with any of the above.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We may never achieve profitability from future operations.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully commercialize our current products and complete the development of, and obtain the regulatory approvals necessary for, the manufacture and commercialization of our product candidates. To become and remain profitable, we and/or our licensees must succeed in developing and commercializing products that generate significant revenue. This will require us and/or our licensees to be successful in a range of challenging activities, including completing pre-clinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling any products for which we or our licensees may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. To date, none of our approved licensed products, including Vitrasert, Retisert and ILUVIEN, has generated significant revenues to us from sales. We do not know the extent

to which DEXYCU or YUTIQ, or any of our other product candidates, if approved, will generate significant revenue for us, if at all. We may never succeed in these activities and, even if we do, we may never generate revenues significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately project when or if we will be able to achieve profitability from operations. Even if we do so, 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. Our ability to generate revenue from our current or future products and product candidates will depend on a number of factors, including:

- our ability to successfully commercialize of DEXYCU and YUTIQ;
- our ability to complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities, if we choose to commercialize DEXYCU outside the U.S. and YUTIQ in unpartnered jurisdictions outside the U.S.;
- the size of the markets in the territories for which we gain regulatory approval;
- our ability to further develop our commercial organization capable of sales, marketing and distribution for DEXYCU and YUTIQ, and any of our other product candidates for which we may obtain marketing approval;
- our ability to enter into and maintain commercially reasonable agreements with manufacturers, wholesalers, distributors and other third parties in our supply chain;
- our success in establishing a commercially viable price for our products;
- our ability to manufacture commercial quantities of our products at acceptable cost levels;
- our ability to obtain coverage and adequate reimbursement from third parties, including government payors; and
- our ability to successfully complete development activities, including the necessary clinical trials, with respect to our other product candidates.

We will need to raise additional capital in the future, which may not be available on favorable terms and may be dilutive to stockholders or impose operational restrictions.

We will need to raise additional capital in the future to help fund our continued commercialization of DEXYCU and YUTIQ, and for the development and commercialization of our other product candidates. The amount of additional capital we will require will be influenced by many factors, including, but not limited to:

- the success of our commercialization of DEXYCU and YUTIQ;
- the cost of commercialization activities for DEXYCU and YUTIQ, including product manufacturing, marketing, sales and distribution;
- product revenues received from sales of DEXYCU and YUTIQ;
- our clinical development plans for EYP-1901 and our other product candidates including a shorter duration version of YUTIQ for posterior segment uveitis;
- the outcome, timing and cost of the regulatory approval process for EYP-1901 and our other product candidates, including the potential for the FDA to require that we perform more studies and clinical trials than those we currently expect;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- the amount of royalties and other payments we receive under our collaboration agreements, including ILUVIEN for DME and, in EMEA, ILUVIEN for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye;
- whether and when we are able to enter into strategic arrangements for our products or product candidates and the nature of those arrangements;
- the costs involved in preparing, filing, and prosecuting patent applications, and maintaining, and enforcing our intellectual property rights;
- changes in our operating plan, resulting in increases or decreases in our need for capital;
- our views on the availability, timing and desirability of raising capital; and
- the costs of operating as a public company.

We do not know if additional capital will be available to us when needed or on terms favorable to us or our stockholders. Collaboration, licensing or other commercial agreements may not be available on favorable terms, or at all. We do not know the extent to which we will receive funds from the commercialization of DEXYCU, YUTIQ or ILUVIEN. If we seek to sell our equity securities under our at-the-market, ("ATM"), program or in another offering, we do not know whether and to what extent we will be able to do so, or on what terms. Further, the rules and regulations of the Nasdaq Stock Market LLC, ("Nasdaq"), require us to obtain stockholder approval for sales of our equity securities under certain circumstances, which could delay or prevent us from raising additional capital from such sales. Also, the state of the economy and financial and credit markets at the time or times we seek any additional financing may make it more difficult or more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and dilute our existing stockholders' equity, and funding through collaboration, licensing or other commercial agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may delay, reduce the scope of, or eliminate research or development programs, independent U.S. commercialization of DEXYCU and YUTIQ, or other new products, if any, postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs, or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

The anticipated benefits of the Icon Acquisition may not be fully realized and may take longer to realize than expected.

On March 28, 2018, the "Icon Closing Date", we and our wholly-owned subsidiary, Oculus Merger Sub, Inc., entered into a merger agreement (the "Merger Agreement"), with Icon Bioscience, Inc. ("Icon") and the other signatories thereto, pursuant to which we acquired Icon through a reverse triangular merger, which we refer to as the Icon Acquisition. The Icon Acquisition was consummated on the Icon Closing Date. The anticipated benefits of the Icon Acquisition may not be fully realized and may take longer to realize than expected. We have devoted and will continue to devote significant management attention and resources to the commercial sale of DEXYCU and potential further development of product candidates and other programs utilizing the Verisome technology platform we acquired in the Icon Acquisition. Delays or unexpected difficulties in the development or commercial sale process could adversely affect our business, financial results and financial condition. We also may not realize the full achievement of the benefits of the Icon Acquisition within a reasonable period of time. In addition, we may have not discovered during the due diligence process unknown factors regarding Icon that could produce unintended and unexpected consequences for us. Undiscovered factors could cause us to incur potentially material financial liabilities and prevent us from achieving the expected benefits from the Icon Acquisition within our desired time frames, if at all.

Our profitability will be impacted by our obligations to make royalty and milestone payments to the former securityholders of Icon and other third-party collaborators.

In connection with the Icon Acquisition, we made a $15.0 million cash payment upon the closing of the Icon Acquisition and are obligated to pay certain post-closing contingent cash payments upon the achievement of specified milestones and based upon certain net sales and partnering revenue standards, in each case subject to the terms and conditions set forth in the Merger Agreement. These include but are not limited to (i) a one-time cash payment of $15.0 million payable within 30 days following the first commercial sale of DEXYCU in the U.S., which we paid to the former securityholders of Icon in April 2019, (ii) sales milestone payments totaling up to $95.0 million, beginning no earlier than three years after the October 1, 2018 effective date of the pass-through reimbursement code approved by CMS, upon the achievement of certain sales thresholds and subject to certain CMS reimbursement conditions set forth in the Merger Agreement, (iii) quarterly earn-out payments equal to 12% on net sales of DEXYCU, which earn-out payments will increase to 16% of net sales of DEXYCU in a given year beginning in the calendar quarter for a given year to the extent aggregate annual consideration of DEXYCU exceeds $200.0 million in such year, (iv) quarterly earn-out payments equal to 20% of partnering revenue received by us for DEXYCU outside of the U.S., and (v) single-digit percentage quarterly earn-out payments with respect to net sales and/or partnering income, if any, resulting from future clinical development, regulatory approval and commercialization of any other product candidates we might develop utilizing the Verisome technology acquired in the Icon Acquisition. As of December 31, 2019, we made royalty payments totaling $224,000 in connection with net sales of DEXYCU.

Our profitability with respect to DEXYCU is impacted by our obligations to make payments to the former securityholders of Icon. Although we believe, under such circumstances, that the increase in revenue will exceed the corresponding payments, our obligations to the former securityholders of Icon and other third-party collaborators could have a material adverse effect on our business, financial condition and results of operations if we are unable to manage our operating costs and expenses at profitable levels.

Our failure to comply with the covenants or other terms of the Loan Agreement, including as a result of events beyond our control, could result in a default under the Loan Agreement that could materially and adversely affect the ongoing viability of our business.

On February 13, 2019, (the "Loan Closing Date"), we, as the borrower, and EyePoint Pharmaceuticals US, Inc. and Icon Bioscience, Inc., as Guarantors, entered into a loan agreement (the "Loan Agreement") with CRG and the lenders party thereto ("Lenders"), providing for a senior secured term loan of up to $60 million (the "Loan"). On the Loan Closing Date, the Initial Advance was issued. Up to $15 million of the Loan may be advanced between the Loan Closing Date and June 30, 2019 at our sole option, and, subject to us and the Guarantors achieving product revenue from YUTIQ and DEXYCU of at least $25 million during any

consecutive three-month period ending on or prior to March 31, 2020, up to an additional $10 million may be subsequently advanced (collectively, the "Additional Advances").

The Loan is due and payable on December 31, 2023, or the Maturity Date. The proceeds of the Initial Advance were used to repay certain of our existing indebtedness and associated obligations, to pay fees and expenses related to the Loan Agreement, and will otherwise be used for general working capital and corporate purposes. We used the net proceeds from the Additional Advance of $15 million of the Loan to pay the development milestone following the first commercial sale of DEXYCU in the U.S., which we paid to the former securityholders of Icon in April 2019. The Loan bears interest at a per annum rate (subject to increase during an event of default) equal to 12.5%, of which 2.5% may be paid in-kind at our election, so long as no default or event of default under the Loan Agreement has occurred and is continuing. We are required to make quarterly, interest only payments until the Maturity Date. In addition, we are required to pay an upfront fee of 1.5% of the principal amount of the Loan (excluding any paid-in-kind amounts), which is payable as amounts are advanced under the Loan. Upon repayment of the Loan, we are also required to pay an exit fee equal to 6% of the aggregate principal amounts advanced under the Loan Agreement.

In addition, the repayment of all unpaid principal and accrued interest under the Loan may be accelerated upon consummation of a specified change of control transaction or the occurrence of certain events of default (as specified in the Loan Agreement), including, among other things:

- our default in a payment obligation under the Loan Agreement;
- our default in a payment obligation under any of our other debt agreements evidencing indebtedness in an aggregate principal amount in excess of $500,000;
- our breach of the negative covenants or, subject to specified cure periods, other terms of the Loan Agreement;
- invalidity of the loan documents, including CRG ceasing to have a first priority, perfected security interest on any material portion of the collateral;
- the occurrence of a material adverse effect (as specified in the Loan Agreement);
- certain specified insolvency and bankruptcy-related events; and
- an injunction lasting more than 90 days or a mandatory recall or voluntary withdrawal of any product that results in liability in excess of the greater of $4,000,000 and 7.5% of our last twelve months' revenue.

Subject to any applicable cure period set forth in the Loan Agreement, upon the occurrence of a bankruptcy-related event of default, all amounts outstanding with respect to the Loan (principal, accrued interest, exit fee and any prepayment fees) would become due and payable immediately, and, upon the occurrence of any other event of default, the majority Lenders may accelerate all or any amounts outstanding with respect to the Loan. Our assets or cash flow may not be sufficient to fully repay our obligations under the Loan Agreement if the obligations thereunder are accelerated upon an event of default. Further, if we are unable to repay, refinance or restructure our obligations under the Loan Agreement, the Lenders could proceed to protect and enforce their rights under the Loan Agreement by exercising such remedies as are available to the Lenders thereunder and in respect thereof under applicable law, either by suit in equity or by action at law, or both, whether for specific performance of any covenant or other agreement contained in the Loan Agreement or in aid of the exercise of any power granted in the Loan Agreement. The foregoing would materially and adversely affect the ongoing viability of our business.

Our Loan Agreement contains restrictions that limit our flexibility in operating our business.

The Loan Agreement contains various covenants that limit our ability to engage in specified types of transactions without the Lenders' prior consent. These covenants limit our ability to, among other things:

- sell, transfer, lease or dispose of our assets;
- create, incur or assume additional indebtedness;
- encumber or permit liens on certain of our assets;
- make restricted payments, including paying dividends on, repurchasing or making distributions with respect to, our common stock;
- make specified investments (including loans and advances);
- consolidate, merge, sell or otherwise dispose of all or substantially all of our assets;
- enter into certain transactions with our affiliates;
- permit our cash and cash equivalents held in certain deposit accounts to be less than the greater of (i) $5,000,000 and (ii) to the extent we have incurred certain permitted debt, the minimum cash balance, if any, required of us by the creditors of such permitted debt at any time; and
- permit our annual product revenue from YUTIQ and DEXYCU to fall below certain agreed projection levels.

The covenants in our Loan Agreement may limit our ability to take certain actions that may be in our long-term best interests. In the event that we breach one or more covenants, the Lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, plus penalties and interest, including the exit fee and any prepayment fees, terminate their

commitments to extend further credit and foreclose on the collateral granted to them to secure such indebtedness. Such repayment could have a material adverse effect on our business, operating results and financial condition.

Certain potential payments to the Lenders could impede a sale of our company.

Subject to certain exceptions, we are required to make mandatory prepayments of the Loan with the proceeds derived from asset sales and insurance proceeds. In addition, we may make a voluntary prepayment of the Loan, in whole or in part, at any time. All mandatory and voluntary prepayments of the Loan are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs after December 31, 2019 and on or prior to December 31, 2020, 5% of the aggregate outstanding principal amount of the Loan being prepaid and (ii) if prepayment occurs after December 31, 2020 and on or prior to December 31, 2021, an amount equal to 3% of the aggregate outstanding principal amount of the Loan being prepaid. No prepayment premium is due on any principal prepaid after December 31, 2021. These provisions may make it more costly for a potential acquirer to engage in a business combination transaction with us. Provisions that have the effect of discouraging, delaying or preventing a change in control could discourage a third party from attempting to acquire us, limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

To service our indebtedness, we will require a significant amount of cash and our ability to generate cash depends on many factors beyond our control.

Our ability to make cash payments on our indebtedness will depend on our ability to generate significant operating cash flow in the future. This ability is, to a significant extent, subject to general economic, financial, competitive, legislative, regulatory and other factors, that will be beyond our control. In addition, our business may not generate sufficient cash flow from operations to enable us to pay our indebtedness or to fund our other liquidity needs. In any such circumstance, we may need to refinance all or a portion of our indebtedness, on or before maturity. We may not be able to refinance any indebtedness on commercially reasonable terms or at all. If we cannot service our indebtedness, we may have to take actions such as selling assets, seeking additional equity or reducing or delaying capital expenditures, strategic acquisitions and investments. Any such action, if necessary, may not be effected on commercially reasonable terms or at all. The instruments governing our indebtedness may restrict our ability to sell assets and our use of the proceeds from such sales.

We have a limited number of authorized shares of common stock available for issuance and we will not be able to issue additional shares for future capital raising transactions or strategic transactions unless we obtain stockholder approval to amend our certificate of incorporation to increase the number of authorized shares of common stock.

We have 150 million authorized shares of common stock. As of March 1, 2020, we had 124.7 million shares of common stock outstanding, 16.3 million shares of common stock issuable upon the exercise of outstanding stock options or settlement of outstanding restricted stock units, 71,251 shares of common stock issuable upon the settlement of outstanding deferred stock units, 486,812 shares of common stock issuable upon the exercise of outstanding warrants, 5.2 million shares of common stock reserved for future issuance under our stock option plans and 938,340 shares reserved for future issuance under the 2019 Employee Stock Purchase Plan. As a result, as of March 1, 2020, we had approximately 2.3 million authorized shares of common stock available for issuance. In addition, we have granted the underwriters of our February 2020 underwritten public offering an option for a period of 30 days to purchase an additional 2,250,000 shares of our common stock at the public offering price less underwriting discounts and commissions, which option expires on March 22, 2020. If the underwriters exercise the option, we would have approximately 66,000 authorized shares of common stock available for issuance. In either case, we are limited by the number of additional shares available for future capital raising transactions or strategic transactions unless we obtain stockholder approval to amend our certificate of incorporation to increase the number of authorized shares of common stock. This may cause a delay in our future capital raising, collaboration, partnership or other strategic transactions, and may have a material adverse effect on our business and financial condition.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense.

As part of our business strategy, we may continue to pursue acquisitions or licenses of assets or businesses, or strategic alliances and collaborations, to expand our existing technologies and operations, such as our recent acquisition of Icon. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a detrimental effect on our financial condition, results of operations, and cash flows. We may not be able to find suitable acquisition or licensing candidates, and if we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable collaboration partners or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions, licenses or collaborations, we may choose to issue debt or shares of our common stock as consideration. Any such issuance of shares would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

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

As of December 31, 2019, including pre-acquisition amounts related to Icon , we had U.S. net operating loss ("NOL") carryforwards of approximately $236.6 million for U.S. federal income tax and approximately $190.1 million for state income tax purposes available to offset future taxable income and U.S. federal and state research and development tax credits of approximately $3.5 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"). Our U.S. NOL carryforwards begin to expire in 2023 if not utilized.

Our U.S. NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under Section 382, and corresponding provisions of U.S. state law, 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 U.S. NOLs and other pre-change tax attributes, such as research and development tax credits, to offset its post-change income may be limited. The latest analysis performed under Section 382, performed through September 30, 2018, confirmed that the exercise of certain warrants in late September 2018 resulted in a greater than 50% cumulative ownership change, which will cause annual limitations on the use of our then existing NOL balances and other pre-change tax attributes. As a result, if we earn net taxable income in future periods, our ability to use our pre-change U.S. NOL carryforwards to offset U.S. federal taxable income will be subject to limitations, which could potentially result in increased future tax liabilities to us.

In addition, we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, including through completed or contemplated financings, some of which may be outside of our control. If we determine that a future ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Our operating results may fluctuate significantly from period to period.

Our operating results have fluctuated significantly from period to period in the past and may continue to do so in the future due to many factors, including:

- the costs of our ongoing commercialization efforts and investments in sales and marketing infrastructure;
- costs of internally funded research and development, including contract research organizations, or CROs, and other costs related to clinical development and costs of pre-clinical studies and research;
- developments with respect to our products and product candidates, both licensed and independently developed, including pre-clinical and clinical trial data and results, regulatory developments and marketing and sales results;
- timing, receipt and amount of revenues, including our product sales of YUTIQ and DEXYCU and receipt and recognition of collaborative research and development, licensing, milestone, royalty and other payments;
- announcement, execution, amendment and termination of collaboration and other commercial agreements;
- scope, duration and success of collaboration and other commercial agreements;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators' operations and financial results; and
- changes in accounting estimates, policies or principles and intangible asset impairments.

Due to fluctuations in our operating results, quarterly comparisons of our financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of future performance. In addition, investors may react adversely if our reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors in the financial community, which may result in decreases in our stock price.

RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS AND PRODUCT CANDIDATES

Our current business strategy relies heavily on our ability to successfully commercialize DEXYCU and YUTIQ in the U.S. Our approved products may not achieve market acceptance or be commercially successful.

Our ability to successfully commercialize DEXYCU and YUTIQ in the U.S. is critical to the execution of our business strategy. Neither DEXYCU nor YUTIQ may achieve market acceptance among retinal specialists and other doctors, patients, government health administration authorities and other third-party payors, and may not be commercially successful in the U.S. The degree of market acceptance and commercial success of our approved products will depend on a number of factors, including the following:

- the acceptance of our products by patients and the medical community and the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing treatments;
- our ability to obtain reimbursement for our products from third party payors at levels sufficient to support commercial success;
- the cost effectiveness of our products;
- the effectiveness of our marketing, sales and distribution strategies and operations;
- our ability and the ability of our contract manufacturing organizations, or CMOs, as applicable, to manufacture commercial supplies of our products, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with cGMP regulations;
- the degree to which the approved labeling supports promotional initiatives for commercial success;
- a continued acceptable safety profile of our products;
- results from additional clinical trials of our products or further analysis of clinical data from completed clinical trials of our products by us or our competitors;
- our ability to enforce our intellectual property rights;
- our products' potential advantages over other therapies;
- our ability to avoid third-party patent interference or patent infringement claims; and
- maintaining compliance with all applicable regulatory requirements.

As many of these factors are beyond our control, we cannot assure you that we will ever be able to generate meaningful revenues through product sales. In particular, if governments, private insurers, governmental insurers and other third-party payors do not provide adequate and timely coverage and reimbursement levels for our products or limit the frequency of administration, the market acceptance of our products and product candidates will be limited. Governments, governmental insurers, private insurers and other third-party payors attempt to contain healthcare costs by limiting coverage and the level of reimbursement for products and, accordingly, they may challenge the price and cost-effectiveness of our products or refuse to provide coverage for our products. Any inability on our part to successfully commercialize DEXYCU and YUTIQ, and our other product candidates in the U.S. or any foreign territories where they may be approved, or any significant delay in such approvals, could have a material adverse impact on our ability to execute upon our business strategy and our future business prospects.

If we are unable to maintain agreements with third parties to market and sell DEXYCU and YUTIQ, we may be unable to generate any revenue from these products.

We have contracted to use an outsourced CSO to commercialize DEXYCU and YUTIQ. Any CSO that we use may not dedicate sufficient resources to the commercialization of our products or may otherwise fail in its commercialization due to factors beyond our control. Additionally, any CSO that we use may fail to comply with applicable legal or regulatory requirements or may enter into agreements with other parties that have products and services that could compete with our products.

In the event that we fail to successfully commercialize DEXYCU or YUTIQ through a CSO, we may also enter into a strategic collaboration with a third party. We face significant competition in seeking appropriate strategic collaborators, and these strategic collaborations can be intricate and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic collaborations because of the numerous risks and uncertainties associated with establishing strategic partnerships.

We do not know if we will decide to directly commercialize any future product candidates ourselves, if approved. If we decide to commercialize a product in one or more countries, there is no assurance we will be able to hire and manage a successful sales and marketing capability or have the financial resources necessary to fund independent commercialization of any products in any country.

Our products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a product 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, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more of our products.

Our success also depends in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover 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. Third-party payors also may seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations, before covering our products for those patients. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. For example, under current Medicare Part B policy, payment to hospital outpatient departments and ambulatory surgical centers for products furnished to patients during a procedure is typically packaged into the payment for the associated procedure and thus not paid separately. Products granted pass-through status are excluded from this payment packaging policy and currently receive separate payment from the associated procedure for a period of three years. While DEXYCU has been granted pass-through status and will receive separate payment in these settings from Medicare for a period of three years (measured on the basis of the date Medicare receives its first claim for reimbursement for DEXYCU), at the end of that three year period, or if such three-year period is shortened by a change in law, regulation or Administrative interpretation, payment for DEXYCU may be packaged into the payment for the associated procedure and no longer be paid separately, which we expect would materially decrease our revenues from sales of DEXYCU and correspondingly have a material adverse effect on our results of operations and financial condition.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacturing, selling and distribution costs. 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 products 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 products 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 profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

We participate in the Medicaid Drug Rebate program. This program requires us to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the “basic” portion of the rebate for each product is set by law as the larger of: (i) 23.1% of quarterly average manufacturer price, or AMP, or (ii) the difference between quarterly AMP and the quarterly best price available from us to any commercial or non-governmental customer, or Best Price. AMP must be reported on a monthly and quarterly basis and Best Price is reported on a quarterly basis only. In addition, the rebate also includes the “additional” portion, which adjusts the overall rebate amount upward as an “inflation penalty” when the drug’s latest quarter’s AMP exceeds the drug’s AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index-Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation-adjusted AMP from the first full quarter of sales. The rebate amount is computed each quarter based on our report to CMS of current quarterly AMP and Best Price for our drug. We are required to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any

such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision.

Federal law also requires that any manufacturer that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program, which is administered by the Health Resources and Services Administration, or HRSA, requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include, but are not limited to, a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Any changes to the definition of AMP and the Medicaid rebate amount under the Affordable Care Act or other legislation could affect our 340B ceiling price calculations and negatively impact our results of operations.

HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under the new regulation. HRSA has also implemented a ceiling price reporting requirement related to the 340B program under which we are required to report 340B ceiling prices to HRSA on a quarterly basis. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report average sales price, or ASP, information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the ASP based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we must complete an application process with the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under this program, we would be obligated to make our "innovator" drugs available for procurement on an FSS contract and charge a price to four federal agencies—VA, U.S. Department of Defense, or DoD, Public Health Service and U.S. Coast Guard—that is no higher than the statutory Federal Ceiling Price, or FCP. The FCP is based on the non-federal average manufacturer price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. We also expect to participate in the Tricare Retail Pharmacy program, under which we would pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to TRICARE beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. The requirements under the 340B, FSS, and TRICARE programs will impact gross-to-net revenue for our current products and any product candidates that are commercialized in the future and could adversely affect our business and operating results.

We are shipping YUTIQ directly to physician offices or clinics to be administered to patients. YUTIQ is being shipped to physician offices or clinics primarily through specialty pharmacies and distributors. Most prefer to buy the product directly through our select distributors under a "buy and bill" model. Physicians who may not be willing to purchase our products through a specialty distributor because they do not prefer the buy and bill method may prefer to have another entity called a specialty pharmacy ship them the product at no cost to the physician. The specialty pharmacy bills the health plan for our product directly and then ships the product to the physician such that no costs are incurred by the physician. We have obtained a permanent "J" code for YUTIQ which assists physicians and hospitals in their ability to bill all payer types for the product.

We are shipping DEXYCU to ambulatory surgical centers, or ASCs, or to hospital outpatient surgical centers through specialty pharmacies and distributors. DEXYCU is being reimbursed for Medicare Part B patients in these settings through a transitional pass-through payment utilizing a "J" code. After the initial 3-year period (measured on the basis of the date Medicare receives its first claim for reimbursement for DEXYCU), DEXYCU may not qualify for separate payment and, therefore, may be subject to cataract bundled payment rates, which would significantly limit our ability to gain utilization and subsequent revenues.

If we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our price reporting and other obligations under the Medicaid Drug Rebate program, Medicare Part B, the 340B program, and the VA/FSS program are described in the risk factor entitled "Our products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business." Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. In the case of Medicaid pricing data, if we become aware that our reporting for a prior period was incorrect or has

changed as a result of a recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data were originally due. Such restatements and recalculations will increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program and may require us to offer refunds to covered entities.

We are liable for errors associated with our submission of pricing data. That liability could be significant. In addition to retroactive Medicaid rebates and the potential for issuing 340B program refunds, if we are found to have knowingly submitted false AMP, best price, or Non-FAMP information to the government, we may be liable for significant civil monetary penalties per item of false information. If we are found to have made a misrepresentation in the reporting of our ASP, the Medicare statute provides for significant civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly AMP and best price data on a timely basis could result in a significant civil monetary penalty per day for each day the information is late beyond the due date. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Significant civil monetary penalties also could apply to late submissions of Non-FAMP information. Civil monetary penalties could also be applied if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. In addition, claims submitted to federally-funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the federal civil False Claims Act. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We cannot assure you that our submissions will not be found by CMS or another governmental agency to be incomplete or incorrect.

Even though regulatory approval for DEXYCU and YUTIQ has been obtained in the U.S., we will still face extensive FDA regulatory requirements and may face future regulatory difficulties.

Even though regulatory approval for DEXYCU and YUTIQ has been obtained in the U.S., the FDA and state regulatory authorities may still impose significant restrictions on the indicated uses or marketing of DEXYCU and YUTIQ, or impose ongoing requirements for potentially costly post-approval studies or post-marketing surveillance. For example, as part of its approval of DEXYCU for the treatment of postoperative ocular inflammation, the FDA required under the Pediatric Research Equity Act, or PREA, that a Phase 3/4 prospective, randomized, active treatment-controlled, parallel-design multicenter trial be conducted to evaluate the safety of DEXYCU for the treatment of inflammation following ocular surgery for childhood cataract. This pediatric study will likely require us to undergo a costly and time-consuming development process. If we do not meet our obligations under the PREA for this pediatric study, the FDA may issue a non-compliance letter and may also consider DEXYCU to be misbranded and subject to potential enforcement action. We submitted a pediatric study protocol to the FDA as required. We have identified clinical sites and are currently conducting study start-up activities that are expected to lead to dosing of a first patient later this year.

We are also subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-marketing information. The holder of an approved NDA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA regulations and may be subject to other potentially applicable federal and state laws. The applicable regulations in countries outside the U.S. grant similar powers to the competent authorities and impose similar obligations on companies.

In addition, manufacturers of drug products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and adherence to commitments made in the NDA. We may also need to comply with some of the FDA's manufacturing regulations for devices with respect to YUTIQ. We and our third-party providers are generally required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

In addition to cGMP, the FDA may require that YUTIQ manufacturers comply with the Quality System Regulation, or QSR, which sets forth the FDA's manufacturing quality standards for medical devices, and other applicable government regulations and corresponding foreign standards. If we, or a regulatory authority, discover previously unknown problems with DEXYCU or YUTIQ, such as adverse events of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory authority may impose restrictions relative to DEXYCU, YUTIQ or their respective manufacturing facilities, including requiring recall or withdrawal of the product from the market, suspension of manufacturing, or other FDA action or other action by foreign regulatory authorities.

If we fail to comply with applicable regulatory requirements for DEXYCU or YUTIQ, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, modify or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or a pending application for marketing authorization or supplements to an NDA or to an application for marketing authorization submitted by us;
- seize our product; and/or
- refuse to allow us to enter into supply contracts, including government contracts.

Our relationships with physicians, patients and payors in the U.S. are subject to applicable anti-kickback, fraud and abuse laws and regulations. In addition, we are subject to patient privacy regulation by both the federal government and the states in which we conduct our business. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations and financial conditions.

Our current and future operations with respect to the commercialization of DEXYCU and YUTIQ are subject to various U.S. federal and state healthcare laws and regulations. These laws impact, among other things, our proposed sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals and others who may prescribe, recommend, purchase or provide our products, and other parties through which we market, sell and distribute our products. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws include, but are not limited to, the following:

- The U.S. federal Anti-Kickback Statute prohibits persons or entities from, among other things, knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and Medicare patients, prescribers, purchasers and formulary managers on the other. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution and administrative sanction, the exemptions and safe harbors are drawn narrowly, and practices or arrangements that involve remuneration may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection, and therefore would be subject to a facts and circumstances analysis to determine potential Anti-Kickback statute liability.

- The federal civil False Claims Act (which can be enforced through "qui tam," or whistleblower actions, by private citizens on behalf of the federal government) prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government. Many pharmaceutical and other healthcare companies have been investigated or subject to lawsuits by whistleblowers and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. In addition, the government and private whistleblowers have pursued False Claims Act cases against pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.
- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, and its implementing regulations, impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and impose notification obligations in the event of a breach of the privacy or security of individually identifiable health information.
- Numerous federal and state laws and regulations that address privacy and data security, including state data breach notification laws, state health information and/or genetic privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act, or FTC Act), govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming, and companies that do not comply with these state laws may face civil penalties.
- The majority of states have adopted analogous laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers. Other states have adopted laws that, among other things, require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities. In addition, some states have laws requiring pharmaceutical sales representatives to be registered or licensed, and still others impose limits on co-pay assistance that pharmaceutical companies can offer to patients.
- The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or pharmaceutical company may fail to comply fully with one or more of these requirements. 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 do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. 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, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting requirements if we become subject to a corporate integrity agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate

negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

The occurrence of any event or penalty described above may inhibit our ability to commercialize DEXYCU and YUTIQ in the U.S. and generate revenues, which would have a material adverse effect on our business, financial condition and results of operations.

If the market opportunities for our products and product candidates are smaller than we believe they are, our results of operations may be adversely affected and our business may suffer.

We focus our research and product development primarily on treatments of eye diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our products and product candidates, are based on estimates. These estimates may prove to be incorrect and new studies or clinical trials may change the estimated incidence or prevalence of these diseases. The number of patients in the U.S. and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

If any of our products have newly discovered or developed safety problems, our business would be seriously harmed.

All of our approved products are and will be subject to continued oversight by the FDA or other foreign regulatory bodies, and we cannot assure you that newly discovered or developed safety issues will not arise. Although we have seen no issue to date, we cannot rule out that issues may arise in the future. For example, with the use of any newly marketed drug by a wider patient population, serious adverse events may occur from time to time that initially do not appear to relate to the drug itself. If such events are subsequently associated with the drug, or if any other safety issue emerges, we or our collaboration partners may voluntarily, or FDA or other regulatory authorities may require that we suspend or cease marketing of our approved products or modify how we or they market our approved products. In addition, newly discovered safety issues may subject us to substantial potential liabilities and adversely affect our financial condition and business.

The Affordable Care Act and any changes in healthcare laws may increase the difficulty and cost for us to commercialize DEXYCU and YUTIQ in the U.S. and affect the prices we may obtain.

The U.S. has enacted or proposed legislative and regulatory changes affecting the healthcare system that could affect our ability to profitably sell DEXYCU and YUTIQ, prevent or delay marketing of our other product candidates, and restrict or regulate post-approval activities. The U.S. government and state legislatures also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription products.

The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of DEXYCU and YUTIQ in the U.S. are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs or biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D (such manufacturer discounts were increased from 50% to 70% effective as of January 1, 2019 as required by the Bipartisan Budget Act of 2018);
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- price reporting requirements for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;
- addition of entity types eligible for participation in the Public Health Service Act's 340B drug pricing program;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and

- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation or implementation. For example, on December 22, 2017, the U.S. government signed into law comprehensive tax legislation, referred to as the Tax Cuts and Jobs Act, or the Tax Act, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drugs plans, commonly known as the "donut hole," by raising the required manufacturer point-of-sale discount from 50% to 70% off the negotiated price effective as of January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible. It is unclear how the Affordable Care Act and its implementation, as well as efforts to repeal or replace, or invalidate, the Affordable Care Act, or portions thereof, will affect our business, financial condition and results of operations. It is possible that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of DEXYCU and YUTIQ in the U.S. or to successfully commercialize either product in the U.S.

We also expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for DEXYCU and YUTIQ in the U.S., and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenues, attain profitability or successfully commercialize DEXYCU and YUTIQ in the U.S.

Patient assistance programs for pharmaceutical products have come under increasing scrutiny by governments, legislative bodies and enforcement agencies. These activities may result in actions that have the effect of reducing prices or demand for our products, harming our business or reputation, or subjecting us to fines or penalties.

Recently, there has been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and copay assistance programs and manufacturers' donations to third-party charities that provide such assistance. If we, our vendors or donation recipients, are deemed to have failed to comply with relevant laws, regulations or government guidance in any of these areas, we could be subject to criminal and civil sanctions, including significant fines, civil monetary penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid, and burdensome remediation measures. Actions could also be brought against executives overseeing our business or other employees.

It is possible that any actions taken by the Department of Justice (DOJ) as a result of this industry-wide inquiry could reduce demand for our products and/or reduce coverage of our products, including by federal and state health care programs such as Medicare and Medicaid. If any or all of these events occur, our business, prospects and stock price could be materially and adversely affected.

If competitive products are more effective, have fewer side effects, are more effectively marketed and/or cost less than our products or product candidates, or receive regulatory approval or reach the market earlier, our product candidates may not be approved, and our products or product candidates may not achieve the sales we anticipate and could be rendered noncompetitive or obsolete.

We believe that pharmaceutical, drug delivery and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations and individual scientists are seeking to develop drugs, therapies, products, approaches or methods to treat our targeted diseases or their underlying causes. For our targeted diseases, competitors have alternate therapies that are already commercialized or are in various stages of development, ranging from discovery to advanced clinical trials. Any of these drugs, therapies, products, approaches or methods may receive government approval or gain market acceptance more rapidly than our products and product candidates, may offer therapeutic or cost advantages, or may more effectively treat our targeted diseases or their underlying causes, which could result in our product candidates not being approved, reduce demand for our products and product candidates or render them noncompetitive or obsolete.

Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. Our competitors may succeed in developing alternate technologies and products that, in comparison to the products or product candidates we have and are seeking to develop:

- are more effective and easier to use;
- are more economical;
- have fewer side effects;
- offer other benefits; or
- may otherwise render our products less competitive or obsolete.

Many of these competitors have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals or clearances and manufacturing and marketing products than we do.

Guidelines, recommendations and studies published by various organizations could reduce the use of our products and potential use of product candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors' products and product candidates. Any such guidelines, recommendations or studies that reflect negatively on our products or product candidates, either directly or relative to our competitive products, could result in current or potential decreased use, sales of, and revenues from one or more of our products and product candidates. Furthermore, our success depends in part on our and our partners' ability to educate healthcare providers and patients about our products and product candidates, and these education efforts could be rendered ineffective by, among other things, third-parties' guidelines, recommendations or studies.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our products and the diseases our therapies are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend the company or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

The micro-insert for ILUVIEN and YUTIQ delivers FA, a corticosteroid that is associated with certain adverse side effects in the eye, which may affect the success of this micro-insert for treatment of DME and non-infectious uveitis affecting the posterior segment of the eye.

The micro-insert for both ILUVIEN and YUTIQ delivers the non-proprietary corticosteroid FA, which is associated with cataract formation and elevated IOP and may increase the risk of glaucoma and related surgery to manage those side effects. These side effects shown in the Phase 3 trials for ILUVIEN resulted in limitations to the approved indications of ILUVIEN, and sales of ILUVIEN may be adversely affected by the potential side effects from FA relative to other treatments for DME. The extent of ILUVIEN's long-term side-effect profile beyond month 36 is not yet known. Alimera is conducting a five-year post-authorization, open label registry study of the safety of ILUVIEN in 800 patients treated with the European labeled indication, which was a condition of European approval. In July 2017, Alimera announced that the Medicines and Healthcare Products Regulatory Agency gave final approval for Alimera to cap total enrollment at 550 patients, with the last three-year patient follow-up visit anticipated in January 2020. Data from this study or other commercial experience could result in the withdrawal of ILUVIEN's marketing approval in one or more jurisdictions. Further, delay in the commercial launch of ILUVIEN in jurisdictions where ILUVIEN has already received marketing authorization could result in the withdrawal of marketing or regulatory authorization for ILUVIEN. In addition, the perception by physicians of this benefit of efficacy versus the side-effect profile could adversely affect sales of ILUVIEN.

YUTIQ has achieved encouraging safety results through the last follow-up visit at month 24 in its first Phase 3 trials and at month 12 in its second Phase 3 trial. However, there is no assurance that encouraging safety results will continue in these trials. There is also no assurance that the overall long-term risk-benefit profile for YUTIQ will be favorable or that it will be determined to be safe over the long-term for the treatment of non-infectious uveitis affecting the posterior segment of the eye in light of potential side effects from FA. These side effects may adversely affect sales of YUTIQ. In addition, because the micro-insert for ILUVIEN and YUTIQ are substantially the same, any safety issues that arise with respect to the ILUVIEN micro-insert could raise concerns about the YUTIQ micro-insert, which could cause us to suspend marketing of YUTIQ or subject us to substantial liability, which would adversely affect our financial condition and business.

DEXYCU is an intraocular suspension that delivers dexamethasone, a corticosteroid that is associated with certain adverse side effects in the eye, which may affect the success of DEXYCU for the treatment of post-operative inflammation.

DEXYCU is an intraocular suspension that delivers dexamethasone, a corticosteroid, which is associated with certain adverse side effects in the eye. The safety analyses from DEXYCU's clinical trials revealed that the most commonly reported adverse reactions were increases in IOP, corneal edema and iritis, a type of uveitis affecting the front of the eye. These side effects may adversely affect sales of DEXYCU.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, it could reduce our sales of those products or product candidates.

In the U.S., after an NDA is approved, the product generally becomes a "listed drug" which can, in turn, be relied upon by potential competitors in support of approval of an ANDA. The Federal Food, Drug, and Cosmetic Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create generic, non-infringing versions of a drug to facilitate the approval of an ANDA. These manufacturers might show that their product has the same active ingredients, dosage form, strength, route of administration, conditions of use, and labeling as our product candidate and might conduct a relatively inexpensive study to demonstrate that the generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product. These generic equivalents would be significantly less costly than ours to bring to market, and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of DEXYCU and YUTIQ, and any other product candidates that we may develop and commercialize.

We face the risk of product liability exposure as we commercialize DEXYCU and YUTIQ, and other product candidates that we may develop and commercialize. We also may face product liability claims from patients who are treated with any of our product candidates in clinical trials. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- termination of clinical trial sites or entire trial programs that we conduct in the future relating to DEXYCU, YUTIQ or our product candidates;
- withdrawal of clinical trial participants from any future clinical trial relating to DEXYCU, YUTIQ or our product candidates;
- significant costs to defend the related litigation;
- substantial money awards to patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage.

We currently carry product liability insurance with coverage up to $15.0 million in the aggregate, with a per incident limit of $15.0 million, which may not be adequate to cover all liabilities that we may incur. Further, 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. Our inability to maintain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of DEXYCU and YUTIQ, or the development and commercialization of our other product candidates.

Additionally, any agreements we may enter into in the future with collaborators in connection with the development or commercialization of DEXYCU, YUTIQ or any of our other product candidates may entitle us to indemnification against product liability losses, but such indemnification may not be available or adequate should any claim arise. In addition, several of our agreements require us to indemnify third parties and these indemnification obligations may exceed the coverage under our product liability insurance policy.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Our promotional materials, statements and training methods must comply with applicable laws and regulations, including FDA's prohibition of the promotion of unapproved, or off-label, use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's independent choice of treatment within the practice of medicine. If the FDA determines that our promotional materials, statements or activities constitute promotion of an off-label use, we could be required to modify our promotional materials, statements or training methods or subject us to regulatory or enforcement actions, such as the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, disgorgement of money, operating restrictions or criminal penalties. We may also be subject to actions by other governmental entities or private parties, such as the U.S. civil False Claims Act, civil whistleblower or "qui tam" actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional materials or activities to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities. In that event, our reputation could be damaged and market adoption of our approved products could be impaired.

Even though FDA approval for DEXYCU has been obtained in the U.S., we may never obtain approval for or successfully commercialize it outside of the U.S., which would limit our ability to realize its full market potential.

In order to market DEXYCU outside of the U.S., we must obtain marketing authorizations and comply with numerous and varying regulatory requirements of other countries regarding quality, safety and efficacy. Clinical trials conducted in one country may not be accepted by foreign regulatory authorities, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of DEXYCU in those countries. While our management team has experience in obtaining foreign regulatory approvals at other companies, we, as a company, do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, we would not be able to realize the full market potential of DEXYCU.

RISKS RELATED TO *THE* REGULATORY APPROVAL AND CLINICAL DEVELOPMENT OF OUR PRODUCT CANDIDATES

The clinical development and regulatory approval processes of the FDA or other foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to achieve favorable clinical outcomes or to obtain regulatory approval for our product candidates, our business may be substantially harmed.

The time required to obtain approval by the FDA or other foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory agency. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the regulatory authority may not accept our application for filing;
- the regulatory authority may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the regulatory authority that a product candidate is safe and effective for its proposed indication and/or that its clinical and other benefits outweigh its safety risks;
- the regulatory authority may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the approval of a drug application or marketing authorization application;
- the regulatory authority may fail to approve our or our third-party manufacturers' manufacturing processes or facilities for clinical and commercial supplies; and
- the approval policies or regulations of the regulatory authority may change in a manner rendering our clinical data insufficient for approval;
- the uncertainty inherent in early stage product development, such as EYP-1901.

We cannot be certain that any of our current product candidates will receive regulatory approval. If we do not receive regulatory approval for our product candidates, our business may be substantially harmed.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

All of our product development is at earlier stages. Product development at all stages involves a high degree of risk, and only a small proportion of research and development programs result in product candidates that advance to pivotal clinical trials or result in approved products. There is no assurance that any feasibility study agreements we enter into with third parties, or our own research and development programs and collaborations, will result in any new product candidates, or that we or any licensees will commence clinical trials for any new product candidates or continue clinical trials once commenced. If clinical trials conducted by or for us or any licensees for any product candidates do not provide the necessary evidence of safety and efficacy, those product candidates will not receive the necessary regulatory approvals, cannot be sold, and will not generate revenues for us.

We may also experience delays in clinical trials of our product candidates or the time required to complete clinical trials for our product candidates may be longer than anticipated. Our future clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed, or even terminated, for a variety of reasons, including, but not limited to:

- decisions not to pursue development of product candidates due to pre-clinical or clinical trial results or market factors;
- lack of sufficient funding;
- inability to attract clinical investigators for trials;
- inability to recruit patients in sufficient numbers or at the expected rate;
- decisions by licensees not to exercise options for products or not to pursue or promote products licensed to them;
- adverse side effects;
- failure of trials to demonstrate safety and efficacy;
- failure to meet FDA or other regulatory agency requirements for clinical trial design, or inadequate clinical trial design;
- inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product candidate;
- failures by, changes in our (or our licensees') relationship with, or other issues at, CROs, vendors and investigators responsible for pre-clinical testing and clinical trials;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or foreign regulatory authorities;
- inability to obtain supplies and/or to manufacture sufficient quantities of materials for use in clinical trials;
- stability issues with clinical materials;
- failure to comply with GLP, GCP, cGMP or similar foreign regulatory requirements that affect the conduct of pre-clinical and clinical studies and the manufacturing of product candidates;
- requests by regulatory authorities for additional data or clinical trials;
- governmental or regulatory agency assessments of pre-clinical or clinical testing that differ from our (or our licensees') interpretations or conclusions;
- governmental or regulatory delays, or changes in approval policies or regulations; and
- developments, clinical trial results and other factors with respect to competitive products and treatments.

If clinical trials for our or our licensees' product candidates are delayed or terminated for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize our product candidates could be materially harmed.

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 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.

We have historically based our research and development efforts primarily on our proprietary technologies for the treatment of chronic eye diseases. As a result of pursuing the development of product candidates using our proprietary technologies, we may fail to develop product candidates or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development.

Initial results from a clinical trial do not ensure that the trial will be successful and success in early stage clinical trials does not ensure success in later-stage clinical trials.

Results from pre-clinical testing, early clinical trials, investigator-sponsored studies and other data and information often do not accurately predict final pivotal clinical trial results. In addition, data from one pivotal clinical trial may not be predictive of the results of other pivotal clinical trials for the same product candidate, even if the trial designs are the same or similar. Data obtained from pre-clinical studies and clinical trials are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Adverse side effects may be observed in clinical trials that delay, limit or prevent regulatory approval, and even after a product candidate has received marketing approval, the emergence of adverse side effects in more widespread clinical practice may cause the product's regulatory approval to be limited or even rescinded. Additional trials necessary for approval may not be undertaken or may ultimately fail to establish the safety and efficacy of our product candidates.

In addition, while the clinical trials of our product candidates are designed based on the available relevant information, in view of the uncertainties inherent in drug development, such clinical trials may not be designed with a focus on indications, patient populations, dosing regimens, safety or efficacy parameters or other variables that will provide the necessary safety and efficacy data to support regulatory approval to commercialize the product. In addition, the methods we select to assess particular safety or efficacy parameters may not yield statistically significant results regarding our product candidates' effects on patients. Even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. Pre-clinical and clinical data can be interpreted in different ways. Accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways from us or our partners, which could delay, limit or prevent regulatory approval.

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to institutional review boards or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are required to conduct additional clinical trials or other studies with respect to our product candidates beyond those that we currently contemplate, or if we are unable to successfully complete our clinical trials or other studies, we may be delayed in obtaining regulatory approval of any of our product candidates, we may not be able to obtain regulatory approval at all or we may obtain approval of indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for our product candidates. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business would be harmed.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our product candidates, our competitors could develop and commercialize technology and products similar to ours, and our competitive position could be harmed.

Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the U.S. and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. We seek patent protection for many different aspects of our product candidates, including their compositions, their methods of use, processes for their manufacture, and any other aspects that we deem to be commercially important to the development of our business.

The patent prosecution process is expensive and time-consuming, and we and any licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our product candidates or delivery technologies at a reasonable cost, in a timely fashion, or at all. For technology licensed to third parties, we may not have the right to control the preparation, filing and/or prosecution of the corresponding patent applications, or to maintain patent rights corresponding to such technology. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is also possible that we, or any licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised, and we might not be able to prevent third parties from making, using, and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid or unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition, and operating results.

The patent positions of pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue, are highly uncertain. For example, recent changes to the patent laws of the U.S. provide additional procedures for third parties to challenge the validity of issued patents. Under the Leahy-Smith America Invents Act, or AIA, which was signed into law on September 16, 2011, patents issued from applications with an effective filing date after March 15, 2013 may be challenged by third parties using the post-grant review procedure which allows challenges for a number of reasons, including prior art, sufficiency of disclosure, and subject matter eligibility. Under the AIA, patents may also be challenged under the *inter partes* review

procedure. *Inter partes* review provides a mechanism by which any third party may challenge the validity of any issued U.S. Patent in the USPTO on the basis of prior art. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings as compared to the evidentiary standard relied on in U.S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

With respect to foreign jurisdictions, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Also, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant.

Our patents and patent applications, even if unchallenged by a third party, may not adequately protect our intellectual property or prevent others from designing around our claims. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the U.S. Further, the examination process may require us to narrow the claims of pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. 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 sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be impaired.

As of March 1, 2020, we had 379 patents or granted applications and 110 pending patent applications, including patents and pending applications covering our Durasert, Verisome and other technologies. With respect to these patent rights, we do not know whether any of our patent applications will result in issued patents or, if any of our patent applications do issue, whether such patents will protect our technology in whole or in part, or whether such patents will effectively prevent others from commercializing competitive technologies and products. There is no guarantee that any of our issued or granted patents will not later be found invalid or unenforceable. Furthermore, since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. For applications with an effective filing date before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the U.S. transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the U.S. resulting from the AIA.

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, until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, that we were the first to file for patent protection of such inventions, or that we have found all of the potentially relevant prior art relating to our patents and patent applications that could invalidate one or more of our patents or prevent one or more of our patent applications from issuing. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate oppositions, interferences, re-examinations, post-grant reviews, *inter partes* reviews, nullification or derivation actions in court or before patent offices or similar proceedings challenging the validity, enforceability, or scope of such patents, which may result in the patent claims being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties.

Furthermore, 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 product candidates might expire before or shortly after such product 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 the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of any party from whom we may license patents from in the future. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In a patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. A court may decide that a patent of ours or of any of our future licensors is not valid, or is unenforceable, or may 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. In addition, to the extent that we have to file patent litigation in a federal court against a U.S. patent holder, we would be required to initiate the proceeding in the state of incorporation or residency of such entity. With respect to the validity question, for example, we cannot be certain that no invalidating prior art exists. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found unenforceable, or interpreted narrowly, and it could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products. Such a loss of patent protection could compromise our ability to pursue our business strategy.

As noted above, interference proceedings brought by the USPTO for applications with an effective filing date before March 16, 2013, or for patents issuing from such applications may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with any of our future licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U.S. 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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. 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.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or other foreign patent offices, 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 invalidate or reduce the scope of, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs 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.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. may be less extensive than those in the U.S. In addition, the laws and practices of some foreign countries do not protect intellectual property rights, especially those relating to life sciences, to the same extent as federal and state laws in the U.S. For example, novel formulations of drugs and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Also, some foreign countries, including EU countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. Consequently, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, and we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions into or within the U.S. or other jurisdictions. This could limit our potential revenue opportunities. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property. We may not prevail in any lawsuits that we initiate in these foreign countries and the damages or other remedies awarded, if any, may not be commercially meaningful.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which could be uncertain and could harm our business.

Our commercial success depends upon our ability, and the ability of our partners and collaborators, to develop, manufacture, market and sell our products and product candidates, if approved, and use our proprietary technologies without infringing the proprietary rights of third parties. While many of our product candidates are in pre-clinical studies and clinical trials, we believe that the use of our product candidates in these pre-clinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the U.S., which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our other product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and expensive and time-consuming patent litigation before our product candidates may be commercialized. There can be no assurance that our products or product candidates do not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event.

There is considerable intellectual property litigation in the 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 product candidates, including interference or derivation proceedings before the USPTO. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

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 commercializing our products or product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market products or product candidates based on our technology, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenues sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court order, to cease commercializing our products or product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. A finding of infringement could prevent us from commercializing our products or product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our commercialization efforts, delay our research and development efforts and limit our ability to continue our operations. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with our products or product candidates. In these circumstances, we may need to defend or assert our patents by various means, including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Changes in either U.S. or foreign patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products or product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity, and it therefore is costly, time-consuming and inherently uncertain. As noted above, the AIA has significantly changed U.S. patent law. In addition to transitioning from a "first-to-invent" to "first-to-file" system, the AIA also limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge issued patents in the USPTO via post-grant review or *inter partes* review, for example. All of our U.S. patents, even those issued before March 16, 2013, may be challenged by a third party seeking to institute *inter partes* review.

Depending on decisions by the U.S. Congress, the federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may be subject to claims asserting that our employees, consultants, independent contractors and advisors have wrongfully used or disclosed confidential information and/or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed confidential information and/or intellectual property, including trade secrets or other proprietary information, of the companies that any such individual currently or formerly worked for or provided services to. Litigation may be necessary to defend against these claims. If we fail in 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 defending against such claims, litigation could result in substantial costs and be a distraction to our business.

In addition, while we require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Intellectual property rights do not prevent all potential threats to competitive advantages we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage.

The following examples are illustrative:

- others may be able to make drug and device components that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or any of our licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or any of our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- the prosecution of our pending patent applications may not result in granted patents;
- granted patents that we own or have licensed may not cover our products or may be held not infringed, invalid or unenforceable, as a result of legal challenges by our competitors;
- with respect to granted patents that we own or have licensed, especially patents that we either acquire or in-license, if certain information was withheld from or misrepresented to the patent examiner, such patents might be held to be unenforceable;
- patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product;

- our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent application for certain technologies, trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

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

In addition to seeking patent protection for certain aspects of our product candidates and technologies, we also consider trade secrets, including confidential and unpatented know-how, important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by customarily entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, outside scientific and commercial collaborators, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. 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. In addition, our trade secrets may otherwise become known, including through a potential cybersecurity breach, or may be independently developed by competitors.

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 in the U.S. and certain foreign jurisdictions 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 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.

If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We expect to rely on trademarks as one means to distinguish any of our approved products from the products of our competitors. We have received registrations for DEXYCU®, YUTIQ®, DELIVERING INNOVATION TO THE EYE® and Durasert®. ILUVIEN® is Alimera's trademark. Retisert® and Vitrasert® are Bausch & Lomb's trademarks. The Verisome® technology is exclusively licensed to us by Ramscor, Inc and the Verisome® mark is owned by Ramscor, Inc. Our and our licensees' trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. For our trademarks, we have entered into a co-existence agreement with Sun Pharma and a settlement agreement with Merck allowing continued, though somewhat limited, use of two of our marks. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively.

RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES

Public health epidemics, pandemics or outbreaks, including the recent coronavirus pandemic, could adversely affect our business.

Public health epidemics, pandemics or outbreaks, and the resulting business or economic disruptions resulting therefrom, could adversely impact our business as well as our ability to raise capital. In December 2019, a novel strain of coronavirus (COVID-19) was identified in Wuhan, China. The virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 100 countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world.

The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, new information that may emerge concerning the severity of COVID-19 and public and private actions to contain COVID-19 or treat its impact. COVID-19 has and will likely continue to result in social, economic and labor instability in the countries in which we or the third parties with whom we engage operate. For example, we have licensed clinical development, regulatory, reimbursement and distribution rights for DEXYCU and Durasert FA to Ocumension in Mainland China, Hong Kong, Macau and Taiwan. Ocumension's ability to conduct clinical trials may be materially and adversely affected due to COVID-19, which could have the result of, among other things, delaying the enrollment of patients in

clinical trials, causing delays in the delivery of product supply for clinical trials and affecting the ability of clinical investigators, contract research organizations and other third-party service providers to devote sufficient time and resources to the clinical development programs. While we cannot presently predict the scope and severity of any potential business shutdowns or disruptions, if we or any of the third parties with whom we engage, including the suppliers, manufacturers and other third parties in our global supply chain, clinical trial sites, regulators, surgeons, ASCs, potential business development partners and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. In addition, the pandemic's impact on the medical community and the global economy could have an adverse impact on our sales if, for example, fewer cataract and uveitis procedures are performed than we previously anticipated. Further, any sustained disruption in the capital markets from the COVID-19 pandemic could negatively impact our ability to raise capital.

If we encounter issues with our CMOs or suppliers, we may need to qualify alternative manufacturers or suppliers, which could impair our ability to sufficiently and timely manufacture and supply DEXYCU.

We currently depend on CMOs and suppliers for DEXYCU. Although we could obtain the drug product and other components for DEXYCU from other CMOs and suppliers, we would need to qualify and obtain FDA approval for such CMOs or suppliers as alternative sources, which could be costly and cause significant delays. In addition, the manufacturer of the drug product in DEXYCU conducts its manufacturing operations for us at a single facility. Unless and until we qualify additional facilities, we may face limitations in our ability to respond to manufacturing issues. For example, if regulatory, manufacturing or other problems require this manufacturer to discontinue production at its facility, or if the equipment used for the production of the drug product in this facility is significantly damaged or destroyed by fire, flood, earthquake, power loss or similar events, the ability of such manufacturer to manufacture DEXYCU may be significantly impaired. In the event that this party suffers a temporary or protracted loss of its materials, facility or equipment, we would still be required to obtain FDA approval to qualify a new manufacturer as an alternate manufacturer for the drug product before any drug product manufactured by such manufacturer could be sold or used. Any production shortfall that impairs the supply of DEXYCU could adversely affect our ability to satisfy demand for DEXYCU, which could have a material adverse effect on our product sales, results of operations and financial condition.

We use our own facility for the manufacturing of YUTIQ, which requires significant resources, and which could adversely affect its commercial viability.

We currently manufacture commercial supplies of YUTIQ ourselves at our Watertown, MA facility. We have, and will continue, to perform extensive audits of our suppliers, vendors and contract laboratories. The cGMP requirements govern, among other things, recordkeeping, production processes and controls, personnel and quality control. To ensure that we continue to meet these requirements, we have and will continue to expend significant time, money and effort.

The commercial manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any issue relating to the manufacture of YUTIQ will not occur in the future.

The FDA also may, at any time following approval of a product for sale, audit our manufacturing facilities. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, FDA may issue a Form FDA-483 and/or an untitled or warning letter, or we or the FDA may require remedial measures that may be costly and/or time consuming for us to implement and that may include the temporary or permanent suspension of commercial sales, recalls, market withdrawals, seizures or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us could materially harm our business.

In addition, although we could contract with other third parties to manufacture YUTIQ, we would need to qualify and obtain FDA approval for a contract manufacturer or supplier as an alternative source for YUTIQ, which could be costly and cause significant delays.

Our YUTIQ manufacturing operations depend on our Watertown, MA facility. If this facility is destroyed or is out of operation for a substantial period of time, our business may be adversely impacted.

We currently conduct our manufacturing operations related to YUTIQ in our facility located in Watertown, MA. If regulatory, manufacturing or other problems require us to discontinue production at our Watertown, MA facility, we will not be able to have commercial supply of YUTIQ, which would adversely impact our business. If the facility or the equipment in it is significantly damaged or destroyed by fire, flood, power loss or similar events, we may not be able to quickly or inexpensively replace our facility.

In the event of a temporary or protracted loss of either facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with necessary regulatory requirements.

Off-label sales of ILUVIEN to treat non-infectious uveitis affecting the posterior segment of the eye may adversely affect sales of YUTIQ.

The micro-inserts that comprise ILUVIEN and YUTIQ have substantially the same design, polymers and release rate, and both deliver the corticosteroid FA. Although YUTIQ is considered pharmaceutically different from ILUVIEN and the products are approved for different indications, ILUVIEN is already approved and marketed. It is possible that physicians will prescribe ILUVIEN for the treatment of non-infectious uveitis affecting the posterior segment of the eye on an off-label basis, which could adversely affect the sales of YUTIQ.

If third-party manufacturers, wholesalers and distributors fail to devote sufficient time and resources to DEXYCU or their performance is substandard, our product supply may be impacted.

Our reliance on a limited number of manufacturers, wholesalers and distributors exposes us to the following risks, any of which could limit commercial supply of our products, result in higher costs, or deprive us of potential product revenues:

- our CMOs, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations;
- our wholesalers and distributors could become unable to sell and deliver DEXYCU for regulatory, compliance and other reasons;
- our CMOs, wholesalers and distributors could default on their agreements with us to meet our requirements for commercial supply of DEXYCU;
- our CMOs, wholesalers and distributors may not perform as agreed or may not remain in business for the time required to successfully produce, store, sell and distribute DEXYCU and we may incur additional cost; and
- if our CMOs, wholesalers and distributors were to terminate our arrangements or fail to meet their contractual obligations, we may be forced to delay the commercialization of DEXYCU.

Our reliance on third parties reduces our control over our development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. For example, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates or supply our commercial volume of DEXYCU. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

We do not control the development or commercialization of YUTIQ in the EMEA, which is licensed to Alimera, and as a result we may not realize the full market potential of YUTIQ.

Under the Amended Alimera Agreement, we granted Alimera rights to use our proprietary drug delivery platform for the treatment of uveitis, including non-infectious uveitis affecting the posterior segment of the eye, in the EMEA (under the ILUVIEN trademark) and subsequently withdrew our YUTIQ MAA and orphan drug designation for non-infectious uveitis affecting the posterior segment of the eye . Alimera is now responsible for obtaining all regulatory approvals in the EMEA. Under this agreement, we have no control over Alimera's regulatory activities in the EMEA (with the exception of the completion of our ongoing Phase 3 uveitis clinical trials), including regulatory approvals, and no direct control over commercialization efforts for ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye in the EMEA. Alimera has only limited experience in filing and supporting the applications necessary to obtain marketing approvals for product candidates. Alimera was responsible for filing a Type II variation for ILUVIEN for the treatment of non-infectious uveitis affecting the posterior segment of the eye. In December 2017, Alimera submitted a Type II variation for ILUVIEN to add the indication of recurrent and persistent non-infectious uveitis affecting the posterior segment of the eye to the ILUVIEN label. In January 2018, Alimera received validation of this Type II variation submission in all 17 European countries in which Alimera had previously received regulatory approval for ILUVIEN for DME. According to Alimera's public filings, Alimera submitted follow-up data supporting its Type II variation application in October 2018. Alimera obtained approval for its application in March 2019 and, subject to obtaining pricing and reimbursement in each applicable

country, will be marketed as ILUVIEN. Despite approval, the processes of regulatory authorities are extensive, lengthy, expensive, and uncertain, and such regulatory authorities may delay or limit the development and commercialization of Durasert FA. Further, Alimera may abandon further development of Durasert FA in the EMEA. Because the full market potential of Durasert FA is contingent upon the successful development and commercialization of ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye in the EMEA, we will be dependent on Alimera to achieve the full market potential of Durasert FA. If Alimera does not succeed in obtaining regulatory approval of ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye in the EMEA for any reason, or does not succeed in securing market acceptance of ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye in the EMEA, or elects for any reason to discontinue development of ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye, we will be unable to realize the full market potential of Durasert FA.

If our CROs, vendors and investigators do not successfully carry out their responsibilities or if we lose our relationships with them, our development efforts with respect to our product candidates could be delayed.

We are dependent on CROs, vendors and investigators for pre-clinical testing and clinical trials related to our product development programs. These parties are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If they do not timely fulfill their responsibilities or if their performance is inadequate, the development and commercialization of our product candidates could be delayed. The parties with which we contract for execution of clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our product candidates. In addition, if we or our CROs fail to comply with applicable current Good Clinical Practices, or cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with cGCPs.

Switching or adding additional CROs involves additional cost and requires management time and focus. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our ability to advance our product candidates through clinical trials will be compromised. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Our employees, collaborators, service providers, independent contractors, principal investigators, consultants, CSOs, vendors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, collaborators, independent contractors, principal investigators, consultants, CSOs, vendors and CROs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations; or
- laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from third parties and severe reputational harm.

Although we have adopted a Code of Business Conduct to govern and deter such behaviors, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations.

The success of our current and possible future collaborative and licensing arrangements depends and will depend heavily on the experience, resources, efforts and activities of our licensees, and if they are not successful in developing and marketing our products or product candidates, as applicable, it will adversely affect our revenues, if any, from those products.

Our business strategy includes continuing to leverage our technology platform by entering into collaborative and licensing arrangements for the development and commercialization of our products and product candidates, where appropriate. The success of current and future collaborative and licensing arrangements do and will depend heavily on the experience, resources, skill, efforts and activities of our licensees. Our licensees have had, and are expected to have, significant discretion in making decisions related to the development of product candidates and the commercialization of products under these collaboration agreements. Risks that we face in connection with our collaboration and licensing strategy include the following:

- our collaborative and licensing arrangements are, and are expected to be, subject to termination under various circumstances, including on short notice and without cause;
- we are required, and expect to be required, under our collaborative and licensing arrangements, not to conduct specified types of research and development in the field that is the subject of the arrangement or not to sell products in such field, limiting the areas of research, development and commercialization that we can pursue;
- our licensees may develop and commercialize, either alone or with others, products that are similar to or competitive with our products;
- our licensees may change the focus of their development and commercialization efforts or decrease or fail to increase spending related to our products or product candidates, thereby limiting the ability of these products to reach their potential;
- our licensees may lack the funding, personnel or experience to develop and commercialize our products successfully or may otherwise fail to do so; and
- our licensees may not perform their obligations, in whole or in part.

We currently have collaboration and licensing arrangements with various companies, most significantly Alimera. Although we believe potential revenues from ILUVIEN are important to our future results of operations and financial condition, Alimera has limited experience and limited financial resources. Alimera has reported that its negative cash flows from operations and accumulated deficit raise substantial doubt about its ability to continue as a going concern. Further, due to the limited revenue generated by Alimera to date, Alimera may not be able to maintain compliance with covenants under its loan agreement and, in the event of a default, we do not know whether Alimera will be able to obtain amendments or waivers of those covenants. We do not know if Alimera will be able to raise additional financing if and when required.

If our current and future licensees are not successful in developing and marketing our products, it will adversely affect our revenues, if any, from those products.

Our current licensees may terminate their agreements with us at any time or fail to fulfill their obligations under those agreements, and, if they do, we will lose the benefits of those agreements.

Our licensees have rights of termination under our agreements with them and could terminate those agreements without cause on short notice. Further, our licensees may fail to fulfill their obligations under their agreements, or we may disagree with them over the rights and obligations under those agreements, which could result in breach of the agreements and/or termination. Exercise of termination rights by one or more of our licensees or by us may leave us without the financial benefits and development, marketing or sales resources provided under the terminated agreement. It could be necessary for us to replace, or seek to provide ourselves, the services provided by the licensee, and there is no assurance we would be successful in doing so. It could delay, impair or stop the development or commercialization of products or product candidates licensed to them or require significant additional capital investment by us, which we may not have the resources to fund. If any of our licensees do not perform their obligations under our agreements or if any of those agreements are terminated, it could have an adverse effect on our business, financial condition and results of operations.

There is no assurance that Alimera will successfully commercialize ILUVIEN or that we will receive significant revenues from the commercialization of ILUVIEN.

We are entitled to royalties on a country-by-country and quarter-by-quarter basis on net sales of ILUVIEN where Alimera markets ILUVIEN directly and to a percentage of product revenues, royalties and non-royalty consideration where Alimera sublicenses the marketing of ILUVIEN. The commercialization of ILUVIEN is a significant undertaking by Alimera. Alimera's sales of ILUVIEN have not been significant to date, Alimera has continued to incur operating losses, and it has violated, and in the future may violate, the financial covenants of its loan agreement. We do not know if, when, or to what extent Alimera's ILUVIEN net revenues will increase significantly, which would generate royalties to us from the commercialization of ILUVIEN. The amount and timing of any revenues we receive will be affected by many factors including:

- Alimera's and its distributors' and sublicensees' ability to effectively market and sell ILUVIEN in each country where sold;
- the manner of sale, whether directly by Alimera or by sublicensees or distributors, and the terms of sublicensing and distribution agreements;
- the amount and timing of sales of ILUVIEN in each country;
- regulatory approvals, appropriate labeling, and desirable pricing, insurance coverage and reimbursement;
- competition;
- commencement of marketing in additional countries; and
- Alimera's ability to raise adequate capital as needed to fund its operations, to maintain compliance with its loan agreement and to achieve profitability from its operations.

If Alimera is not successful in commercializing ILUVIEN, it would adversely affect our business, operating results and financial condition.

Sales of ILUVIEN for DME may be materially adversely affected by pricing and reimbursement decisions of regulatory bodies, insurers and others.

Prices, coverage and reimbursement to consumers of ILUVIEN for DME, like other products, are generally regulated by third-party payors, such as government health administration authorities and plans, private health insurers and other organizations and affect ILUVIEN's sales. The timing and complexity of those reimbursements also affect sales. Prices in the EU are generally lower and coverage and access to products more limited than in the U.S. For example, in the U.K. and Scotland, National Health Service coverage is limited to the treatment of the eyes of chronic DME patients unresponsive to existing therapies that have undergone cataract surgery, subject to simple patient access schemes. Alimera may not achieve satisfactory agreements with statutory or other insurers. We do not know what levels of pricing will be approved or reimbursed for ILUVIEN, or what restrictions will be placed on its use or reuse in countries where ILUVIEN is not currently sold. In the U.S., Alimera has offered extended customer payment terms. Future net sales of ILUVIEN and, accordingly, the amount of royalties that we may receive from such net sales, may be adversely affected by pricing and reimbursement decisions, and such effects may be material.

If we or our licensees fail to comply with environmental laws and regulations, our or their ability to manufacture and commercialize products may be adversely affected.

Medical and biopharmaceutical research and development involves the controlled use of hazardous materials, such as radioactive compounds and chemical solvents. We and our licensees are subject to federal, state and local laws and regulations in the U.S. and abroad governing the use, manufacture, storage, handling and disposal of such materials and waste products. We and they could be subject to both criminal liability and civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, claimants may sue us or them for resulting injury or contamination, and the liability may exceed our or their ability to pay. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair the research, development or production efforts of our company or our licensees and harm our operating results.

RISKS RELATED TO OUR INDUSTRY, STRATEGY AND OPERATIONS

If we fail to retain key personnel, our business could suffer.

We are dependent upon the principal members of our management and scientific staff. In addition, we believe that our future success in developing and marketing our products will depend on whether we can attract and retain additional qualified management and scientific personnel as well as a sales and marketing staff. There is strong competition for qualified personnel within the industry in which we operate, and we may not be able to attract and retain such personnel. As we have a small number of employees and we believe our products and product candidates are unique and highly specialized, the loss of the services of one or more of the principal members of our management or scientific staff, or the inability to attract and retain additional personnel and develop expertise as needed, could have a material adverse effect on our results of operations and financial condition.

Changes in management and other key personnel have the potential to disrupt our business, and any such disruption could adversely affect our operations, programs, growth, financial condition or results of operations. Further, new members of management may have different perspectives on programs and opportunities for our business, which may cause us to focus on new business opportunities or reduce or change emphasis on our existing business programs.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

Implementation of our development and commercialization of product strategies will require additional managerial, operational, sales, marketing, financial and other resources. Our current management, personnel and systems may not be adequate to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, employee turnover and reduced productivity. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. Future growth would impose significant added responsibilities on members of management, including:

- managing the commercialization of DEXYCU and YUTIQ;
- overseeing our pre-clinical studies and clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including any sales and marketing personnel engaged in connection with the commercialization of DEXYCU and YUTIQ;
- engaging and managing our relationship with any contract sales organizations; and
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties; and improving our managerial, development, operational and financial systems and procedures.

As our operations expand, we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. Failure to accomplish any of these activities could prevent us from successfully growing our company.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Such an event could cause interruption of our operations. As part of our business, we and our vendors maintain large amounts of confidential information, including non-public personal information on patients and our employees Breaches in security could result in the loss or misuse of this information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, interruption to our operations, damage to our reputation or otherwise have a material adverse effect on our business, financial condition and operating results. We expect to have appropriate information security policies and systems in place in order to prevent unauthorized use or disclosure of confidential information, including non-public personal information, there can be no assurance that such use or disclosure will not occur.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions, which could include civil or criminal penalties, as well as private litigation and/or adverse publicity, any of which could negatively affect our operating results and business.

We may be subject to laws and regulations that address privacy and data security of patients who use our products or product candidates in the U.S. and in states in which we conduct our business. In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, state genetic privacy laws, and federal and state consumer protection and privacy laws (including, for example, Section 5 of the FTC) ACT and the CCPA - govern the collection, use, disclosure, and protection of health-related and other personal information. Compliance with these laws is difficult, constantly
evolving, and time consuming. In addition, state laws govern the privacy and security of health, research and genetic information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with applicable data protection laws and regulations could result in government enforcement actions and create liability for us, which could include civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

For instance, HIPAA imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and imposes notification obligations in the event of a breach of the privacy or security of individually identifiable health information on entities subject to HIPAA and their business associates that perform certain activities that involve the use or disclosure of protected health information on their behalf. We may obtain health information from third parties (e.g., research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA – other than potentially with respect to providing certain employee benefits – we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In the EU, the GDPR imposes strict obligations on the processing of personal data, including relating to the transfer of personal data from the European Economic Area to third countries such as the US. If we act in violation of the GDPR we may face significant penalties of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain violations, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious violations.

We may be exposed to liabilities under the FCPA and other U.S. and foreign anti-corruption anti-money laundering, export control, sanctions, and other trade laws and regulations, and any determination that we violated these laws could have a material adverse effect on our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control. We are also subject to the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, the Proceeds of Crime Act 2002, and possibly other anti-bribery and anti-money laundering laws in countries outside of the U.S. in which we conduct our activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees and third-party intermediaries from authorizing, promising, offering, providing, soliciting, or accepting, directly or indirectly, improper payments or benefits to or from any person whether in the public or private sector. As we commercialize DEXYCU and YUTIQ, and any of other product candidates that we may develop, we may engage with third-party manufacturers and collaborators who operate abroad and are required to obtain certain necessary permits, licenses and other regulatory approvals with respect to our business. Our activities abroad create the risk of unauthorized payments or offers of payments by employees, consultants, sales agents or distributors, even though they may not always be subject to our control. It is our policy to implement safeguards to discourage these practices by our employees, consultants, sales agents and distributors. However, our existing safeguards and any future improvements may prove to be less than effective, and the employees, consultants, sales agents, or distributors of our company may engage in conduct for which we might be held responsible, even if we do not explicitly authorize such activities.

Noncompliance with anti-corruption, anti-money laundering, export control, sanctions, and other trade laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. Responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In addition, the U.S. government may seek to hold us liable for successor liability FCPA violations committed

by companies in which we invest or that we acquire. As a general matter, enforcement actions and sanctions could harm our business, results of operations, and financial condition.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

The trading price of the shares of our common stock has been highly volatile, and purchasers of our common stock could incur substantial losses.

The price of our common stock is highly volatile and may be affected by developments directly affecting our business, as well as by developments out of our control or not specific to us. The pharmaceutical and biotechnology industries, in particular, and the stock market generally, are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volumes of companies in the pharmaceutical and biotechnology industries, including ours, can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, our performance. The price of our common stock and their trading volumes may fluctuate based on a number of factors including, but not limited to:

- the timing, costs and progress of our commercialization efforts;
- clinical trials and their results, and other product and technological developments and innovations;
- FDA and other domestic and international governmental regulatory actions, receipt and timing of approvals of our product candidates, and any denials and withdrawal of approvals;
- competitive factors, including the commercialization of new products in our markets by our competitors;
- advancements with respect to treatment of the diseases targeted by our products or product candidates;
- developments relating to, and actions by, our collaborative partners, including execution, amendment and termination of agreements, achievement of milestones and receipt of payments;
- the success of our collaborative partners in marketing any approved products and the amount and timing of payments to us;
- availability and cost of capital and our financial and operating results;
- actions with respect to pricing, reimbursement and coverage, and changes in reimbursement policies or other practices relating to our products or the pharmaceutical or biotechnology industries generally;
- meeting, exceeding or failing to meet analysts' or investors' expectations, and changes in evaluations and recommendations by securities analysts;
- economic, industry and market conditions, changes or trends; and
- other factors unrelated to us or the pharmaceutical and biotechnology industries.

In addition, low trading volume in our common stock may increase their price volatility. Holders of our common stock may not be able to liquidate their positions at the desired time or price. Finally, we will need to continue to meet the listing requirements of Nasdaq including the minimum stock price, for our stock to continue to be traded on Nasdaq.

Additional shares that may be issued upon the exercise of currently outstanding options or warrants or upon the settlement of restricted, performance or deferred stock units would dilute the voting power of our currently outstanding common stock and could cause our stock price to decline.

As of March 1, 2020, we had outstanding options to acquire approximately 14.2 million shares of our common stock, outstanding restricted stock units to acquire approximately 2.1 million shares of our common stock, outstanding deferred stock units to acquire 71,251 shares of our common stock, and lender warrants to acquire 409,091 and 77,721 shares of our common stock at exercise prices of $1.10 and $1.93, respectively, or approximately 13.5% of our shares on a fully diluted basis. The issuance of shares of our common stock upon exercise of the stock options or warrants or settlement of the restricted, performance or deferred stock units could result in dilution to the interests of other holders of our common stock and could adversely affect our stock price.

EW Healthcare owns a substantial amount of our common stock and can exert significant control over matters subject to stockholder approval, which would prevent new investors from influencing significant corporate decisions.

EW Healthcare, our largest stockholder, beneficially owns 41,903,956 shares of our common stock, or 33.6% of our total outstanding common stock as of March 5, 2020. EW Healthcare has the ability to significantly influence the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, this concentration of voting power in EW Healthcare may: (i) delay, defer or prevent a change in control; (ii) entrench our management and Board; or (iii) delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire.

Future sales of our common stock may depress our stock price.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or as a result of the perception that these sales could occur, which could occur if we issue a large number of shares of common stock (or securities convertible into our common stock) in connection with a future financing, as our common stock is trading at low levels. These factors could make it more difficult for us to raise funds through future offerings of common stock or other equity securities.

Provisions in our charter documents could prevent or delay stockholders' attempts takeover our company.

Our board of directors is authorized to issue "blank check" preferred stock, with designations, rights and preferences as they may determine. Accordingly, our board of directors may in the future, without stockholder approval, issue shares of preferred stock with dividend, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of our common stock. This type of preferred stock could also be issued to discourage, delay or prevent a change in our control. The ability to issue "blank check" preferred stock is a traditional anti-takeover measure. This provision in our charter documents makes it difficult for a majority stockholder to gain control of our company. Provisions like this may be beneficial to our management and our board of directors in a hostile tender offer and may have an adverse impact on stockholders who may want to participate in such a tender offer.

Provisions in our bylaws provide for indemnification of officers and directors, which could require us to direct funds away from our business and the development of our product candidates.

Our bylaws provide for the indemnification of our officers and directors. We may in the future be required to advance costs incurred by an officer or director and to pay judgments, fines and expenses incurred by an officer or director, including reasonable attorneys' fees, as a result of actions or proceedings in which our officers and directors are involved by reason of being or having been an officer or director of our company. Funds paid in satisfaction of judgments, fines and expenses may be funds we need for the operation of our business and the development of our product candidates, thereby affecting our ability to attain profitability.

We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock.

We have never declared or paid cash dividends on our capital stock, and you should not rely on an investment in our common stock to provide dividend income. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the Loan Agreement contains certain covenants that limit our ability to pay or make any dividend and the terms of any future debt agreements may further preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

As we operate in the pharmaceutical and biotechnology industries, we may be especially vulnerable to volatility in the market price of our common stock, especially to the extent that various factors affect the common stock of companies in our industry. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any real property. On May 17, 2018, we amended our lease, dated November 1, 2013, to extend our Watertown, Massachusetts lease term from April 2019 through approximately May 2025 and to add an additional 6,590 square feet of rentable area for a resulting total of 20,240 square feet. Following build-out of the additional space, for which the landlord provided a construction allowance of $671,000, we took occupancy on September 10, 2018. The aggregate leased space consists of 1,750 square feet of laboratory space, 1,000 square feet of Class 10,000 clean room space and 17,490 square feet of office space. We have an option to extend the term of the lease for one additional five-year period at market rates.

We lease 3,000 square feet of office space in Liberty Corner, New Jersey under a lease agreement that expires in June 2022. On June 11, 2018, we subleased an additional 1,381 square feet of office space in this building through May 2022.

We believe our leased facilities are adequate for our present and anticipated needs.

ITEM 3. LEGAL PROCEEDINGS

We are subject to various routine legal proceedings and claims incidental to our business, which management believes will not have a material effect on our financial position, results of operations or cash flows.

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

Our common stock is traded on the Nasdaq Global Market under the trading symbol "EYPT". As of March 5, 2020, we had approximately 100 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Equity Compensation Plan Information

Information required by Item 5 of Form 10-K regarding our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K

Recent Sales of Unregistered Securities

Other than as previously disclosed on our Current Reports on Form 8-K or Quarterly Reports on Form 10-Q filed with the SEC, we did not issue any unregistered equity securities during the twelve months ended December 31, 2019.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. SELECTED FINANCIAL DATA

The following table (in thousands, except per share data) sets forth our selected financial data. The information set forth below should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations", and the audited Consolidated Financial Statements, and the Notes thereto, and other financial information included elsewhere herein. Our historical financial information may not be indicative of our future results of operations or financial position.

	Year Ended December 31, 2019	Year Ended December 31, 2018 (unaudited)	Six Months Transition Period Ended December 31, 2018	Six Months Ended December 31, 2017 (unaudited)	Year Ended June 30, 2018	2017	2016	2
	(In thousands except per share data)							
Consolidated Statements of Operations Data:								
Revenues:								
Product sales, net	$ 16,824	$ —	$ —	$ —	$ —	$ —	$ —	$
License and collaboration agreements	1,361	2,625	1,883	601	1,343	6,569	398	
Royalty income	2,180	1,946	1,045	717	1,618	970	1,222	
Total revenues	20,365	4,571	2,928	1,318	2,961	7,539	1,620	
Operating expenses:								
Cost of sales, excluding amortization of acquired intangible assets	2,687	—	—	—	—	—	—	
Research and development	15,368	18,502	10,412	8,088	16,178	14,880	14,381	
Sales and marketing	29,772	9,658	8,174	—	1,512	—	—	
General and administrative	17,939	15,430	8,901	5,044	11,545	11,235	9,013	
Amortization of acquired intangible assets	2,460	—	—	—	—	—	—	
Total operating expenses	68,226	43,590	27,487	13,132	29,235	26,115	23,394	
Operating (loss) income	(47,861)	(39,019)	(24,559)	(11,814)	(26,274)	(18,576)	(21,774)	
Interest and other income, net	1,054	420	367	49	101	91	72	
Interest expense	(6,176)	(2,362)	(1,642)	—	(720)	—	—	
Loss on extinguishment of debt	(3,810)	—	—	—	—	—	—	
Change in fair value of derivative liability	—	(45,164)	(18,886)	—	(26,278)	—	—	
(Loss) income before income taxes	(56,793)	(86,125)	(44,720)	(11,765)	(53,171)	(18,485)	(21,702)	
Income tax benefit (expense)	—	—	—	—	—	—	155	
Net (loss) income	$ (56,793)	$ (86,125)	$ (44,720)	(11,765)	$ (53,171)	$ (18,485)	$ (21,547)	$
Net (loss) income per share:								
Basic	$ (0.54)	$ (1.27)	$ (0.53)	$ (0.28)	$ (1.15)	$ (0.52)	$ (0.68)	$
Diluted	$ (0.54)	$ (1.27)	$ (0.53)	$ (0.28)	$ (1.15)	$ (0.52)	$ (0.68)	$
Weighted average common shares outstanding:								
Basic	104,307	67,942	85,057	41,980	46,226	35,344	31,623	
Diluted	104,307	67,942	85,057	41,980	46,226	35,344	31,623	

	As of December 31, 2019	As of December 31, 2018	As of December 31, 2017 (unaudited)	As of June 30, 2018	As of June 30, 2017	As of June 30, 2016	As of June 30, 2015
			(In thousands)				
Consolidated Balance Sheet Data:							
Cash and cash equivalents	$ 22,214	$ 45,261	$ 12,876	$ 38,776	$ 16,898	$ 15,313	$ 19,121
Marketable securities	—	—	—	—	—	13,679	9,414
Accounts and other receivables, net	11,368	627	288	353	251	488	622
Intangible assets, net	27,669	30,129	—	31,358	364	1,102	1,925
Total assets	72,971	78,168	14,197	71,670	18,677	31,619	32,367
Long-term debt	47,223	17,621	—	17,309	—	—	—
Derivative liability	—	—	—	19,780	—	—	—
Total deferred revenue-current and long-term	15	30	505	—	50	5,732	5,629
Total stockholders' equity	8,330	37,633	9,905	11,687	13,336	20,881	23,368

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

The following discussion and analysis of financial condition and results of operations should be read in conjunction with our audited Consolidated Financial Statements and related Notes beginning on page F-1 of this Annual Report on Form 10-K. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ significantly from those anticipated or implied in these forward-looking statements as a result of many important factors, including, but not limited to, those set forth under Item 1A, "Risk Factors", and elsewhere in this report.

As previously reported, we changed our fiscal year end to December 31 from June 30, effective January 1, 2019. This Annual report on Form 10-K is for the twelve month period from January 1, 2019 through December 31, 2019. References in this Annual Report to "fiscal 2019" refer to the year ended December 31, 2019. References in this report to "transition period" refer to the six month period ended December 31, 2018. References in this report to "fiscal 2018" refer to the year ended June 30, 2018 and "fiscal 2017" refer to the year ended June 30, 2017. For comparison purposes, unaudited data is shown for the twelve months ended December 31, 2018 and the six months ended December 31, 2017.

The following Management's Discussion and Analysis ("MD&A") provides a narrative of our results of operations for the year ended December 31, 2019 and the comparable period ended December 31, 2018 and the six month transition period ended December 31, 2018 and the comparable period ended December 31, 2017, respectively, and our financial position as of December 31, 2019 and 2018, respectively. The MD&A should be read together with our consolidated financial statements and related notes included on pages F-1 through F-35 of this Annual Report on Form 10-K.

Overview

We are a pharmaceutical company committed to developing and commercializing innovative ophthalmic products for the treatment of eye diseases. We have two products that were approved by the United States ("U.S.") Food and Drug Administration ("FDA") in 2018 and were commercially launched directly in the U.S. during the first quarter of 2019.

DEXYCU (dexamethasone intraocular suspension) 9%, for intraocular administration, was launched directly in the U.S. in March 2019. Indicated for the treatment of post-operative ocular inflammation, DEXYCU is administered as a single dose at the end of ocular surgery and is the first long-acting intraocular product approved by the FDA for this indication. DEXYCU utilizes our proprietary Verisome® drug-delivery platform, which allows for a single intraocular injection that releases dexamethasone, a corticosteroid, over time. There were approximately 3.8 million cataract surgeries performed during 2018 in the U.S. and we launched DEXYCU with a primary focus on its use following cataract surgery. We acquired DEXYCU in connection with its acquisition of Icon Bioscience, Inc. ("Icon") in March 2018.

YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg for intravitreal injection, was launched directly in the U.S. in February 2019. YUTIQ is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, which affects between 60,000 to 100,000 people in the U.S. each year and causes approximately 30,000 new cases of blindness every year, making it the third leading cause of blindness. Injected into the eye in an office visit, YUTIQ is a micro-insert that delivers a micro-dose of a corticosteroid to the back of the eye on a sustained constant (zero order release) basis for up to 36 months. YUTIQ is based on our proprietary Durasert® sustained-release drug delivery technology platform, which can deliver drugs for predetermined periods of time ranging from months to years.

ILUVIEN® for diabetic macular edema ("DME"), our lead licensed product, is sold directly in the U.S. and several European Union ("EU") countries by Alimera Sciences, Inc. ("Alimera"). In July 2017, we expanded its license agreement with Alimera to include the uveitis indication utilizing the Durasert technology in Europe, the Middle East and Africa ("EMEA"), which received European regulatory approval in March 2019 and, subject to obtaining pricing and reimbursement in each applicable country, will be marketed as ILUVIEN. Retisert®, one of our earlier generation products, was approved in 2005 by the FDA for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye and is sold in the U.S. by Bausch & Lomb Inc. ("Bausch & Lomb"). The patent with which Retisert is marked expired in March 2019. As such, Bausch & Lomb discontinued paying royalties after March 2019. Our development programs are focused primarily on developing sustained release products that utilize its Durasert and Verisome technology platforms to deliver approved drugs to treat chronic diseases. Our strategy includes developing products independently while continuing to leverage its technology platforms through collaborations and license agreements.

EYP-1901, 6-Month bioerodible Durasert® Vorolanib - TKI is being advanced as a potential treatment for wet age-related macular degeneration, diabetic retinopathy and retinal vein occlusion. We have completed initial animal PK and toxicology studies and expect to initiate formal GLP toxicology studies in the first quarter of 2020 to support the filing of an Investigational New Drug application with the FDA.

YUTIQ50 is being developed as a 6-month dosing option for treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. We have consulted with the FDA and identified a clinical pathway for an sNDA filing that involves a clinical trial of approximately 60 patients, randomized 2:1. We are currently evaluating the timeline and investment requirements for the initiation of this study

Fiscal 2019 Overview

The fiscal year ended December 31, 2019 was highlighted by the following events:

- We successfully launched our two FDA approved products, YUTIQ and DEXYCU during the first quarter of 2019;
- We added key members of our senior management team, including our Chief Financial Officer and Head of Corporate Development, SVP and Chief Commercial Officer, and our SVP and Chief Technical Officer;
- We refinanced our debt with CRG (from SWK) in February 2019 generating approximately $26M (first and second drawdown) and participated in an underwritten public stock offering generating approximately $20M of gross proceeds to help fund our commercial product launches;

Recent Developments

Recent developments and ongoing activities regarding the commercialization of YUTIQ include:

- Customer demand, represented as units purchased by physicians from our distributors, was up 59% over Q3, driven by underlying growth and the permanent and specific J-Code for YUTIQ in effect as of October 1, 2019.
- Repeat customers represented 87% of order volume, and importantly, 42% of our target account list has ordered, including 98% of the treating uveitis specialists, representing solid adoption with continued growth opportunity.

Recent developments and ongoing activities regarding the commercialization of DEXYCU include:

- Customer demand, represented as units purchased by ambulatory surgical centers from our distributors, was up 111% over Q3 with repeat customers representing 98% of Q4 order volume.
- Since launch, over 14,000 patients have been treated with DEXYCU.
- We secured multiple new agreements for expanded access of DEXYCU, including contracts with The Vision Center Network of America, LLC (VCNA) and EyeSouth Partners which collectively perform approximately 115,000 cataract surgeries per year. We are actively negotiating agreements with additional group purchasing organizations and networks.

- In February 2020, we completed an underwritten public offering of 15,000,000 shares of our common stock at a public offering price of $1.45 per share. The gross proceeds of the offering were $21,750,000, before deducting the underwriting discounts and commissions and other transaction expenses. In addition, underwriters were granted a thirty-day option to purchase up to an additional 2,250,000 shares of common stock at the public offering price, less underwriting discounts and commissions. This offering closed on February 25, 2020.

- In January 2020, we entered into an exclusive license agreement with Ocumension Therapeutics for the development and commercialization in Mainland China, Hong Kong, Macau and Taiwan of DEXYCU for the treatment of post-operative inflammation following ocular surgery. Under the terms of the license agreement, we received an upfront payment of $2 million and will be eligible to receive up to an additional $12.0 million if certain future prespecified development, regulatory and commercial sales milestones are achieved by Ocumension. In addition, we are entitled to receive a mid-single digit sales-based royalty. In exchange, Ocumension will receive exclusive rights to develop and commercialize the product in the greater China territory, at its own cost and expense with us supplying product for clinical trials and commercial sale.

- In November 2019, George O. Elston was appointed Chief Financial Officer and Head of Corporate Development. Mr. Elston brings more than 25 years of diverse financial and senior leadership experience in the biopharmaceutical sector with both global publicly-traded and privately-held organizations. He most recently served as Chief Financial Officer and Head of Corporate Development at Enzyvant Therapeutics and has also held senior executive roles at 2X Oncology, Inc, Juniper Pharmaceuticals, Inc., KBI Biopharma and Optherion, Inc.

R&D Highlights

- In March 2020, we announced positive topline 36-month follow-up data from the second Phase 3 trial of YUTIQ for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. This second double-masked, randomized Phase 3 trial of YUTIQ enrolled 153 patients in 15 clinical centers in India, with 101 eyes treated with YUTIQ

and 52 eyes receiving sham injections. At 36-months, the recurrence rate in YUTIQ randomized eyes was significantly lower than in sham treated eyes (46.5% vs. 75.0%, respectively; p=0.001). Visual acuity gains or losses of 3-lines or more were both similar between treatment groups. Safety data showed no unanticipated side effects at each follow-up timepoint at 12, 24 and 36-months. These positive results were consistent with the findings from the first Phase 3 study of YUTIQ and provide further validation of its long-term ability to reduce uveitic flares.

- In February 2020, EyePoint signed an exclusive license agreement with Equinox Science, LLC, to develop vorolanib, a tyrosine kinase inhibitor, for the treatment of wet age-related macular degeneration ("wAMD"), retinal vein occlusion ("RVO"), and diabetic retinopathy ("DR"). Vorolanib is being developed as EYP-1901 utilizing EyePoint's bioerodible Durasert technology, a miniaturized, injectable, sustained-release intravitreal drug delivery system with a 6-month duration. We recently completed a positive Type B pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration ("FDA") clarifying the pathway for a phase 1 clinical trial. We expect this phase 1 trial to provide data in the second half of 2021. Our proven Durasert technology provides the unique opportunity to investigate EYP-1901 as a six-month treatment option for patients that also has the potential to avoid the frequent injections required for currently available biologics.
- Positive retrospective case study data supporting DEXYCU was highlighted in an oral presentation at the 2020 Caribbean Eye Meeting in an oral session entitled, "Drug Delivery: Real-World Experience With Dexamethasone Intraocular Suspension". The ongoing retrospective study is designed to provide large-scale, real-world data on early experiences with DEXYCU from surgeons. Interim results presented are from 154 patients administered DEXYCU with each time point of data based on patient chart data and frequency of measurement by participating physicians. The proportion of patients with complete anterior chamber cell clearing (cell score=0) was 47.5%, 50.0%, 84.1% and 87.5% at postoperative day 1, 8, 14 and 30, respectively. The proportion of patients with no anterior chamber flares (flare score=0), another measurement of inflammation, was 77.7%, 98.5%, 98.8% and 99.1% at postoperative day 1, 8, 14 and 30, respectively. Mean intraocular pressure at postoperative day 1 was 17.6mmHg, with levels decreasing through to postoperative day 30.

Summary of Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, ("U.S. GAAP"). The preparation of these financial statements requires that we make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. We base our estimates on historical experience, anticipated results and trends and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily available from other sources. By their nature, these estimates, judgments and assumptions are subject to an inherent degree of uncertainty, and management evaluates them on an ongoing basis for changes in facts and circumstances. Changes in estimates are recorded in the period in which they become known. Actual results may differ from our estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 in the accompanying Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K, we believe that the following accounting policies are critical to understanding the judgments and estimates used in the preparation of our financial statements. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies discussed below.

Revenue Recognition

We adopted Accounting Standards Codification 606, *Revenue from Contracts with Customers* ("ASC 606"), with a date of initial application of July 1, 2018. As a result, we updated our accounting policy for revenue recognition to reflect the new standard (see Note 2 in the accompanying Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K). The adoption of ASC 606 represents a change in accounting principle that more closely aligns revenue recognition with the delivery of our services and provides financial statement readers with enhanced disclosures. We applied ASC 606 using the modified retrospective method. The cumulative effect of initially applying the new revenue standard resulted in a $218,000 reduction to the opening balance of accumulated deficit at July 1, 2018.

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) 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) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract, determines those that

are performance obligations and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Product sales, net — We began selling YUTIQ and DEXYCU in February and March 2019, respectively, in the U.S. through a single third-party logistics provider (the "3PL"), which takes title and control to the goods. The 3PL distributes the products through a limited number of specialty distributors and specialty pharmacies (collectively the "Distributors"), with whom we have entered into formal agreements, for delivery to physician practices for YUTIQ and to hospital outpatient departments and ambulatory surgical centers for DEXYCU. Effective December 15, 2019, we terminated our product sales through the 3PL and replaced with the Distributors. We recognize revenue on sales of our products when a customer obtains control of the products, which occurs at a point in time, typically upon delivery. In addition to distribution agreements with customers, we also enter into arrangements with healthcare providers and payors that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of our products.

Reserves for variable consideration — Product sales are recorded at the wholesale acquisition costs, net of applicable reserves for variable consideration. Components of variable consideration include trade discounts and allowances, provider chargebacks and discounts, payor rebates, product returns, and other allowances that are offered within contracts between us and our Distributors, payors, and other contracted purchasers relating to our product sales. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified either as reductions of product revenue and accounts receivable or a current liability, depending on how the amount is to be settled. Overall, these reserves reflect our best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from the estimates, we adjust these estimates, which would affect product revenue and earnings in the period such variances become known.

Distribution fees — We compensate our Distributors for services explicitly stated in our contracts and are recorded as a reduction of revenue in the period the related product sale is recognized.

Provider chargebacks and discounts — Chargebacks are discounts that represent the estimated obligations resulting from contractual commitments to sell products at prices lower than the list prices charged to our Distributors. These Distributors charge us for the difference between what they pay for the product and our contracted selling price. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. Reserves for chargebacks consist of amounts that we expect to pay for units that remain in the distribution channel inventories at each reporting period-end that we expect will be sold under a contracted selling price, and chargebacks that Distributors have claimed, but for which we have not yet settled.

Government rebates — We are subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. Our liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Payor rebates — We enter into contracts with certain private payor organizations, primarily insurance companies, for the payment of rebates with respect to utilization of our products. We estimate these rebates and record such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Co-Payment assistance — We offer co-payment assistance to commercially insured patients meeting certain eligibility requirements. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue.

Product returns — We generally offer a limited right of return based on our returned goods policy, which includes damaged product and remaining shelf life. We estimate the amount of our product sales that may be returned and record this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as reductions to trade receivables, net on the condensed consolidated balance sheets.

License and collaboration agreement revenue — We analyze each element of our license and collaboration arrangements to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. We determine standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, we estimate the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

We recognize sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606-10-55-65. For those milestone payments which are contingent on the occurrence of particular future events, we determine that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the most-likely amount method. As such, we assess each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty associated with these future events, we will not recognize revenue from such milestones until there is a high probability of occurrence, which typically occurs near or upon achievement of the event.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, we do not assess whether a significant financing component exists if the period between when we perform our obligations under the contract and when the customer pays is one year or less. None of our contracts contained a significant financing component as of December 31, 2019.

Reimbursement of costs — We may provide research and development services and incur maintenance costs of licensed patents under collaboration arrangements to assist in advancing the development of licensed products. We act primarily as a principal in these transactions and, accordingly, reimbursement amounts received are classified as a component of revenue to be recognized consistent with the revenue recognition policy summarized above. We record the expenses incurred and reimbursed on a gross basis.

Royalties — We recognize revenue from license arrangements with our commercial partners' net sales of products. Such revenues are included as royalty income. In accordance with ASC 606-10-55-65, royalties are recognized when the subsequent sale of the commercial partner's products occurs. Our commercial partners are obligated to report their net product sales and the resulting royalty due to us typically within 60 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, we recognize royalty income each quarter and subsequently determine a true-up when we receive royalty reports and payment from our commercial partners. Historically, these true-up adjustments have been immaterial.

Feasibility Studies — We recognize revenue over the term of the statements of work under any funded feasibility study agreements. Revenue recognition for consideration, if any, related to a license option right is assessed based on the terms of any such future license agreement or is otherwise recognized at the completion of the feasibility study agreement.

Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized within one year following the balance sheet date are classified as non-current deferred revenue.

Please refer to Note 4 for further details on the license and collaboration agreements into which we have entered and corresponding amounts of revenue recognized for the year ended December 31, 2019, for the six months transition period ended December 31, 2018 and for prior fiscal year periods.

Recognition of Expense in Outsourced Clinical Trial Agreements

We recognize research and development expense with respect to outsourced agreements for clinical trials with contract research organizations ("CROs") as the services are provided, based on our assessment of the services performed. We make our assessments of the services performed based on various factors, including evaluation by the third-party CROs and our own internal review of the work performed during the period, measurements of progress by us or by the third-party CROs, data analysis with respect to work completed and our management's judgment. We have agreements with two CROs to conduct the Phase 3 clinical trial program for YUTIQ, which we expect to complete in the first half of 2020. As of December 31, 2019, there were no material obligations remaining.

During fiscal 2019, the six months ended December 31, 2018 and for fiscal 2018, we recognized approximately $1.2 million, $1.5 million and $4.6 million, respectively, of research and development expense attributable to our YUTIQ Phase 3 clinical trial program. Changes in our estimates or differences between the actual level of services performed and our estimates may result in changes to our research and development expenses in future periods.

Results of Operations

Years Ended December 31, 2019 and 2018

	Year Ended December 31,		Change	
	2019	2018	Amounts	%
		(unaudited)		
		(In thousands except percentages)		
Revenues:				
Product sales, net	$ 16,824	$ —	$ 16,824	N/A
Collaborative research and development	1,361	2,625	(1,264)	(48)%
Royalty income	2,180	1,946	234	12%
Total revenues	20,365	4,571	15,794	346%
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	2,687	—	2,687	N/A
Research and development	15,368	18,502	(3,134)	(17)%
Sales and marketing	29,772	9,658	20,114	208%
General and administrative	17,939	15,430	2,509	16%
Amortization of acquired intangible assets	2,460	—	2,460	N/A
Total operating expenses	68,226	43,590	24,636	57%
Loss from operations	(47,861)	(39,019)	(8,842)	23%
Other income (expense)				
Interest income and other, net	1,054	420	634	151%
Interest expense	(6,176)	(2,362)	(3,814)	(161)%
Loss on extinguishment of debt	(3,810)	—	(3,810)	N/A
Change in fair value of derivative liability	—	(45,164)	45,164	N/A
Other expense, net	(8,932)	(47,106)	38,174	81%
Net loss	$ (56,793)	$ (86,125)	$ 29,332	34%

Product Sales, net

Product sales, net represents the gross sales of DEXYCU and YUTIQ less provisions for product sales allowances and accruals. We commenced U.S. commercial sales of YUTIQ in February 2019 and recorded net sales totaled $12.0 million for fiscal 2019. We commenced commercial sales of DEXYCU in March 2019 and recorded net sales totaled $4.8 million for fiscal 2019. We had no product revenue during the year ended December 31, 2018.

License and collaboration agreement

License and collaboration agreement revenues decreased by $1.3 million, or 48% to $1.4 million for fiscal 2019 compared to the prior year. This decrease was attributable primarily to (i) the $1.7 million payment we received from Ocumension in the year ended December 31, 2018 as initial payment for the YUTIQ license compared with the $1 million payment upon achieving their first development milestone for YUTIQ in China in fiscal 2019 and (ii) $540,000 in lower revenue associated with feasibility studies.

Royalty Income

Royalty income increased by $234,000, or 12%, to $2.2 million in fiscal 2019 compared to $1.9 million in the prior year. The increase was attributable primarily to a combination of an increase in the net sales-based royalty rate from 2% to 4% (effective December 2018) and higher ILUVIEN net sales under the Amended Alimera Agreement. This increase in ILUVIEN royalties was offset by recognizing revenue during only the first quarter of 2019 for Retisert royalty, as the licensee, Bausch and Lomb informed us that they consider this agreement to have ended due to the expiration of certain patents.

Cost of Sales, Excluding Amortization of Acquired Intangible Assets

Cost of sales, excluding amortization of acquired intangible assets, of approximately $2.7 million for fiscal 2019 consisted of costs associated with the manufacturing of YUTIQ and DEXYCU, certain period costs and product shipping costs. We expensed manufacturing costs as research and development expenses in the periods prior to FDA approval of the products. In the fourth quarter of 2018, we began capitalizing inventory costs for YUTIQ and DEXYCU manufactured in preparation for our launch in the United States. We had no cost of sales during the prior year.

Research and Development

Research and development expenses decreased by $3.1 million, or 17%, to $15.4 million for fiscal 2019 from $18.5 million in the prior year. This decrease was attributable primarily to (i) $2.2 million of contract research organization costs for our YUTIQ Phase 3 clinical development program, (ii) $1.8 million of amortization of the acquired intangible asset from the Icon Acquisition (classified as a separate line item post product launches, (iii) $1.1 million related to pre-launch DEXYCU batches for stability and manufacturing testing, and (iv) 887,000 of consulting expense, primarily regulatory related, partially offset by increases of (i) $1.7 million of net personnel and related expenses for the build-out of our medical affairs group and expansion of regulatory and quality staffs and (ii) $1.1 million for medical affairs related program expenses.

Sales and Marketing

With commencement of the commercial launches of DEXYCU and YUTIQ, we continued the build-out of our commercial infrastructure and marketing activities during fiscal 2019. Sales and marketing expenses increased by $20.1 million, or 208%, to $29.8 million for fiscal 2019 from $9.7 million in the prior year. This increase was primarily attributable to (i) $10.6 million related to our contract sales organization which includes our YUTIQ and DEXYCU key account managers, (ii) $4.7 million of marketing programs and agency costs and (iii) $4.7 million of personnel and related costs.

General and Administrative

General and administrative expenses increased by $2.5 million, or 16%, to $17.9 million for fiscal 2019 from $15.4 million in the prior year. This increase was attributable primarily to (i) a $2.5 million increase in personnel and related expenses related to senior management additions and the full year impact of prior additions, in finance, legal, human resources, information technology and business development, including $760,000 of stock-based compensation and (ii) $347,000 in contracted services, primarily in outsourced IT for the build-out of commercial systems, partially offset by a $482,000 decrease in insurance costs, legal, audit and other professional fees.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets totaled $2.5 million for fiscal 2019. This amount was attributable to the DEXYCU product intangible asset that resulted from the Icon Acquisition (see Note 3). Prior to our product launches, the amortization was classified in Research and development.

Interest (Expense) Income

Interest expense totaled $6.2 million for fiscal 2019, which included $596,000 of amortization of debt discount and $1.1 million of non-cash payment-in-kind interest expense all related to the CRG Debt. Interest expense in the year ended December 31, 2018 was $2.4 million and related to the SWK Loan.

Interest income from amounts invested in an institutional money market fund increased to $1.1 million for fiscal 2019 compared to $420,000 in the prior year, due primarily to higher interest-bearing assets and higher money market interest rates.

Loss on Extinguishment of Debt

Repayment of the SWK Loan in February 2019 resulted in a $3.8 million loss on extinguishment of debt, which consisted of (i) a $2.3 million write-off of the remaining balance of unamortized debt discount; (ii) a $1.2 million prepayment penalty; and (iii) a $306,000 make-whole interest payment covering the period from the date of the loan repayment to what would have been the first anniversary of the original loan closing date, or March 28, 2019.

Change in Fair Value of Derivative Liability

Change in fair value of derivative liability totaled $45.2 million for fiscal 2018, attributable to the revaluation of the Second Tranche Warrants liability immediately prior to the late September 2018 exercise of the Second Tranche Warrants (see Note 13). The resulting Second Tranche Warrants derivative liability balance of $38.7 million was reclassified to equity upon exercise of these warrants.

Six Months Ended December 31, 2018 and 2017

	Six Months Ended December 31,		Change	
	2018	2017	Amounts	%
		(unaudited)		
		(In thousands except percentages)		
Revenues:				
Collaborative research and development	$ 1,883	$ 601	$ 1,282	213%
Royalty income	1,045	717	328	46%
Total revenues	2,928	1,318	1,610	122%
Operating expenses:				
Research and development	10,412	8,088	2,324	29%
Sales and marketing	8,174	—	8,174	N/A
General and administrative	8,901	5,044	3,857	76%
Total operating expenses	27,487	13,132	14,355	109%
Operating loss	(24,559)	(11,814)	(12,745)	(108)%
Interest income and other, net	367	49	318	649%
Interest expense	(1,642)	—	(1,642)	N/A
Change in fair value of derivative liability	(18,886)	—	(18,886)	N/A
Net loss	$ (44,720)	$ (11,765)	$ (32,955)	(280)%

Revenues

Collaborative research and development revenue totaled $1.9 million for the six months ended December 31, 2018, an increase of $1.3 million, or 213%, compared to $601,000 for the six months ended December 31, 2017. This increase was attributable primarily to $1.7 million of revenue recognized from an upfront payment received under the Ocumension license, partially offset by a $390,000 decrease in feasibility study revenues earned in the prior six-month period.

Royalty income totaled $1.0 million for the six months ended December 31, 2018, an increase of $328,000, or $46%, compared to $717,000 for the six months ended December 31, 2017. A $392,000 increase in ILUVIEN royalty income from Alimera was partially offset by a $65,000 decrease in Retisert royalty income from Bausch & Lomb.

As a result of the adoption of ASC 606 on July 1, 2018, we recognized two quarters of royalty income under the Amended Alimera Agreement during the six months ended December 31, 2018 compared to one quarter of royalty income during the six months ended December 31, 2017. Commencing December 12, 2018 through calendar year 2020, the royalty rate on net sales of ILUVIEN increased from 2% to 4% (which represents a 6% royalty rate less a 2% offset for Alimera's recovery of accumulated commercialization losses under the Prior Alimera Agreement).

Research and Development

Research and development expenses totaled $10.4 million for the six months ended December 31, 2018, an increase of $2.3 million, or 29%, compared to $8.1 million for the six months ended December 31, 2017. This increase was attributable primarily to (i) a $1.4 million increase in personnel and related expenses, including stock-based compensation, for the build-out of our medical science liaison (MSL) group and expansion of regulatory affairs and quality assurance staffing, (ii) approximately $1.1 million related to the pre-commercialization scale up of DEXYCU manufacturing, (iii) an $867,000 increase in MSL program expenditures, including advisory boards, educational grants and pharmacovigilance and (iv) an $866,000 increase in amortization of finite-lived intangible assets, consisting of $1.2 million for the DEXYCU / Icon intangible asset offset by the completed amortization of our previous patented technology intangible assets as of December 2017; partially offset by a decrease of $2.2 million of costs associated with YUTIQ clinical development from the prior year due primarily to the completion of the first of two Phase 3 clinical trials.

Sales and Marketing

In anticipation of the commercial launch of DEXYCU and YUTIQ, we continued the build-out of our commercial infrastructure and marketing activities that had commenced in the fourth quarter of fiscal 2018. Sales and marketing expense, which totaled $8.2 million for the six months ended December 31, 2018, consisted primarily of (i) approximately $2.8 million of advertising,

promotion and tradeshows, (ii) $2.3 million of personnel and related costs, (iii) $1.4 million of implementation and startup costs pursuant to our contract sales organization agreement, and (iv) $718,000 of professional services primarily related to development of our distribution channel and market access.

General and Administrative

General and administrative expenses totaled $8.9 million for the six months ended December 31, 2018, an increase of $3.9 million, or 76%, compared to $5.0 million for the six months ended December 31, 2017. The increase was attributable primarily to (i) approximately $1.4 million in personnel and related expenses, including $617,000 of stock-based compensation, (ii) $789,000 of consulting services, which included a $263,000 strategic advisory fee related to the Ocumension License Agreement; (iii) approximately $700,000 of legal and audit related costs; and (iv) approximately $273,000 of corporate compliance consulting and monitoring.

Interest (Expense) Income and Other

Interest expense for the six months ended December 31, 2018 consisted of approximately $1.3 million of interest and $312,000 of amortization of debt discount in connection with our SWK Loan, pursuant to which we borrowed $15 million on March 28, 2018 in connection with the Icon acquisition and an additional $5 million on June 26, 2018.

On February 13, 2019, we refinanced the $20 million SWK Loan with a new term loan agreement with CRG that included an initial borrowing of $35 million at an interest rate of 12.5% per annum payable at the end of each calendar quarter. On April 22, 2019, we drew down an additional $15 million pursuant to an option in the loan agreement.

Interest income and other increased to $368,000 for the six months ended December 31, 2018 compared to $49,000 for the prior year period, due primarily to significantly higher average monthly amounts invested in an institutional money market fund and increasing money market interest rates.

Change in Fair Value of Derivative Liability

Change in fair value of derivative liability totaled $18.9 million for the six months ended December 31, 2018, attributable to the revaluation of the Second Tranche Warrants liability immediately prior to the late September 2018 exercise of the Second Tranche Warrants. The resulting Second Tranche Warrants derivative liability balance of $38.7 million was reclassified to equity upon exercise of these warrants.

For a discussion of the fiscal year ended June 30, 2018 compared to the year ended June 30, 2017, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Transition Report on Form 10-KT for the six-month transitional period ended December 31, 2018.

Recently Adopted and Recently Issued Accounting Pronouncements

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board (“FASB”), and are adopted by us as of the specified effective dates. Unless otherwise disclosed below, we believe that the impact of recently issued and adopted pronouncements will not have a material impact on our financial position, results of operations and cash flows or do not apply to our operations.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* (“ASU 2017-01”), to clarify the definition of a business by adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets versus businesses. ASU 2017-01 is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. We adopted this standard early to account for the Icon Acquisition (see Note 3 in the accompanying Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K).

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) (“ASU 2014-09”), which requires an entity to recognize revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for the transfer of promised goods or services to customers. In August 2015, the FASB issued ASU 2015-14, which officially deferred the effective date of ASU 2014-09 by one year, while also permitting early adoption. As a result, ASU 2014-09 became effective on July 1, 2018. We adopted this standard as of July 1, 2018. The adoption of ASC 606 represents a change in accounting principle that more closely aligns revenue recognition with the delivery of our services and provides financial statement readers with enhanced disclosures. We applied ASC 606 using the modified retrospective method. The cumulative effect of initially applying the new revenue standard resulted in a $218,000 reduction to the opening balance of accumulated deficit at July 1, 2018.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"). In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842), Targeted Improvements, which contains certain amendments to ASU 2016-02 intended to provide relief in implementing the new standard. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all operating leases, with an exception provided for leases with a duration of one year or less. We adopted ASU 2016-02 on January 1, 2019 using the modified retrospective transition approach which, pursuant to ASU 2018-11, allows companies to recognize existing leases at the adoption date without requiring comparable period presentation. Comparative periods are presented in accordance with the previous guidance in Accounting Standards Codification ("ASC") 840, Leases.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), to replace the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018. This standard will be effective for us in the first quarter of our fiscal year ending December 31, 2020. We are currently evaluating the impact the adoption of this update will have on our consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12").* The amendments simplify the accounting for income taxes by removing certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. Early adoption is permitted, including adoption in interim or annual periods for which financial statements have not yet been issued. This standard will be effective for us in the first quarter of our fiscal year ending December 31, 2021. We are currently evaluating the impact the adoption of this update will have on our consolidated financial statements.

Liquidity and Capital Resources

Our operations for fiscal 2019 were financed primarily from $45.3 million of cash and cash equivalents at December 31, 2018, approximately $18.3 million of gross proceeds from the March 2019 underwritten stock offering and approximately $11.4 million from the refinancing of our debt with CRG in February 2019 and an additional $15 million drawdown in April 2019. At December 31, 2019, our cash and cash equivalents totaled $22.2 million.

As of December 31, 2019, our long-term debt consisted of $51.1 million, which represented the amount outstanding under the CRG Loan. On February 13, 2019, we refinanced the existing SWK Loan in connection with entering into a new term loan facility (the "Loan") of up to $60 million with CRG (the "Loan Agreement"). Based on an initial loan borrowing of $35.0 million, reduced by aggregate fees and expenses of $875,000, and the repayment of (i) the SWK Loan principal and (ii) approximately $2.7 million representing a contractual prepayment premium, an exit fee and a make whole interest charge, the refinancing provided us with an incremental $11.4 million on the transaction date. We borrowed an additional $15.0 million in April 2019. Subject to achieving product net revenue from YUTIQ and DEXYCU of at least $25 million during any three-month period ending on or before March 31, 2020, we are entitled to borrow up to an additional $10.0 million.

The Loan bears interest at a per annum rate (subject to increase during an event of default) equal to 12.5%, of which 2.5% may be paid in-kind at our election, so long as no default or event of default under the Loan Agreement has occurred and is continuing. We are required to make quarterly, interest only payments until the Maturity Date. In addition, we were required to pay an upfront fee of 1.5% of the principal amount of the Loan (excluding any paid-in-kind amounts), which is payable as amounts are advanced under the Loan. We will also be required to pay an exit fee equal to 6% of the aggregate principal amount advanced under the Loan Agreement.

Subject to certain exceptions, we are required to make mandatory prepayments of the Loan with the proceeds of assets sales and in the event of a change of control of our Company. In addition, we may make a voluntary prepayment of the Loan, in whole or in part, at any time. All mandatory and voluntary prepayments of the Loan are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs after December 31, 2019 and on or prior to December 31, 2020, 5% of the aggregate outstanding principal amount of the Loan being prepaid and (ii) if prepayment occurs after December 31, 2020 and on or prior to December 31, 2021, an amount equal to 3% of the aggregate outstanding principal amount of the Loan being prepaid. No prepayment premium is due on any principal prepaid after December 31, 2021.

Certain of our existing and future subsidiaries, including the Guarantors, are guaranteeing the obligations of ours under the Loan Agreement. Our obligations under the Loan Agreement and the guarantee of such obligations are secured by a pledge of substantially all of our and the Guarantors' assets.

The Loan Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on our and our subsidiaries' abilities, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions and enter into affiliate transactions, in

each case, subject to certain exceptions. In addition, the Loan Agreement contains the following financial covenants requiring us and the Guarantors to maintain:

- liquidity in an amount which shall exceed the greater of (i) $5 million and (ii) to the extent we have incurred certain permitted debt, the minimum cash balance, if any, required of us by the creditors of such permitted debt; and
- annual minimum product revenue from YUTIQ and DEXYCU: (i) for the twelve-month period beginning on January 1, 2020 and ending on December 31, 2020, of at least $45 million, (ii) for the twelve-month period beginning on January 1, 2021 and ending on December 31, 2021, of at least $80 million and (iii) for the twelve-month period beginning on January 1, 2022 and ending on December 31, 2022, of at least $90 million.

We expect that our cash and cash equivalents combined with the February 2020 underwritten public offering proceeds and projected cash inflows from anticipated YUTIQ and DEXYCU product sales can fund our operating plan into 2021. We are closely monitoring ongoing developments in connection with the COVID-19 pandemic, which may negatively impact our commercial prospects and projected cash inflows in 2020. We will continue to assess our cash and cash equivalents and, if circumstances warrant, we will make appropriate adjustments to our operating plan.

However, with the exception of net income for the fiscal year ended June 30, 2015 resulting from our receipt of the $25.0 million ILUVIEN FDA-approval milestone, we have predominantly incurred operating losses since inception, and at December 31, 2019 we had a total accumulated deficit of $465.3 million and working capital of $30.2 million. We do not currently have any significant assured sources of additional financing. We have a limited history of direct commercialization of our products and there is no assurance that we will receive significant revenues from our sales of YUTIQ or DEXYCU to fund operations. In addition to our cash and cash equivalents of $22.2 million at December 31, 2019, we received incremental financing cash flows of approximately $20.3 million net proceeds from our February 2020 stock offering, excluding approximately $300,0000 of additional unpaid share issue costs. As a result, the inherent uncertainty associated with achieving sufficient operating and financing cash flows continue to raise substantial doubt about our ability to continue as a going concern for one year from the issuance of our financial statements included in this Annual Report on Form 10-K.

Our plans that are intended to mitigate those conditions include continuing to fulfill our funding needs through cash inflows from revenue of YUTIQ and DEXYCU product sales, licensing arrangements, additional capital raise or other arrangements. We believe our plans in place will be sufficient to fund our operating plan for the next 12 months. Although we believe such plans, if executed, should provide us with sufficient financing to meet our needs, there is no assurance that additional funding will be achieved and that we will succeed in our future operations. Actual cash requirements could differ from management’s projections due to many factors, including the success of commercialization for YUTIQ and DEXYCU, the actual costs of these commercialization efforts, additional investments in research and development programs, competing technological and market developments and the costs of any strategic acquisitions and/or development of complementary business opportunities.

The amount of additional capital we will require will be influenced by many factors, including, but not limited to:

- the success of our U.S. direct commercialization of DEXYCU for the treatment of postoperative ocular inflammation including, among other things, patient and physician acceptance of DEXYCU and our ability to obtain adequate coverage and reimbursement for DEXYCU;
- the success of our U.S. direct commercialization of YUTIQ for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye including, among other things, patient and physician acceptance of YUTIQ and our ability to obtain adequate coverage and reimbursement for YUTIQ;
- the cost of commercialization activities for DEXYCU and YUTIQ, including product manufacturing, marketing, sales and distribution;
- the success of EYP-1901 as a vital, new six-month treatment for serious eye diseases including wAMD, DR and RVO;
- the timing and clinical development of our product candidates, including EYP-1901 and our YUTIQ50, six-month duration potential treatment for non-infectious uveitis affecting the posterior segment of the eye;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- payments we receive under any new collaboration agreements;
- whether and when we are able to enter into strategic arrangements for our products or product candidates and the nature of those arrangements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims;
- changes in our operating plan, resulting in increases or decreases in our need for capital;
- our views on the availability, timing and desirability of raising capital; and
- the extent to which our business could be adversely impacted by the effects of the COVID-19 coronavirus pandemic or by other pandemics, epidemics or outbreaks.

We do not know if additional capital will be available when needed or on terms favorable to us or our stockholders. Collaboration, licensing or other agreements may not be available on favorable terms, or at all. We do not know the extent to which we will receive funds from the commercialization of YUTIQ or DEXYCU. If we seek to sell our equity securities under our ATM program or in another offering, we do not know whether and to what extent we will be able to do so, or on what terms. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and dilute our existing stockholders' equity, and funding through collaboration, licensing or other commercial agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may delay, reduce the scope of, or eliminate research or development programs, independent commercialization of YUTIQ and DEXYCU, or other new products, if any, postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs, or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

Our consolidated statements of historical cash flows are summarized as follows (in thousands):

	Year ended December 31,		Six Months Ended December 31,	
	2019	2018	2018	2017
		(unaudited)		(unaudited)
Net loss:	$ (56,793)	$ (86,126)	$ (44,720)	$ (11,765)
Changes in operating assets and liabilities	(12,536)	962	(940)	(977)
Other adjustments to reconcile net loss to cash flows from operating activities	12,630	51,677	23,074	1,736
Cash flows used in operating activities	$ (56,699)	$ (33,487)	$ (22,586)	$ (11,006)
Cash flows (used in) provided by investing activities	$ (213)	$ (16,956)	$ (132)	$ (64)
Cash flows provided by financing activities	$ 33,864	$ 82,831	$ 29,204	$ 7,044

Operating cash outflows for the year ended December 31, 2019 totaled $56.7 million, primarily due to our net loss of $56.8 million, reduced by $12.6 million of non-cash expenses, which included $4.7 million of stock-based compensation, a $3.8M loss on extinguishment of our SWK debt and $2.5 million amortization of the DEXYCU finite-lived intangible asset. Further use of cash in operating activities resulted from primarily an increase of $11.1 million in accounts receivable from our launch of our two commercial products, a $4.6 million increase in prepaid expenses primarily related to commercialization activities and a $1.9 million increase in product inventory.

Operating cash outflows for the year ended December 31, 2018 totaled $33.5 million, primarily attributable to our net loss of $86.1 million, reduced by $51.2 million of non-cash expenses, primarily from the $45.2 million change in fair value of our derivative liability and $4.0 million of stock-based compensation. Further adjustments of cash in operating activities resulted primarily from an increase in accounts payable and accrued expenses partially offset by a decrease in deferred revenue related to a feasibility study.

Operating cash outflows for the six months ended December 31, 2018 totaled $22.6 million, primarily due to our net loss of $44.7 million, reduced by $23.1 million of non-cash expenses, which included $18.9 million change in fair value of derivative liability, $2.6 million of stock-based compensation and $1.3 million amortization of the DEXYCU finite-lived intangible asset. Further use of cash in operating activities resulted from primarily an initial $279,000 of YUTIQ product inventory and a $652,000 net increase in prepaid expenses primarily related to pre-commercialization activities.

Operating cash outflows for the six months ended December 31, 2017 totaled $11.0 million, primarily attributable to our net loss of $11.8 million, reduced by $1.7 million of non-cash expenses, primarily stock-based compensation. Further use of cash in operating activities resulted primarily from a decrease of accounts payable and accrued expenses partially offset by an increase in deferred revenue related to a feasibility study.

Cash flows from investing activities for the year ended December 31, 2018 consisted principally of $16.8 million of cash used, net of cash acquired plus transaction costs, for the Icon acquisition. Purchases of property and equipment totaled $213,000 in fiscal 2019 and $132,000 in the six months and twelve months ended December 31, 2018.

Cash flows from financing activities for fiscal 2019 totaled $33.9 million and consisted primarily of (i) $33.8 million of net proceeds from the initial drawdown under the CRG Loan Agreement, net of debt issue costs, (ii) $18.3 million of net proceeds from the issuance of 10,526,500 shares of our Common Stock, (iii) $14.8 million of net proceeds from our second drawdown under the

CRG Loan Agreement offset by payment of a $15.0 million development milestone that was due to the former Icon security holders following the first commercial sale of DEXYCU, (iv) $398,000 of proceeds from the exercise of stock options, (v) $4.3 million of net proceeds from the issuance of 2,998,877 shares of our Common Stock sold utilizing our ATM.; partially offset by (vi) $22.7 million repayment of the SWK Loan, which included principal of $20.0 million, a $1.2 million prepayment penalty, a $1.2 million exit fee and $306,000 of make whole interest.

Cash flows from financing activities for the year ended December 31, 2018 were related primarily to the Icon acquisition and to support investments in commercial infrastructure, sales, marketing and medical affairs in preparation for the launch of DEXYCU and YUTIQ. These financing cash flows included approximately (i) $35.0 million of aggregate gross proceeds from the sale of 8,606,324 shares of common stock in the First Tranche Transaction and the sale of 20,184,224 Units in the Second Tranche Transaction and (ii) $20.0 million of gross proceeds from a term loan agreement with SWK. Share issue and debt issue costs totaled approximately $1.9 million in connection with these financing transactions. Cash flows from financing activities for the six months and inclusive for the twelve months ended December 31, 2018 consisted primarily of (i) approximately $28.9 million of gross proceeds from the exercise of the Second Tranche Warrants. Cash flows from financing activities for the six months ended December 31, 2017 consisted of $7.0 million of proceeds, net of share issue costs, from sales of 5,900,000 common shares under our ATM program.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that would be material to investors.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this Item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item may be found on pages F-1 through F-35 of this Annual Report on Form 10-K.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019. The term “disclosure controls and procedures”, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure 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 that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2019, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

(a) Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) or 15d-15(f) of the Exchange Act, as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel 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 U.S., and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of management and our directors; and
- 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 financial statements.

All internal control systems, no matter how well designed, have inherent limitations and may not prevent or detect misstatements. Projections of any evaluations of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control—Integrated Framework (2013)*. Based on this assessment, our management concluded that, as of such date, our internal control over financial reporting was effective based on those criteria.

Deloitte & Touche LLP, the independent registered public accounting firm that audited our consolidated financial statements, has issued an attestation report on our internal control over financial reporting as of December 31, 2019, which is included on page F-3 of our Annual Report on Form 10-K.

(b) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the last quarter of the period covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting**.**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of EyePoint Pharmaceuticals, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of EyePoint Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2019, based on the criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2019, of the Company and our report dated March 13, 2020, expressed an unqualified opinion on those financial statements, and included explanatory paragraphs regarding the Company's adoption of new accounting standards and the substantial doubt about the Company's ability to continue as a going concern.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management's Report on Internal Control over Financial Reporting*. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 13, 2020

ITEM 9B. OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference from our definitive proxy statement relating to our 2020 annual meeting of stockholders, pursuant to Regulation 14A of the Exchange Act of 1934, also referred to in this Annual Report on Form 10-K as our 2020 Proxy Statement, which we expect to file with the SEC no later than April 29, 2020.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Corporate Governance

We have adopted a written Code of Business Conduct that applies to all of our employees, officers and directors. This Code of Business Conduct is designed to ensure that our business is conducted with integrity and in compliance with SEC regulations and Nasdaq listing standards. The Code of Business Conduct covers adherence to laws and regulations as well as professional conduct, including employment policies, conflicts of interest and the protection of confidential information. The Code of Business Conduct is available under “Governance Overview” within the “Investors – Corporate Governance” section of our website at www.eyepointpharma.com.

We intend to disclose any future amendments to, or waivers from, the Code of Business Conduct that affect our directors or senior financial and executive officers within four business days of the amendment or waiver by posting such information on the website address and location specified above.

Other Information

The other information required to be disclosed in Item 10 is hereby incorporated by reference to our 2020 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2020 Proxy Statement.

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

The information required to be disclosed in Item 12 is hereby incorporated by reference to our 2020 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required to be disclosed in Item 13 is hereby incorporated by reference to our 2020 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required to be disclosed in Item 14 is hereby incorporated by reference to our 2020 Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENTS

(a)(1) Financial Statements

The financial statements filed as part of this report are listed on the Index to Consolidated Financial Statements on page F-1.

(a)(2) Financial Statement Schedules

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in our Consolidated Financial Statements or Notes thereto.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

(a)(3) Exhibits.

		Incorporated by Reference to SEC Filing		
Exhibit No.	Exhibit Description	Form	SEC Filing Date	Exhibit No.
	Articles of Incorporation and By-Laws			
3.1	Certificate of Incorporation of pSivida Corp.	8-K12G3	06/19/08	3.1
3.2	Certificate of Amendment of the Certificate of Incorporation of pSivida Corp.	10-K	09/13/17	3.2
3.3	Certificate of Amendment of the Certificate of Incorporation of pSivida Corp.	8-K	04/02/18	3.1
3.4	Certificate of Amendment of Certificate of Incorporation, as amended of EyePoint Pharmaceuticals, Inc.	8-K	06/27/18	3.1
3.5	By-Laws of EyePoint Pharmaceuticals, Inc.	10-K	09/18/18	3.5
3.6	Amendment No. 1 to the By-Laws of EyePoint Pharmaceuticals, Inc.	8-K	11/06/18	3.1
	Instruments Defining the Rights of Security Holders			
4.1	Form of Specimen Stock Certificate for Common Stock	8-K12G3	06/19/08	4.1
4.2	Warrant to Purchase Common Stock of pSivida Corp., issued March 28, 2018, to SWK Funding, LLC	8-K	03/29/18	4.1
4.3	Registration Rights Agreement, dated as of March 28, 2018, by and among pSivida Corp. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P.	8-K	03/29/18	10.3
4.4	Second Registration Rights Agreement, dated as of June 25, 2018, by and among EyePoint Pharmaceuticals, Inc. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P. and each other person identified on the signature pages thereto	8-K	06/27/18	10.1
4.5(a)	Description of Securities of EyePoint Pharmaceuticals, Inc.			
	Material Contracts - Management Contracts and Compensatory Plans			
10.1	Employment Agreement between pSivida Corp. and Nancy Lurker, dated September 15, 2016	10-Q	11/08/16	10.1
10.2	Amended and Restated Performance-Based Restricted Stock Unit Award Agreement, dated December 21, 2016, by and between pSivida Corp. and Nancy Lurker	8-K	12/23/16	10.1
10.3	Nonstatutory Stock Option Inducement Award granted to Nancy Lurker, subject to shareholder approval, with effect from September 15, 2016	10-Q	11/08/16	10.3

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
10.4	Employment Agreement, between EyePoint Pharmaceuticals, Inc. and Dario Paggiarino, dated March 27, 2018	10-Q	05/10/18	10.7
10.5	Employment Agreement between EyePoint Pharmaceuticals, Inc. Scott Jones, dated May 30, 2019	10-Q	08/07/19	10.4
10.6	Employment Agreement, dated November 14, 2019, by and between EyePoint Pharmaceuticals, Inc. and George Elston	8-K	11/19/19	10.1
10.7+	Form of Stock Option Certificate for grants to executive officers under the pSivida Corp. 2008 Incentive Plan	8-K	09/10/08	10.1
10.8+	Form of Stock Option Certificate for grants to executive officers under the EyePoint Pharmaceuticals, Inc. 2016 Long Term Incentive Plan, as amended	10-Q	02/08/18	10.1
10.9+	Form of Deferred Stock Unit Award for grants to non-executive directors under the EyePoint Pharmaceuticals, Inc. 2016 Long Term Incentive Plan, as amended	10-Q	02/08/18	10.2
10.10+	Form of Stock Option Award Agreement for Inducement grants to executive officers	10-K	09/18/18	10.15
10.11	2008 Equity Incentive Plan, as amended on November 19, 2009	10-K	09/10/15	10.6
10.12	pSivida Corp. 2016 Long Term Incentive Plan, as amended	10-Q	02/09/17	4.1
10.13+	Form of Restricted Stock Unit Award for grants to executive officers under the pSivida Corp. 2016 Long Term Incentive Plan, as amended	10-K	09/13/17	10.18
10.14+	Form of Performance-Based Stock Unit Award for grants under the pSivida Corp. 2016 Long Term Incentive Plan, as amended	10-K	09/13/17	10.19
10.15	Stock Option Award Agreement, dated August 14, 2018, by and between EyePoint Pharmaceuticals, Inc. and John Weet	10-Q	11/09/18	10.5
10.16	Stock Option Award Agreement, dated November 26, 2018, by and between EyePoint Pharmaceuticals, Inc. and Ron Honig	10-K	03/18/19	10.25
10.17	EyePoint Pharmaceuticals, Inc. 2016 Long Term Incentive Plan	8-K	06/28/19	10.1
10.18	Amendment No. 1 to EyePoint Pharmaceuticals, Inc. 2016 Long Term Incentive Plan	8-K	06/28/19	10.2
10.19	EyePoint Pharmaceuticals, Inc. 2019 Employee Stock Purchase Plan	8-K	06/28/19	10.3
10.20+	Form of Indemnification Agreement between EyePoint Pharmaceuticals, Inc. and its officers and directors	10-Q	08/07/19	10.5
	Material Contracts - Leases			
10.21	Lease Agreement between pSivida Corp. and Farley White Aetna Mills, LLC dated November 1, 2013	10-Q	11/13/13	10.1
10.22	First Amendment of Lease, dated February 6, 2014, between Farley White Aetna Mills and pSivida Corp.	10-K	09/18/18	10.24
10.23	Second Amendment of Lease, dated May 14, 2018, between Whetstone Riverworks Holdings, LLC and EyePoint Pharmaceuticals, Inc.	10-K	09/18/18	10.25
	Material Contracts - License and Collaboration Agreements			

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
10.24#	Second Amended and Restated Collaboration Agreement by and between pSivida US, Inc. and Alimera Sciences, Inc. dated July 10, 2017	10-K	09/13/17	10.23
	Material Contracts - Other Agreements			
10.25	Securities Purchase Agreement, dated as of March 28, 2018, by and among pSivida Corp. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P.	8-K	03/29/18	10.1
10.26	Second Securities Purchase Agreement, dated as of March 28, 2018, by and among pSivida Corp. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P. and each other person identified on the signature pages thereto	8-K	03/29/18	10.2
10.27	Agreement and Plan of Merger, dated March 28, 2018, by and among pSivida Corp., Oculus Merger Sub, Inc., Icon Bioscience, Inc. and Shareholder Representative Services LLC	8-K	03/29/18	10.5
10.28	At Market Issuance Sales Agreement, dated January 18, 2019, by and between EyePoint Pharmaceuticals, Inc. and B. Riley FBR, Inc.	8-K	01/18/19	10.1
10.29	Term Loan Agreement, dated February 13, 2019, among EyePoint Pharmaceuticals, Inc., as Borrower, EyePoint Pharmaceuticals US, Inc. and Icon Bioscience, Inc., as Subsidiary Guarantors, and CRG Servicing LLC, as Administrative Agent and Collateral Agent	8-K	02/19/19	10.1
10.30	Fee Letter, dated February 13, 2019, by and between EyePoint Pharmaceuticals, Inc. and CRG Servicing LLC	8-K	02/19/19	10.2
10.31	Waiver To Term Loan Agreement, dated November 19, 2019, among EyePoint Pharmaceuticals, as Borrower, EyePoint Pharmaceuticals US, Inc. and Icon Bioscience, Inc., as subsidiary guarantors and CRG Servicing LLC, as Administrative Agent and Collateral Agent	8-K	11/22/19	10.1
10.32(a)#	Exclusive License Agreement, dated February 3, 2020, between EyePoint Pharmaceuticals, Inc. and Equinox Science, LLC			
	Other Exhibits			
21.1(a)	Subsidiaries of EyePoint Pharmaceuticals, Inc.			
23.1(a)	Consent of Independent Registered Public Accounting Firm, Deloitte & Touche LLP			
31.1(a)	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended			
31.2(a)	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended			
32.1(a)	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(a)	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
101	The following materials from EyePoint Pharmaceuticals' Annual Report on Form 10-K for the year ended December 31, 2019, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at December 31, 2019 and 2018; (ii) Consolidated Statements of Comprehensive Loss for the year ended December 31, 2019, the six months ended December 31, 2018, and the years ended June 30, 2018 and 2017; (iii) Consolidated Statements of Stockholders' Equity for the year ended December 31, 2019, the six months ended December 31, 2018, and the years ended June 30, 2018 and 2017; (iv) Consolidated Statements of Cash Flows for the year ended December 31, 2019, the six months ended December 31, 2018, and the years ended June 30, 2018 and 2017; and (v) Notes to Consolidated Financial Statements.			

Portions of this exhibit have been omitted in compliance with Item 601 of Regulation S-K.

+ The final versions of documents denoted as "form of" have been omitted pursuant to Rule 12b-31. Such final versions are substantially identical in all material respects to the filed versions of such documents, provided that the name of the investor, and the investor's and/or the Company's signatures are included in the final versions.

(a) Filed herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

EYEPOINT PHARMACEUTICALS, INC.

By: /s/ Nancy Lurker
Nancy Lurker
President and Chief Executive Officer

Date: March 13, 2020

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 in the capacities and on the dates indicated.

Name	Title	Date
/s/ GÖRAN ANDO **Göran Ando**	Chairman of the Board of Directors	March 13, 2020
/s/ NANCY LURKER **Nancy Lurker**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2020
/s/ GEORGE ELSTON **George Elston**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 13, 2020
/s/ WENDY DICICCO Wendy DiCicco	Director	March 13, 2020
/s/ DAVID J. MAZZO **David J. Mazzo**	Director	March 13, 2020
/s/ DOUGLAS GODSHALL **Douglas Godshall**	Director	March 13, 2020
/s/ JAY DUKER **Jay Duker**	Director	March 13, 2020
/s/ KRISTINE PETERSON **Kristine Peterson**	Director	March 13, 2020
/s/ RONALD W. EASTMAN **Ronald W. Eastman**	Director	March 13, 2020
/s/ JOHN LANDIS **John Landis**	Director	March 13, 2020
/s/ DAVID R. GUYER **David R. Guyer**	Director	March 13, 2020

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of EyePoint Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of EyePoint Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2019 and December 31, 2018, the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2019, six month period ended December 31, 2018, and the years ended June 30, 2018 and 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and December 31, 2018, and the results of its operations and its cash flows for the year ended December 31, 2019, six month period ended December 31, 2018, and the years ended June 30, 2018 and 2017, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 13, 2020, expressed an unqualified opinion on the Company's internal control over financial reporting.

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 combination of the Company's limited currently available cash, cash equivalents and available borrowings, together with its history of losses, and the uncertainty in timing of cash receipts from its newly launched products raises substantial doubt about the Company's 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.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has adopted Accounting Standards Update 842, *Leases*, using the modified retrospective approach on January 1, 2019.

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for revenue from contracts with customers in the six month period ended December 31, 2018 due to the adoption of Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*, using the modified retrospective method on July 1, 2018.

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

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 13, 2020
We have served as the Company's auditor since 2008.

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands except share amounts)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 22,214	$ 45,261
Accounts and other receivables, net	11,368	627
Prepaid expenses and other current assets	5,997	1,434
Inventory	2,138	279
Total current assets	41,717	47,601
Property and equipment, net	357	288
Operating lease right-of-use assets	3,078	—
Intangible assets, net	27,669	30,129
Restricted cash	150	150
Total assets	$ 72,971	$ 78,168
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,192	$ 2,640
Accrued expenses	6,832	3,789
Accrued development milestone	—	15,000
Deferred revenue	15	30
Operating lease liabilities - current portion	481	—
Total current liabilities	11,520	21,459
Long-term debt	47,223	17,621
Operating lease liabilities - noncurrent portion	2,898	—
Other long-term liabilities	3,000	1,455
Total liabilities	64,641	40,535
Contingencies (Note 16)		
Stockholders' equity:		
Preferred stock, $.001 par value, 5,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, $.001 par value, 150,000,000 shares authorized ; 109,417,322 and 95,372,236 shares issued and outstanding at December 31, 2019 and 2018, respectively	109	95
Additional paid-in capital	472,667	445,192
Accumulated deficit	(465,286)	(408,493)
Accumulated other comprehensive income	840	839
Total stockholders' equity	8,330	37,633
Total liabilities and stockholders' equity	$ 72,971	$ 78,168

See notes to consolidated financial statements

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands except per share data)

	Year Ended December 31, 2019	Six Months Ended December 31, 2018	Year Ended June 30, 2018	Year Ended June 30, 2017
Revenues:				
Product sales, net	$ 16,824	$ —	$ —	$ —
License and collaboration agreements	1,361	1,883	1,343	6,569
Royalty income	2,180	1,045	1,618	970
Total revenues	20,365	2,928	2,961	7,539
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	2,687	—	—	—
Research and development	15,368	10,412	16,178	14,880
Sales and marketing	29,772	8,174	1,512	—
General and administrative	17,939	8,901	11,545	11,235
Amortization of acquired intangible assets	2,460	—	—	—
Total operating expenses	68,226	27,487	29,235	26,115
Loss from operations	(47,861)	(24,559)	(26,274)	(18,576)
Other income (expense):				
Interest and other income, net	1,054	367	101	91
Interest expense	(6,176)	(1,642)	(720)	—
Loss on extinguishment of debt	(3,810)	—	—	—
Change in fair value of derivative liability	—	(18,886)	(26,278)	—
Total other expense, net	(8,932)	(20,161)	(26,897)	91
Net loss	$ (56,793)	$ (44,720)	$ (53,171)	$ (18,485)
Net loss per share:				
Basic and diluted	$ (0.54)	$ (0.53)	$ (1.15)	$ (0.52)
Weighted average common shares outstanding:				
Basic and diluted	104,307	85,057	46,226	35,344
Net loss	$ (56,793)	$ (44,720)	$ (53,171)	$ (18,485)
Other comprehensive income (loss):				
Foreign currency translation adjustments	1	1	5	(21)
Net unrealized gain on marketable securities	—	—	—	2
Other comprehensive income (loss)	1	1	5	(19)
Comprehensive loss	$ (56,792)	$ (44,719)	$ (53,166)	$ (18,504)

See notes to consolidated financial statements

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands except share data)

	Common Stock		Additional		Accumulated Other	Total
	Number of Shares	Par Value Amount	Paid-In Capital	Accumulated Deficit	Comprehensive Income	Stockholders' Equity
Balance at June 30, 2016	34,172,919	34	312,208	(292,213)	852	20,881
Cumulative effect of change in accounting principle (Note 2)	—	—	122	(122)	—	—
Net loss	—	—	—	(18,485)	—	(18,485)
Other comprehensive loss	—	—	—	—	(19)	(19)
Issuance of stock, net of issue costs	5,100,000	5	8,399	—	—	8,404
Exercise of stock options	84,080	—	99	—	—	99
Stock-based compensation	—	—	2,456	—	—	2,456
Balance at June 30, 2017	39,356,999	39	323,284	(310,820)	833	13,336
Net loss	—	—	—	(53,171)	—	(53,171)
Other comprehensive income	—	—	—	—	5	5
Issuance of stock, net of issue costs	34,690,548	35	47,947	—	—	47,982
Fair value of warrants issued	—	—	355	—	—	355
Exercise of stock options	310,900	—	503	—	—	503
Vesting of stock units	153,601	—	(27)	—	—	(27)
Stock-based compensation	—	—	2,704	—	—	2,704
Balance at June 30, 2018	74,512,048	74	374,766	(363,991)	838	11,687
Net loss	—	—	—	(44,720)	—	(44,720)
Other comprehensive income	—	—	—	—	1	1
Cumulative effect adjustment for adoption of new accounting principle (Note 2)	—	—	—	218	—	218
Exercise of warrants	20,184,224	21	28,842	—	—	28,863
Exercise of stock options	362,291	—	536	—	—	536
Vesting of stock units	313,673	—	(168)	—	—	(168)
Settlement of derivative liability	—	—	38,666	—	—	38,666
Stock-based compensation	—	—	2,550	—	—	2,550
Balance at December 31, 2018	95,372,236	$ 95	$ 445,192	$ (408,493)	$ 839	$ 37,633
Net loss	—	—	—	(56,793)	—	(56,793)
Other comprehensive income	—	—	—	—	1	1
Issuance of stock, net of issue costs	13,525,377	13	22,614	—	—	22,627
Exercise of stock options	223,426	1	413	—	—	414
Vesting of stock units	296,283	—	(120)	—	—	(120)
Stock-based compensation	—	—	4,568	—	—	4,568
Balance at December 31, 2019	109,417,322	$ 109	$ 472,667	$ (465,286)	$ 840	$ 8,330

See notes to consolidated financial statements

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	Six Months Ended December 31,	Year Ended June 30,	
	2019	2018	2018	2017
Cash flows from operating activities:				
Net loss	$ (56,793)	$ (44,720)	$ (53,171)	$ (18,485)
Adjustments to reconcile net loss to cash flows used in operating activities:				
Amortization of intangible assets	2,460	1,229	981	724
Depreciation of property and equipment	144	97	167	91
Amortization of debt discount	596	312	209	—
Amortization of bond (discount) premium on marketable securities	—	—	—	(9)
Non-cash interest expense	1,052	—	—	—
Loss on extinguishment of debt	3,810	—	—	—
Amortization of noncurrent portion of deferred revenue	—	—	—	(5,585)
Stock-based compensation	4,568	2,550	2,704	2,456
Change in fair value of derivative liability	—	18,886	26,278	—
Changes in operating assets and liabilities:				
Accounts receivable and other current assets	(15,304)	(711)	(167)	120
Inventory	(1,859)	(279)	—	—
Accounts payable and accrued expenses	4,596	(204)	1,162	304
Right-of-use assets and operating lease liabilities	46	—	—	—
Deferred revenue	(15)	30	(50)	(97)
Deferred rent	—	224	(20)	(9)
Net cash used in operating activities	(56,699)	(22,586)	(21,907)	(20,490)
Cash flows from investing activities:				
Purchases of marketable securities	—	—	—	(5,052)
Maturities of marketable securities	—	—	—	18,743
Acquisition of Icon Bioscience Inc., net of cash acquired	—	—	(16,780)	—
Purchases of property and equipment	(213)	(132)	(108)	(147)
Proceeds from sale of property and equipment	—	—	—	33
Net cash (used in) provided by investing activities	(213)	(132)	(16,888)	13,577
Cash flows from financing activities:				
Proceeds from exercise of warrants	—	28,863	—	—
Proceeds from issuance of stock, net of issuance costs	22,627	—	41,515	8,404
Proceeds from issuance of long-term debt	50,000	—	20,000	—
Payment of debt issue costs	(1,341)	—	(1,347)	—
Payment of long-term debt principal	(20,000)	—	—	—
Payment of extinguishment of debt costs	(2,716)	—	—	—
Net settlement of stock units to satisfy statutory tax withholding	(120)	(195)	—	—
Proceeds from exercise of stock options	414	536	503	99
Payment of contingent development milestone	(15,000)	—	—	—
Net cash provided by financing activities	33,864	29,204	60,671	8,503
Effect of foreign exchange rate changes on cash and cash equivalents	1	(1)	2	(5)
Net increase (decrease) in cash, cash equivalents and restricted cash	(23,047)	6,485	21,878	1,585
Cash, cash equivalents and restricted cash at beginning of year	45,411	38,926	17,048	15,463
Cash, cash equivalents and restricted cash at end of year	$ 22,364	$ 45,411	$ 38,926	$ 17,048
Supplemental cash flow information:				
Cash interest paid	$ 4,870	$ 1,241	$ 258	$ —
Supplemental disclosure of non-cash investing and financing activities:				
Accrued development milestone	—	—	15,000	—
Accrued term loan exit fee	3,000	—	1,200	—
Fair value of second tranche purchase liability	—	—	4,734	—
Fair value of warrants issued with debt	—	—	355	—
Fair value of second tranche warrants	—	—	18,165	—

See notes to consolidated financial statements

1. Operations

EyePoint Pharmaceuticals, Inc. (together with its subsidiaries, the "Company"), incorporated in Delaware, is a pharmaceutical company committed to developing and commercializing innovative ophthalmic products for the treatment of eye diseases. The Company has two products, YUTIQ® and DEXYCU®, which were approved by the United States ("U.S.") Food and Drug Administration ("FDA") in 2018.

YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg for intravitreal injection, was launched directly in the U.S. in February 2019. YUTIQ is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, which affects between 60,000 to 100,000 people in the U.S. each year and causes approximately 30,000 new cases of blindness every year, making it the third leading cause of blindness. Injected into the eye in an office visit, YUTIQ is a micro-insert that delivers a micro-dose of a corticosteroid to the back of the eye on a sustained constant (zero order release) basis for up to 36 months. YUTIQ is based on the Company's proprietary Durasert® sustained-release drug delivery technology platform, which can deliver drugs for predetermined periods of time ranging from months to years.

DEXYCU (dexamethasone intraocular suspension) 9%, for intraocular administration, was launched directly in the U.S. in March 2019. Indicated for the treatment of post-operative ocular inflammation, DEXYCU is administered as a single dose at the end of ocular surgery and is the first long-acting intraocular product approved by the FDA for this indication. DEXYCU utilizes the Company's proprietary Verisome® drug-delivery platform, which allows for a single intraocular injection that releases dexamethasone, a corticosteroid, over time. There were approximately 3.8 million cataract surgeries performed during 2018 in the U.S. and the Company launched DEXYCU with a primary focus on its use following cataract surgery. The Company acquired DEXYCU in connection with its acquisition of Icon Bioscience, Inc. ("Icon") in March 2018.

ILUVIEN® for diabetic macular edema ("DME"), the Company's lead licensed product, is sold directly in the U.S. and several European Union ("EU") countries by Alimera Sciences, Inc. ("Alimera"). In July 2017, the Company expanded its license agreement with Alimera to include the uveitis indication utilizing the Durasert technology in Europe, the Middle East and Africa ("EMEA"), which received European regulatory approval in March 2019 and, subject to obtaining pricing and reimbursement in each applicable country, will be marketed as ILUVIEN. Retisert®, one of the Company's earlier generation products, was approved in 2005 by the FDA for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye and is sold in the U.S. by Bausch & Lomb Inc. ("Bausch & Lomb"). The patent with which Retisert is marked expired in March 2019. As such, Bausch & Lomb discontinued paying royalties after March 2019.

EYP-1901, 6-Month bioerodible Durasert Vorolanib – Tyrosine Kinase Inhibitor ("TKI") is being advanced as a potential treatment for wet age-related macular degeneration ("wAMD"), diabetic retinopathy ("DR") and retinal vein occlusion ("RVO"). The Company has completed initial animal pharmacokinetic and toxicology studies and expect to initiate GLP toxicology studies in the first quarter of 2020 to support the filing of an Investigational New Drug application with the FDA.

YUTIQ50 is being developed as a 6-month dosing option for treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. The Company has consulted with the FDA and identified a clinical pathway for an sNDA filing that involves a clinical trial of approximately 60 patients, randomized 2:1. The Company is currently evaluating the timeline and investment requirements for the initiation of this study.

The Company's development programs are focused primarily on developing sustained release products that utilize its Durasert technology platform to deliver drugs to treat chronic diseases. The Company's strategy includes developing products independently while continuing to leverage its technology platforms, including Verisome, through collaborations and license agreements.

Liquidity

The Company has a history of operating losses and has not had significant recurring cash inflows from revenue. The Company's operations have been financed primarily from sales of its equity securities, issuance of debt and a combination of license fees, milestone payments, royalty income and other fees received from its collaboration partners. In the first quarter of 2019, the Company commenced the U.S. launch of its first two commercial products, YUTIQ and DEXYCU. However, the Company, has no history of direct commercialization of its products and management does not yet have sufficient historical evidence to assert that it is probable that the Company will receive sufficient revenues from its product sales to fund operations. As of December 31, 2019, the Company has had recurring operating losses since its inception and has an accumulated deficit of approximately $465.3 million and working capital of $30.2 million. In addition to total cash and cash equivalents of $22.2 million at December 31, 2019, the Company received net proceeds of $20.3 million on February 25, 2020 from the issuance of common stock ("Common Stock"), excluding approximately $300,000 of additional unpaid share issue costs (see Note 18).

Accordingly, the foregoing conditions, taken together, continue to raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of these financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company's plans that are intended to mitigate those conditions include continuing to fulfill its funding needs through cash inflows from revenue of YUTIQ and DEXYCU product sales, licensing arrangements, additional capital raise or other arrangement. The Company believes its plans in place will be sufficient to fund the Company's operating plan for the next 12 months. Although the Company believes such plans, if executed, should provide the Company sufficient financing to meet its needs, there is no assurance that additional funding will be achieved and that the Company will succeed in its future operations. Actual cash requirements could differ from management's projections due to many factors, including the success of commercialization for YUTIQ and DEXYCU, the actual costs of these commercialization efforts, additional investments in research and development programs, competing technological and market developments and the costs of any strategic acquisitions and/or development of complementary business opportunities.

2. Significant Accounting Policies

Basis of Presentation

The consolidated financial statements are presented in U.S. dollars in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP") and include the accounts of EyePoint Pharmaceuticals, Inc. and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Change in Fiscal Year

As previously reported, the Company changed its fiscal year end to December 31 from June 30 effective January 1, 2019. This Annual report on Form 10-K is for the twelve months ended December 31, 2019, which may be referred to in this report as fiscal 2019. The Company previously filed a Transition Report for the six-month transitional financial statements as of and for the period ended December 31, 2018, which was referred to as the transition period. The years ended June 30, 2018 and 2017 may be referred to herein as fiscal 2018 and fiscal 2017, respectively.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts and disclosure of assets and liabilities at the date of the consolidated financial statements and the reported amounts and disclosure of revenues and expenses during the reporting periods. Significant management estimates and assumptions include, among others, those related to reserves for variable consideration related to product sales, revenue recognition for multiple-deliverable arrangements, recognition of expense in outsourced clinical trial agreements, realization of deferred tax assets and the valuation of derivative liabilities, stock options and other equity awards. Actual results could differ from these and other estimates.

Foreign Currency

The functional currency of the Company and each of its subsidiaries is the currency of the primary economic environment in which each such entity operates —the U.S. dollar or the Pound Sterling.

Assets and liabilities of the Company's foreign subsidiary are translated at period-end exchange rates. Amounts included in the consolidated statements of comprehensive loss and cash flows are translated at the weighted average exchange rates for the period. Gains and losses from currency translation are included in accumulated other comprehensive income as a separate component of stockholders' equity in the consolidated balance sheets. The balance of accumulated other comprehensive income attributable to foreign currency translation was $840,000 and $839,000 at December 31, 2019 and 2018, respectively. Foreign currency gains or losses arising from transactions denominated in foreign currencies, whether realized or unrealized, are recorded in interest and other income, net in the consolidated statements of comprehensive loss and were not significant for all periods presented.

Cash Equivalents

Cash equivalents represent highly liquid investments with maturities of three months or less at the date of purchase, principally consisting of institutional money market funds.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and marketable securities. At December 31, 2019, a total of $20.0 million, representing all of the Company's interest-bearing cash equivalent balances, were concentrated in one U.S. Government institutional money market fund that had investments consisting primarily of U.S. Government Agency debt, U.S. Treasury debt, U.S. Treasury Repurchase Agreements and U.S.

Government Agency Repurchase Agreements. Generally, these deposits may be redeemed upon demand and, therefore, the Company believes they have minimal risk. The Company had no investments in marketable securities at December 31, 2019 and 2018, respectively. The Company's investment policy, approved by the Company's Board of Directors, includes guidelines relative to diversification and maturities designed to preserve principal and liquidity.

As of December 31, 2019, accounts receivable from the Third-party Logistics Provider (the "3PL"), ASD Specialty Healthcare LLC, FFF Enterprises, Inc., and McKesson Specialty Care Distribution LLC accounted for 37.0%, 34.0%, 15%, and 12.0% of total accounts receivable, respectively. For the year ended December 31, 2019, revenues from the 3PL, ASD Specialty Healthcare LLC, and Alimera Sciences accounted for 56.0%, 15.0%, and 10.0% of total revenues, respectively.

Fair Value Measurements

The Company accounts for certain assets and liabilities at fair value. The hierarchy below lists three levels of fair value based on the extent to which inputs used in measuring fair value are observable in the market. The Company categorizes each of its fair value measurements in one of these three levels based on the lowest level input that is significant to the fair value measurement in its entirety. These levels are:

- Level 1 – Inputs are quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets and liabilities.
- Level 2 – Inputs are directly or indirectly observable in the marketplace, such as quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets or liabilities with insufficient volume or infrequent transaction (less active markets).
- Level 3 – Inputs are unobservable estimates that are supported by little or no market activity and require the Company to develop its own assumptions about how market participants would price the assets or liabilities.

The carrying amounts of cash equivalents, accounts receivable, accounts payable and accrued expenses approximate fair value because of their short-term maturity.

Accounts and Other Receivables, Net

Receivables arise primarily from the Company's products sold in the U.S. The balance in accounts and other receivables, net consists primarily of amounts due from customers, net of applicable revenue reserves. The majority of the Company's accounts receivable have standard payment terms that require payment within 120-154 days. The Company performs ongoing credit evaluations of its customers' financial condition and continuously monitor collections and payments from its customers and analyzes accounts that are past due for collectability. Amounts determined to be uncollectible are charged or written off against the reserve. To date, given the nature and limited history of collectability of the Company's accounts receivable, the Company recorded no allowance for doubtful accounts as of December 31, 2019.

Inventory

Inventory is stated at the lower of cost or net realizable value, net on a first-in, first-out ("FIFO") basis. The inventory costs for YUTIQ include purchases of various components and the active pharmaceutical ingredient ("API") and internal labor and overhead for the product manufactured in the Company's Watertown, MA facility. The inventory costs for DEXYCU include purchased components, the API and third-party manufacturing and assembly.

Capitalization of inventory costs begins after FDA approval of the product. Prior thereto, inventory costs of products and product candidates are recorded as research and development expense, even if this inventory may later be sold as commercial product.

The Company assesses the recoverability of inventory and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Write-downs are based on the age of the inventory, lower of cost or market, along with significant management judgments concerning future demands for the inventory. Such impairment charges, should they occur, are recorded within cost of sales, excluding amortization of acquired intangible assets. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory might be recorded in future periods.

Cost of sales, excluding amortization of acquired intangible assets, consist of costs associated with the manufacture of YUTIQ and DEXYCU, certain period costs, product shipping and, as applicable, royalty expense.

Debt and Equity Instruments

Debt and equity instruments are classified as either liabilities or equity in accordance with the substance of the contractual arrangement.

Derivative Instruments

Derivative financial liabilities are recorded at fair value, with gains and losses arising from changes in fair value recognized in change in fair value of derivative liability within the consolidated statements of comprehensive loss at each period end while such instruments are outstanding. The Company's derivative liabilities from certain financing transactions were primarily valued using Monte Carlo simulation models. Refer to Notes 10, 11 and 13 for additional information.

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives (generally three to five years) using the straight-line method. Leasehold improvements are amortized on a straight-line basis over the shorter of the remaining non-cancellable lease term or their estimated useful lives. Repair and maintenance costs are expensed as incurred. When assets are retired or sold, the assets and accumulated depreciation are derecognized from the respective accounts and any gain or loss is recognized.

Leases

The Company leases real estate and office equipment under operating leases. Its primary real estate lease contains rent holiday and rent escalation clauses.

The Company adopted Accounting Standards Codification No. 842, Leases ("ASC 842"), as of January 1, 2019. The adoption of ASC 842 represents a change in accounting principle that establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all operating leases, with an exception provided for leases with a duration of one year or less. The Company applied ASC 842 using the modified retrospective transition approach which, allows companies to recognize existing leases at the adoption date without requiring comparable period presentation. Comparative periods are presented in accordance with the previous guidance in Accounting Standards Codification ("ASC") 840, Leases.

In adopting the new standard, the Company elected to utilize the available package of practical expedients permitted under the transition guidance within the new standard, which does not require the reassessment of the following: (i) whether existing or expired arrangements are or contain a lease, (ii) the lease classification of existing or expired leases, and (iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. Additionally, the Company elected to combine lease and non-lease components and to exclude leases with a term of 12 months or less. The adoption of this accounting standard resulted in recording operating lease ROU assets for three real estate operating lease arrangements and corresponding operating lease liabilities of $3.5 million and $3.7 million, respectively, as of January 1, 2019. The operating lease assets at adoption were lower than the operating lease liabilities because the balance of the Company's deferred rent liabilities at December 31, 2018, which represented lease incentives, was reclassified into operating lease assets. The adoption of the standard did not have a material effect on the Company's consolidated statements of operations or consolidated statements of cash flows.

Under Topic 842, the Company determines whether the arrangement is or contains a lease at inception. Operating leases are recognized on the consolidated balance sheets as ROU assets, current portion of lease liabilities and long-term lease liabilities. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected remaining lease term. For this purpose, the Company considers only payments that are fixed and determinable at the time of commencement. The operating lease ROU assets also include any lease payments made and adjustments for prepayments and lease incentives. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilized its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Impairment of Intangible Assets

The Company's finite life intangible assets include the DEXYCU product (utilizing the Verisome technology) following the March 2018 acquisition of Icon. The DEXYCU intangible asset is being amortized on a straight-line basis over its estimated useful life of thirteen years. The intangible asset lives were determined based upon the anticipated period that the Company would derive future cash flows from the intangible assets, considering the effects of legal, regulatory, contractual, competitive and other economic factors. The Company continually monitors whether events or circumstances have occurred that indicate that the remaining estimated useful life of its intangible assets may warrant revision. The Company assesses potential impairments to its intangible assets when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recognized when the future undiscounted net cash flows expected to result from the use of an asset are less than its carrying value. If the Company considers an asset to be impaired, the impairment charge to be recognized is measured as the amount by which the carrying value of the asset exceeds its estimated fair value.

Revenue Recognition

The Company adopted Accounting Standards Codification No. 606, Revenue from Contracts with Customers ("ASC 606"), as of July 1, 2018. The adoption of ASC 606 represents a change in accounting principle that more closely aligns revenue recognition with the delivery of the Company's services. The Company applied ASC 606 using the modified retrospective method. The cumulative effect of initially applying the new revenue standard resulted in a $218,000 reduction to the opening balance of accumulated deficit at July 1, 2018.

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, Revenue from Contracts with Customers ("ASC 606"), the Company performs the following five steps: (i) identify the contract(s) 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) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Product sales, net — The Company began selling YUTIQ and DEXYCU in February and March 2019, respectively, in the U.S. through a single third-party logistics provider (the "3PL"), which takes title to and control of the goods. The 3PL distributes the products through a limited number of specialty distributors and specialty pharmacies (collectively the "Distributors"), with whom the Company has entered into formal agreements, for delivery to physician practices for YUTIQ and to hospital outpatient departments and ambulatory surgical centers for DEXYCU. Effective December 15, 2019, the Company terminated its product sales through the 3PL and replaced with the Distributors. The Company recognizes revenue on sales of its products when a customer obtains control of the products, which occurs at a point in time, typically upon delivery. In addition to distribution agreements with customers, the Company also enters into arrangements with healthcare providers and payors that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products.

Reserves for variable consideration — Product sales are recorded at the wholesale acquisition costs, net of applicable reserves for variable consideration. Components of variable consideration include trade discounts and allowances, provider chargebacks and discounts, payor rebates, product returns, and other allowances that are offered within contracts between the Company and its Distributors, payors, and other contracted purchasers relating to the Company's product sales. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified either as reductions of product revenue and accounts receivable or a current liability, depending on how the amount is to be settled. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the estimates, the Company adjusts these estimates, which would affect product revenue and earnings in the period such variances become known.

Distribution fees — The Company compensates its Distributors for services explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product sale is recognized.

Provider chargebacks and discounts — Chargebacks are discounts that represent the estimated obligations resulting from contractual commitments to sell products at prices lower than the list prices charged to the Company's Distributors. These Distributors charge the Company for the difference between what they pay for the product and the Company's contracted selling price. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. Reserves for chargebacks consist of amounts that the Company expects to pay for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold under a contracted selling price, and chargebacks that Distributors have claimed, but for which the Company has not yet settled.

Government rebates — The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Payor rebates — The Company contracts with certain private payor organizations, primarily insurance companies, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Co-Payment assistance — The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirements. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue.

Product returns — The Company generally offers a limited right of return based on its returned goods policy, which includes damaged product and remaining shelf life. The Company estimates the amount of its product sales that may be returned and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as reductions to trade receivables, net on the condensed consolidated balance sheets.

License and collaboration agreement revenue — The Company analyzes each element of its license and collaboration arrangements to determine the appropriate revenue recognition. The terms of the license agreement may include payment to the Company of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

The Company recognizes sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606-10-55-65. For those milestone payments which are contingent on the occurrence of particular future events, the Company determines that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the most-likely amount method. As such, the Company assesses each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty associated with these future events, the Company will not recognize revenue from such milestones until there is a high probability of occurrence, which typically occurs near or upon achievement of the event.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of December 31, 2019.

Reimbursement of costs — The Company may provide research and development services and incur maintenance costs of licensed patents under collaboration arrangements to assist in advancing the development of licensed products. The Company acts primarily as a principal in these transactions and, accordingly, reimbursement amounts received are classified as a component of revenue to be recognized consistent with the revenue recognition policy summarized above. The Company records the expenses incurred and reimbursed on a gross basis.

Royalties — The Company recognizes revenue from license arrangements with its commercial partners' net sales of products. Such revenues are included as royalty income. In accordance with ASC 606-10-55-65, royalties are recognized when the subsequent sale of the commercial partner's products occurs. The Company's commercial partners are obligated to report their net product sales and the resulting royalty due to the Company typically within 60 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, the Company recognizes royalty income each quarter and subsequently determines a true-up when it receives royalty reports and payment from its commercial partners. Historically, these true-up adjustments have been immaterial.

Feasibility Studies — The Company recognizes revenue over the term of the statements of work under any funded feasibility study agreements. Revenue recognition for consideration, if any, related to a license option right is assessed based on the terms of any such future license agreement or is otherwise recognized at the completion of the feasibility study agreement.

Deferred Revenue

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized within one year following the balance sheet date are classified as non-current deferred revenue.

Please refer to Note 4 for further details on the license and collaboration agreements into which the Company has entered and corresponding amounts of revenue recognized for the year ended December 31, 2019, for the six months transition period ended December 31, 2018 and for prior fiscal year periods.

Research and Development

Research and development costs are charged to operations as incurred. These costs include all direct costs, including cash and stock-based compensation and benefits for research, clinical development, quality assurance, quality control, operations and medical affairs personnel, amortization of intangible assets, third-party costs and services for clinical trials, clinical materials, pre-clinical programs, regulatory and medical affairs, external consultants, and other operational costs related to the Company's research and development of its product candidates.

Stock-Based Compensation

The Company may award stock options and other equity-based instruments to its employees, directors and consultants pursuant to stockholder-approved plans. In the fourth quarter of fiscal 2017, the Company early adopted Accounting Standards Update ("ASU") No. 2016-09 ("ASU 2016-09"), *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, pursuant to which it elected to account for forfeitures as they occur. As a result, the Company recorded an adjustment of $122,000 to accumulated deficit and additional paid-in capital as of July 1, 2016.

Compensation cost related to such share-based payment awards is based on the fair value of the instrument on the grant date and is recognized on a graded vesting basis over the requisite service period for each separately vesting tranche of the awards.

The Company may also grant share-based payment awards that are subject to objectively measurable performance and service criteria. Compensation expense for performance-based awards begins at such time as it becomes probable that the respective performance conditions will be achieved. The Company continues to recognize the grant date fair value of performance-based awards through the vesting date of the respective awards so long as it remains probable that the related performance conditions will be satisfied.

The Company estimates the fair value of stock option awards using the Black-Scholes option valuation model and the fair value of performance stock units, restricted stock units and deferred stock units based on the observed grant date fair value of the underlying Common Stock.

Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. For periods in which the Company reports net income, diluted net income per share is determined by adding to the weighted-average number of common shares outstanding the average number of dilutive common equivalent shares using the treasury stock method, unless the effect is anti-dilutive.

Outstanding potential Common Stock equivalents excluded from the calculation of diluted earnings per share because the effect would have been anti-dilutive were as follows:

	Year Ended December 31,	Six Months Ended December 31,	Year Ended June 30,	
	2019	2018	2018	2017
Stock options	10,909,800	8,139,377	7,750,244	6,895,685
ESPP	137,368	—	—	—
Warrants	486,812	486,812	20,671,036	623,605
Restricted stock units	786,899	1,090,213	1,398,129	948,500
Performance stock units	—	370,000	466,668	210,000
Deferred stock units	—	35,418	35,001	—
	12,320,879	10,121,820	30,321,078	8,677,790

Comprehensive Loss

Comprehensive loss is comprised of net loss, foreign currency translation adjustments and unrealized gains and losses on available-for-sale marketable securities.

Income Tax

The Company accounts for income taxes under the asset and liability method. Deferred income tax assets and liabilities are computed for the expected future impact of differences between the financial reporting and income tax bases of assets and liabilities and for the expected future benefit to be derived from tax credits and loss carry forwards. Such deferred income tax computations are measured based on enacted tax laws and rates applicable to the years in which these temporary differences are expected to be

recovered or settled. A valuation allowance is provided against net deferred tax assets if, based on the available evidence, it is more likely than not that some or all of the net deferred tax assets will not be realized.

The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more likely than not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the uncertainty. The Company accounts for interest and penalties related to uncertain tax positions as part of its income tax benefit.

Recently Adopted and Recently Issued Accounting Pronouncements

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board ("FASB") and are adopted by the Company as of the specified effective dates. Unless otherwise disclosed below, the Company believes that recently issued and adopted pronouncements will not have a material impact on the Company's financial position, results of operations and cash flows or do not apply to the Company's operations.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations* (Topic 805) ("ASU 2017-01"): Clarifying the Definition of a Business, to clarify the definition of a business by adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets versus businesses. ASU 2017-01 is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted this standard early to account for the acquisition of Icon (see Note 3).

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) ("ASU 2014-09"), which requires an entity to recognize revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for the transfer of promised goods or services to customers. In August 2015, the FASB issued ASU 2015-14, which officially deferred the effective date of ASU 2014-09 by one year, while also permitting early adoption. As a result, ASU 2014-09 became effective on July 1, 2018. The Company adopted this standard as of July 1, 2018. The adoption of ASC 606 represents a change in accounting principle that more closely aligns revenue recognition with the delivery of the Company's services and provides financial statement readers with enhanced disclosures. The Company applied ASC 606 using the modified retrospective method. The cumulative effect of initially applying the new revenue standard resulted in a $218,000 reduction to the opening balance of accumulated deficit at July 1, 2018.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"). In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842), Targeted Improvements, which contains certain amendments to ASU 2016-02 intended to provide relief in implementing the new standard. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all operating leases, with an exception provided for leases with a duration of one year or less. The Company adopted ASU 2016-02 on January 1, 2019 using the modified retrospective transition approach which, pursuant to ASU 2018-11, allows companies to recognize existing leases at the adoption date without requiring comparable period presentation. Comparative periods are presented in accordance with the previous guidance in Accounting Standards Codification ("ASC") 840, Leases.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)* ("ASU 2016-13")*: Measurement of Credit Losses on Financial Instruments*, to replace the current incurred loss impairment methodology for financial assets measured at amortized cost with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information, including forecasted information, to develop credit loss estimates. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018. This standard will be effective for the Company in the first quarter of its fiscal year ending December 31, 2020. The Company is currently evaluating the impact the adoption of this update will have on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)* ("ASU 2019-12")*: Simplifying the Accounting for Income Taxes*. The amendments simplify the accounting for income taxes by removing certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. Early adoption is permitted, including adoption in interim or annual periods for which financial statements have not yet been issued. This standard will be effective for the Company in the first quarter of its fiscal year ending December 31, 2021. The Company is currently evaluating the impact the adoption of this update will have on its consolidated financial statements.

3. Acquisition of Icon Bioscience, Inc.

On March 28, 2018, the Company and its newly-created wholly-owned subsidiary, Oculus Merger Sub, Inc., acquired Icon, a specialty biopharmaceutical company, through a reverse triangular merger (the "Icon Acquisition") pursuant to an Agreement and Plan of Merger (the "Merger Agreement") between the Company, Icon, and Shareholder Representative Services LLC ("SRS"), solely in its capacity as representative of Icon's securityholders. The Icon Acquisition was accounted for as an asset acquisition because substantially all of the fair value of the gross assets acquired were deemed to be concentrated in a group of similar identifiable assets related to Icon's lead product, DEXYCU. A portion of the Icon Acquisition was funded by a debt financing and an equity financing, both of which closed concurrently with the Icon Acquisition (see Notes 10 and 11).

Pursuant to the Merger Agreement, the Company made a closing payment of $15.0 million to SRS, net of an estimated $127,000 working capital adjustment, and is obligated to pay certain post-closing contingent cash payments upon the achievement of specified milestones and based upon certain net sales and partnering revenue standards, in each case subject to the terms and conditions set forth in the Merger Agreement. These include but are not limited to (i) a one-time development milestone of $15.0 million payable in cash upon the first commercial sale of DEXYCU in the U.S., (ii) sales milestone payments totaling up to $95.0 million upon the achievement of certain sales thresholds and subject to certain Centers for Medicare & Medicaid Services ("CMS") reimbursement conditions set forth in the Merger Agreement, (iii) quarterly earn-out payments equal to 12% on net sales of DEXYCU in a given year, which earn-out payments will increase to 16% of net sales of DEXYCU in such year beginning in the calendar quarter for such year to the extent aggregate annual DEXYCU consideration exceeds $200.0 million in such year, (iv) quarterly earn-out payments equal to 20% of partnering revenue received by the Company for DEXYCU outside of the U.S., and (v) single-digit percentage quarterly earn-out payments with respect to net sales and/or partnering income, if any, resulting from future clinical development, regulatory approval and commercialization of any other product candidates the Company acquired in the Icon Acquisition. Following the first commercial sale of DEXYCU, the Company paid the $15.0 million one-time development milestone to SRS in April 2019.

The purchase price on the date of the Icon Acquisition was $32.0 million and was comprised of the closing consideration of $15.0 million, including the assumption of an estimated $127,000 of net current liabilities of Icon, the contingent development milestone payment of $15.0 million and transaction costs of approximately $2.0 million. Given the stage of development of DEXYCU, the Company determined these payments did not represent research and development costs. The contingent consideration in the form of sales milestones will be capitalized as additional intangible assets when any such consideration becomes probable and can be reasonably estimated. Sales-based royalty payments will be expensed as incurred.

The purchase price was allocated to a single finite-lived intangible asset with an expected amortization life of approximately 13 years. The intangible asset is being amortized on a straight-line basis over that period. The acquisition did not have a net tax impact due to a full valuation allowance against the acquired net deferred tax assets.

For the year ended December 31, 2019, the Company accrued sales-based royalty expense of $781,000, as a component of cost of sales.

4. Product Revenue Reserves and Allowances

The Company's product revenues have been primarily from sales of YUTIQ and DEXYCU in the U.S., which it began shipping to its 3PL in February 2019 and March 2019, respectively.

Net product revenues by product for the year ended December 31, 2019 were as follows (in thousands):

	Year Ended December 31, 2019
YUTIQ	$ 12,046
DEXYCU	4,778
Total product sales, net	$ 16,824

The following table summarizes activity in each of the product revenue allowance and reserve categories for the year ended December 31, 2019 (in thousands):

	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Beginning balance at January 1, 2019	$ —	$ —	$ —	$ —
Provision related to sales in the current year	2,301	429	732	3,462
Adjustments related to prior period sales	—	—	—	—
Deductions applied and payments made	(683)	(158)	(380)	(1,221)
Ending balance at December 31, 2019	$ 1,618	$ 271	$ 352	$ 2,241

Returns are recorded as a reduction of accounts receivable on the condensed consolidated balance sheets. Chargebacks, discounts and fees and rebates are recorded as a component of accrued expenses on the condensed consolidated balance sheets (See Note 8).

License and Collaboration Agreements and Royalty Income

Alimera

Under a collaboration agreement with Alimera, as amended in March 2008 (the “Prior Alimera Agreement”), the Company licensed to Alimera the rights to develop, market and sell certain product candidates, including ILUVIEN for DME, and Alimera assumed all financial responsibility for the development of the licensed products. The Company was entitled to receive a share of any net profits (as defined) on sales of each licensed product (including ILUVIEN) by Alimera, measured on a quarter-by-quarter and country-by-country basis, and Alimera was entitled to recover a share of previously incurred and unapplied net losses (as defined) for commercialization of each product in a country. The Company was also entitled to reimbursement of certain patent maintenance costs with respect to the patents licensed to Alimera.

On July 10, 2017, the Company entered into a further amended and restated collaboration agreement (the “Amended Alimera Agreement”), pursuant to which the Company (i) licensed its then Durasert three-year uveitis product candidate (currently marketed by the Company as YUTIQ in the U.S.) to Alimera for regulatory approval and distribution under its ILUVIEN trade name in EMEA and (ii) converted the net profit share arrangement for each licensed product (including ILUVIEN) under the Prior Alimera Agreement to a sales-based royalty on a calendar quarter basis commencing July 1, 2017, with payments from Alimera due 60 days following the end of each quarter.

Following the completion of the Amended Alimera Agreement, Alimera filed a Type II variation in December 2017 for ILUVIEN for the treatment of non-infectious uveitis affecting the posterior segment of the eye in all seventeen European countries in which it previously received regulatory approval for ILUVIEN for DME. In March 2019, Alimera received regulatory approval for the uveitis indication. After the label for this new indication is finalized consistent with each such country’s local requirements, Alimera has indicated that it plans to commercialize the product for this indication under its ILUVIEN trademark.

Under the Amended Alimera Agreement, sales-based royalties started at the rate of 2%. Commencing December 12, 2018, the royalty rate increased to 6% on aggregate calendar year net sales up to $75.0 million and to 8% on any calendar year net sales in excess of $75.0 million. Alimera’s share of contingently recoverable accumulated ILUVIEN commercialization losses under the Prior Alimera Agreement, capped at $25.0 million, are being reduced as follows: (i) $10.0 million was cancelled in lieu of an upfront license fee on the effective date of the Amended Alimera Agreement; (ii) for the period from December 12, 2018 through calendar year 2020, 50% of earned sales-based royalties in excess of 2% will be offset against quarterly royalty payments otherwise due from Alimera; (iii) in March 2019, another $5.0 million was cancelled upon Alimera’s receipt of regulatory approval for ILUVIEN for the uveitis indication; and (iv) commencing in calendar year 2021, 20% of earned sales-based royalties in excess of 2% will be offset against quarterly royalty payments otherwise due from Alimera until such time as the balance of the original $25 million of recoverable commercialization losses has been fully recouped. At December 31, 2019, the remaining recoverable balance of these commercialization losses was approximately $8.9 million.

Revenue recognized under the Amended Alimera Agreement totaled $2.1 million in the year ended December 31, 2019, $627,000 in the six months ended December 31, 2018 and $723,000 in fiscal 2018. In addition to patent fee reimbursements in those periods, the Company recorded sales-based royalty income totaled $2.0 million in the year ended December 31, 2019, $588,000 in the six months ended December 31, 2018 and $575,000 in fiscal 2018.

Bausch & Lomb

Pursuant to a licensing and development agreement, as amended, Bausch & Lomb has a worldwide exclusive license to make and sell Retisert in return for royalties based on sales. Royalty income was $204,000 in the year ended December 31, 2019, $456,000 in the six months ended December 31, 2018, approximately $1.0 million in fiscal 2018 and $970,000 in fiscal 2017. The patent with which Retisert is marketed expired in March 2019. As such, pursuant to our agreement with Bausch & Lomb, payment of sales-based royalties concluded at the end of March 2019. Accounts receivable from Bausch & Lomb was $0 at December 31, 2019 and $253,000 at December 31, 2018.

OncoSil Medical

The Company entered into an exclusive, worldwide royalty-bearing license agreement in December 2012, amended and restated in March 2013, with OncoSil Medical UK Limited (f/k/a Enigma Therapeutics Limited), a wholly-owned subsidiary of OncoSil Medical Ltd (“OncoSil”) for the development of BrachySil, the Company’s previous product candidate for the treatment of pancreatic and other types of cancer. The Company received an upfront fee of $100,000 and is entitled to 8% sales-based royalties, 20% of sublicense consideration and milestone payments based on aggregate product sales. OncoSil is obligated to pay an annual license maintenance fee of $100,000 by the end of each calendar year, the most recent of which was received in December 2019. For each calendar year commencing with 2014, the Company is entitled to receive reimbursement of any patent maintenance costs, sales-based royalties and sub-licensee sales-based royalties earned, but only to the extent such amounts, in the aggregate, exceed the $100,000 annual license maintenance fee. As of December 31, 2019, OncoSil has not received regulatory approval in any jurisdiction. In March 2019 the Clinical Oversight Committee of the British Standards Institute (“BSI”) advised OncoSil that insufficient clinical benefit had been demonstrated to recommend approval of its longstanding CE Mark application. In October 2019, Oncosil announced that it had completed its follow up meeting with BSI and is focused on submitting an updated Clinical Evaluation Report for CE Mark approval. The Company has no consequential performance obligations under the OncoSil license agreement. As of December 31, 2019, no deferred revenue was recorded for this agreement.

Ocumension Therapeutics

In November 2018, the Company entered into an exclusive license agreement with Ocumension Therapeutics (“Ocumension”) for the development and commercialization of its three-year micro insert using the Durasert technology for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye (YUTIQ in the U.S.) in Mainland China, Hong Kong, Macau and Taiwan. The Company received a one-time upfront payment of $1.75 million from Ocumension and is eligible to receive up to (i) $7.25 million upon the achievement by Ocumension of certain prescribed development and regulatory milestones, and (ii) $3.0 million commercial sales-based milestones. In addition, the Company is entitled to receive mid-single digit sales-based royalties. Ocumension has also received a special approval by the Hainan Province People's Government to market this product for chronic, non-infectious posterior segment uveitis in the Hainan Bo Ao Lecheng International Medical Tourism Pilot Zone (“Hainan Pilot Zone”). In March 2019, the Company entered into a Memorandum of Understanding (“MOU”), pursuant to which, the Company will supply product for the clinical trials and Hainan Pilot Zone use. Paralleling to Ocumension’s normal registration process of the product with the Chinese Regulatory Authorities, the MOU modified the Company’s entitlement to the development and regulatory milestones of up to $7.25 million under the license agreement to product supply milestones or development milestones, whichever comes first, totaling up to $7.25 million. In August 2019, the Company began shipping this product to Ocumension.

The Company was required to provide a fixed number of hours of technical assistance support to Ocumension at no cost, which was completed already and no future performance obligation exists. Ocumension is responsible for all development, regulatory and commercial costs, including any additional technical assistance requested. Ocumension has a first right of negotiation for an additional exclusive license to the Company’s shorter-duration line extension candidate for this indication.

In August 2019, the Company received a $1.0 million development milestone payment from Ocumension triggered by the approval of its Investigational New Drug (“IND”) in China for this program. The IND allows the importation of finished product into China for use in a clinical trial to support regulatory filing.

In January 2020, the Company entered into an exclusive license agreement with Ocumension for the development and commercialization in Mainland China, Hong Kong, Macau and Taiwan of DEXYCU for the treatment of post-operative inflammation following ocular surgery. Pursuant to the terms of the license agreement, the Company received upfront payments of $2.0 million from Ocumension in February 2020 and will be eligible to receive up to (i) 6.0 million upon the achievement by Ocumension of certain prescribed development and regulatory milestones, and (ii) 6.0 million commercial sales-based milestones. In addition, the Company is entitled to receive mid-single digit sales-based royalties. In exchange, Ocumension will receive exclusive rights to develop and commercialize DEXYCU in Mainland China, Hong Kong, Macau and Taiwan, at its own cost and expense with the Company supplying product for clinical trials and commercial sale. In addition, Ocumension will receive a fixed number of hours of technical assistance support from the Company at no cost.

In the year ended December 31, 2019, revenue recognized under the license agreement and MOU with Ocumension totaled $1.1 million. In addition to $91,000 of revenue from product sales, $1.0 million was recognized as license and collaboration agreement revenue. In the six months ended December 31, 2018, $1.7 million was recognized as license and collaboration agreement revenue. As of December 31, 2019 and 2018, $0 and $30,000 of deferred revenue was recorded for this agreement, respectively.

Equinox Science, LLC

In February 2020, the Company entered into an Exclusive License Agreement with Equinox Science, LLC ("Equinox"), pursuant to which Equinox granted us an exclusive, sublicensable, royalty-bearing right and license to certain patents and other Equinox intellectual property to research, develop, make, have made, use, sell, offer for sale and import the compound vorolanib and any pharmaceutical products comprising the compound for the prevention or treatment of age-related macular degeneration, diabetic retinopathy and retinal vein occlusion using our proprietary localized delivery technologies, in each case, throughout the world except China, Hong Kong, Taiwan and Macau.

In consideration for the rights granted by Equinox, the Company (i) made a one time, non-refundable, non-creditable upfront cash payment of $1.0 million to Equinox in February 2020, and (ii) agreed to pay milestone payments totaling up to $50 million upon the achievement of certain development and regulatory milestones, consisting of (a) completion of a Phase II clinical trial for the Compound or a Licensed Product, (b) the filing of a new drug application or foreign equivalent for the Compound or a Licensed Product in the United States, European Union or United Kingdom and (c) regulatory approval of the Compound or a Licensed Product in the United States, European Union or United Kingdom.

The Company also agreed to pay Equinox tiered royalties based upon annual net sales of Licensed Products in the Territory. The royalties are payable with respect to a Licensed Product in a particular country in the Territory on a country-by-country and Licensed Product-by-Licensed Product basis until the later of (i) twelve years after the first commercial sale of such Licensed Product in such country and (ii) the first day of the month following the month in which a generic product corresponding to such Licensed Product is launched in such country (collectively, the "Royalty Term"). The royalty rates range from the high-single digits to low-double digits depending on the level of annual net sales. The royalty rates are subject to reduction during certain periods when there is no valid patent claim that covers a Licensed Product in a particular country.

Research Agreements

The Company from time to time enters into funded agreements to evaluate the potential use of its technology systems for sustained release of third-party drug candidates in the treatment of various diseases. Consideration received is generally recognized as revenue over the term of the feasibility study agreement. Revenue recognition for consideration, if any, related to a license option right is assessed based on the terms of any such future license agreement or is otherwise recognized at the completion of the feasibility study agreement. Revenues under feasibility study agreements totaled $135,000 for the year ended December 31, 2019, $15,000 in the six months ended December 31, 2018, $1.1 million in fiscal 2018 and $211,000 in fiscal 2017, respectively. At December 31, 2019, $15,000 deferred revenue was recorded for the feasibility study agreements.

5. Inventory

Inventory consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Raw materials	$ 1,476	$ 198
Work in process	346	41
Finished goods	316	40
Total inventory	$ 2,138	$ 279

6. Intangible Assets

The reconciliation of intangible assets for the year ended December 31, 2019 and the six months ended December 31, 2018 was as follows (in thousands):

	Year Ended December 31, 2019	Six Months Ended December 31, 2018
Patented technologies		
Gross carrying amount at beginning of period	$ 68,322	$ 68,322
Gross carrying amount at end of period	68,322	68,322
Accumulated amortization at beginning of period	(38,193)	(36,964)
Amortization expense	(2,460)	(1,229)
Accumulated amortization at end of period	(40,653)	(38,193)
Net book value at end of period	$ 27,669	$ 30,129

The net book value of the Company's intangible assets at December 31, 2019 and 2018 is summarized as follows (in thousands):

	December 31, 2019	December 31, 2018	Estimated Remaining Useful Life at December 31, 2019 (Years)
Patented technologies			
DEXYCU / Verisome	$ 27,669	$ 30,129	11.25
	$ 27,669	$ 30,129	

The Company amortizes its intangible assets with finite lives on a straight-line basis over their respective estimated useful lives. Amortization expense totaled $2.5 million in the year ended December 31, 2019, $1.2 million in the six months ended December 31, 2018, $981,000 in fiscal 2018, and $724,000 in fiscal 2017.

In connection with the Icon Acquisition (see Note 3), the initial purchase price of $32.0 million was attributed to the DEXYCU product intangible asset. This finite-lived intangible asset is being amortized on a straight-line basis over its expected remaining useful life of 11.25 years at the rate of approximately $2.5 million per year. Amortization expense was reported as a component of cost of sales for the year ended December 31, 2019 and was included in research and development for the six months ended December 31, 2018, and the fiscals 2018 and 2017.

7. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Property and equipment	$ 1,095	$ 882
Leasehold improvements	101	101
Gross property and equipment	1,196	983
Accumulated depreciation and amortization	(839)	(695)
	$ 357	$ 288

Depreciation expense totaled $144,000 in the year ended December 31, 2019, $97,000 in the six months ended December 31, 2018, $167,000 in fiscal 2018 and $91,000 in fiscal 2017.

8. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Personnel costs	$ 3,263	$ 1,998
Clinical trial costs	345	798
Professional fees	700	571
Sales chargebacks, rebates and other revenue reserves	1,889	—
Interest	—	343
Other	635	79
	$ 6,832	$ 3,789

9. Leases

On May 17, 2018, the Company amended the lease for its headquarters in Watertown, Massachusetts. The original five-year lease for approximately 13,650 square feet of combined office and laboratory space was set to expire in April 2019. Under the amendment, the Company leased an additional 6,590 square feet of rentable area of the building, with a commencement date of September 10, 2018. The amendment extended the term of the lease for the combined space through May 31, 2025. The landlord agreed to provide the Company a construction allowance of up to $670,750 to be applied toward the aggregate work completed on the total space. The Company has an option to further extend the term of the lease for one additional five-year period. Per the terms of the lease agreement, the Company does not have a residual value guarantee. The Company previously provided a cash-collateralized $150,000 irrevocable standby letter of credit as security for the Company's obligations under the lease, which was extended through the period that is four months beyond the expiration date of the amended lease. The Company will also be required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises in excess of new base year amounts.

In July 2017, the Company leased approximately 3,000 square feet of office space in Basking Ridge, New Jersey under a lease term extending through June 2022, with two five-year renewal options at 95% of the then-prevailing market rates. In addition to base rent, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts. In June 2018, the Company subleased an additional 1,381 square feet of adjoining space from Caladrius Biosciences, Inc. ("Caladrius") through May 2022. The Chief Executive Officer of Caladrius is a director of the Company. Per the terms of the lease and sublease agreements, the Company does not have any residual value guarantees.

The Company identified and assessed the following significant assumptions in recognizing its ROU assets and corresponding lease liabilities:

- As the Company's leases do not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company utilized the borrowing rate under its existing 5-year term loan facility (see Note 9) as the discount rate.
- Since the Company elected to account for each lease component and its associated non-lease components as a single combined component, all contract consideration was allocated to the combined lease component.
- The expected lease terms include noncancelable lease periods. Renewal option periods have not been included in the determination of the lease terms as they are not deemed reasonably certain of exercise.
- Variable lease payments, such as common area maintenance, real estate taxes and property insurance are not included in the determination of the lease's ROU asset or lease liability.

As of December 31, 2019, the weighted average remaining term of the Company's operating leases was 5.2 years and the lease liabilities arising from obtaining ROU assets reflect a weighted average discount rate of 12.5%. Maturities of lease liabilities due under these operating lease agreements as of December 31, 2019 are as follows (in thousands):

2020	867
2021	889
2022	849
2023	815
2024	830
Thereafter	346
Total lease payments	4,596
Less imputed interest	(1,217)
Total operating lease liabilities	3,379
Less: current portion	481
Non-current portion	$ 2,898

Operating lease expense recognized during the year ended December 31, 2019 related to ROU assets was $852,000, excluding $36,000 of variable lease costs, respectively, and were included in general and administrative expense in the Company's statement of comprehensive loss. Cash paid for amounts included in the measurement of operating lease liabilities was $808,000 for the year ended December 31, 2019.

As previously disclosed in the Company's Transition Report on Form 10-K for the six months ended December 31, 2018, and, under the previous lease accounting standard, ASC 840, *Leases*, the Company's total future minimum lease payments under non-cancellable operating leases at December 31, 2018 were as follows (in thousands):

2019	$ 826
2020	879
2021	895
2022	849
2023 and beyond	1,990
	$ 5,439

10. Term Loan Agreement

CRG Term Loan Agreement

On February 13, 2019 (the "CRG Closing Date"), the Company entered into the CRG Loan Agreement among the Company, as borrower, CRG Servicing LLC, as administrative agent and collateral agent (the "Agent"), and the lenders party thereto from time to time (the "Lenders"), providing for a senior secured term loan of up to $60 million (the "CRG Loan"). On the CRG Closing Date, $35 million of the CRG Loan was advanced (the "CRG Initial Advance"). The Company utilized the proceeds from the CRG Initial Advance for the repayment in full of all outstanding obligations under its prior credit agreement (the "SWK Credit Agreement") with SWK Funding LLC ("SWK"). In April 2019, the Company exercised its option to borrow an additional $15 million of the CRG Loan (the "CRG Second Advance"). The Company may draw up to an additional $10 million, subject to achievement of prescribed three-month trailing product revenues of YUTIQ and DEXYCU on or before March 31, 2020.

The CRG Loan is due and payable on December 31, 2023 (the "Maturity Date"). The CRG Loan bears interest at a fixed rate of 12.5% per annum payable in arrears on the last business day of each calendar quarter. The Company is required to make quarterly, interest only payments until the Maturity Date. So long as no default has occurred and is continuing, the Company may elect on each applicable interest payment date to pay 2.5% of the 12.5% per annum interest as Paid In-Kind ("PIK"), whereby such PIK amount would be added to the aggregate principal amount and accrue interest at 12.5% per annum. Through December 31, 2019, total PIK amounts of $1.1 million have been added to the principal balance of the CRG Loan. In addition, the Company is required to pay an upfront fee of 1.5% of amounts borrowed under the CRG Loan (excluding any paid-in-kind amounts), which is payable as amounts are advanced under the CRG Loan. The Company will also be required to pay an exit fee equal to 6% of (i) the aggregate principal amounts advanced and (ii) PIK amounts issued, under the CRG Loan Agreement. In connection with the CRG Initial Advance, a 1.5% financing fee of $525,000 and an expense reimbursement of $350,000 were deducted from the net borrowing proceeds. In connection with the CRG Second Advance, a 1.5% financing fee of $225,000 was deducted from the net borrowing proceeds.

Upon the occurrence of a bankruptcy-related event of default, all amounts outstanding with respect to the CRG Loan become due and payable immediately, and upon the occurrence of any other Event of Default (as defined in the CRG Loan Agreement), all or

any amounts outstanding with respect to the CRG Loan may become due and payable upon request of the Agent or majority Lenders. Subject to certain exceptions, the Company is required to make mandatory prepayments of the CRG Loan with the proceeds of assets sales and in the event of a change of control of the Company. In addition, the Company may make a voluntary prepayment of the CRG Loan, in whole or in part, at any time. All mandatory and voluntary prepayments of the CRG Loan are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs on or prior to December 31, 2019, an amount equal to 10% of the aggregate outstanding principal amount of the CRG Loan being prepaid, (ii) if prepayment occurs after December 31, 2019 and on or prior to December 31, 2020, 5% of the aggregate outstanding principal amount of the CRG Loan being prepaid and (iii) if prepayment occurs after December 31, 2020 and on or prior to December 31, 2021, an amount equal to 3% of the aggregate outstanding principal amount of the Loan being prepaid. No prepayment premium is due on any principal prepaid after December 31, 2021. Certain of the Company's existing and future subsidiaries are guaranteeing the obligations of the Company under the CRG Loan Agreement. The obligations of the Company under the CRG Loan Agreement and the guarantee of such obligations are secured by a pledge of substantially all of the Company's and the guarantors' assets.

The CRG Loan Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on our and our subsidiaries' abilities, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the CRG Loan Agreement contains the following financial covenants requiring the Company and the Guarantors to maintain:

- liquidity in an amount which shall exceed the greater of (i) $5 million and (ii) to the extent the Company has incurred certain permitted debt, the minimum cash balance, if any, required of the Company by the creditors of such permitted debt; and
- annual minimum product revenue from YUTIQ and DEXYCU: (i) for the twelve-month period beginning on January 1, 2019 and ending on December 31, 2019, of at least $15 million, (ii) for the twelve-month period beginning on January 1, 2020 and ending on December 31, 2020, of at least $45 million, (iii) for the twelve-month period beginning on January 1, 2021 and ending on December 31, 2021, of at least $80 million and (iv) for the twelve-month period beginning on January 1, 2022 and ending on December 31, 2022, of at least $90 million.

In November 2019, CRG waived the financial covenant associated with the Company's revenue derived from sales of its products, DEXYCU and YUTIQ, for the twelve-month period ending December 31, 2019.

The total debt discount related to the CRG Initial Advance was approximately $3.2 million and consisted of (i) the accrual of a $2.1 million exit fee; (ii) the $525,000 upfront fee; and (iii) $591,000 of legal and other transaction costs. This amount is being amortized as additional interest expense over the term of the Loan using the effective interest rate method.

The total debt discount related to the CRG Second Advance was approximately $1.1 million and consisted of (i) the accrual of a $900,000 exit fee; and (ii) the $225,000 upfront fee. This amount is being amortized as additional interest expense over the term of the Loan using the effective interest rate method.

Amortization of debt discount under the CRG Loan totaled $512,000 for the year ended December 31, 2019.

SWK Credit Agreement

On March 28, 2018 (the "SWK Closing Date"), the Company entered into the SWK Credit Agreement among the Company, as borrower, SWK, as agent, and the lenders party thereto from time to time, providing for a senior secured term loan of up to $20 million (the "SWK Loan"). On the SWK Closing Date, $15 million of the SWK Loan was advanced (the "SWK Initial Advance"). The remaining $5 million of the SWK Loan was advanced on June 26, 2018 (the "SWK Additional Advance").

In connection with the SWK Loan, the Company issued a warrant (the "SWK Warrant") to the Agent to purchase (a) 409,091 shares of Common Stock (the "Initial Advance Warrant Shares") at an exercise price of $1.10 per share and (b) 77,721 shares of Common Stock (the "Additional Advance Warrant Shares") at an exercise price of $1.93 per share (see Note 10). The SWK Warrant is exercisable (i) with respect to the Initial Advance Warrant Shares, any time on or after the SWK Closing Date until the close of business on the 7-year anniversary of the SWK Initial Advance and (ii) with respect to the Additional Advance Warrant Shares, any time on or after the closing of the SWK Additional Advance until the close of business on the 7-year anniversary of the SWK Additional Advance. The Agent may exercise the SWK Warrant on a cashless basis at any time. In the event the Agent exercises the SWK Warrant on a cashless basis, the Company will not receive any proceeds.

The Additional Advance Warrant Shares were recorded as a liability at the Closing Date and were remeasured at fair value at each reporting period until the date of the SWK Additional Advance. The aggregate fair value of the Additional Advance Warrant Shares at the Closing Date was $69,000. The Initial Advance Warrant Shares were recorded as equity on the Company's balance sheet at their relative fair value of $284,000. The remaining $14.6 million of the proceeds received were allocated to the SWK Initial

Advance term loan. Upon the closing of the SWK Additional Advance in June 2018, the Additional Advance Warrant Shares were re-valued at $87,000 and reclassified to equity.

The total debt discount related to the SWK Initial Advance was $2.1 million and was comprised of (1) $1.8 million, which included a 1.5% upfront fee, a 6% exit fee (the "Exit Fee") and legal and other transaction costs, which were ratably allocated to each of the two tranches of the SWK Loan based upon the total principal amount available to the Company under each tranche and (2) $353,000 related to the aggregate fair value of the Initial Advance Warrant Shares and the Additional Advance Warrant Shares. This amount was being amortized as additional interest expense over the term of the SWK Loan using the effective interest rate method.

The total debt issue costs related to the SWK Additional Advance was $299,000 and was comprised of the allocated portions of the 1.5% upfront fee and the Exit Fee. This amount was recorded as a prepaid expense to be amortized ratably from the SWK Closing Date through December 31, 2018. Through the date of the SWK Additional Advance, $97,000 was amortized and the remaining balance of $202,000 was reclassified to debt discount in June 2018. Together with the 6% Exit Fee on the SWK Additional Advance and other transaction costs, total debt discount of $652,000 associated with the SWK Additional Advance was to be amortized over the remaining life of the SWK Additional Advance portion of the SWK Loan using the effective interest rate method.

The SWK Loan was originally scheduled to mature on March 27, 2023 and bore interest at a per annum rate of the three-month LIBOR rate (subject to a 1.5% floor) plus 10.50%. On February 13, 2019, the Company repaid the SWK Loan in connection with the consummation of the CRG Loan Agreement. In addition to repayment of the $20 million principal balance, the Company paid (i) a $1.2 million prepayment penalty, (ii) the $1.2 million Exit Fee, (iii) accrued and unpaid interest of $664,000 through that date and (iv) an additional make-whole interest payment of $306,000 covering the additional period through what would have been the first anniversary of the SWK Loan. In connection with the prepayment of the SWK Loan, the Company recorded a loss on extinguishment of debt of $3.8 million in the three months ended March 31, 2019. In addition to the prepayment penalty and make-whole interest payment amounts, the loss on extinguishment of debt included the write-off of the remaining balance of unamortized debt discount of approximately $2.3 million.

Amortization of debt discount under the SWK Loan totaled $84,000 in the first quarter of 2019 through the SWK loan extinguishment date. The Company recorded $312,000 of amortized deferred debt issue costs and debt discount for the six months ended December 31, 2018 and $209,000 in fiscal 2018.

11. Stockholders' Equity

2019 Equity Financing

ATM Facility

In January 2019, the Company entered into an at-the-market program (the "ATM Program"). Pursuant to the ATM Program, under a Form S-3 shelf registration statement that was declared effective by the SEC in December 2018, the Company may, at its option, offer and sell shares of its Common Stock from time to time for an aggregate offering price of up to $20.0 million. The Company will pay the sales agent a commission of up to 3.0% of the gross proceeds from any future sales of such shares.

During the year ended December 31, 2019, the Company sold 2,998,871 shares of its Common Stock at a weighted average price of $1.50 per share for gross proceeds of approximately $4.5 million. Share issue costs, including sales agent commissions, totaled $221,000 during the reporting period.

Share Offering

In February 2020, the Company sold 15,000,000 shares of common stock in an underwritten public offering at a price of $1.45 per share for gross proceeds of $21.75 million. Underwriter discounts and commissions and other share issue costs totaled approximately $1.75 million.

In April 2019, the Company sold 10,526,500 shares of common stock in an underwritten public offering at a price of $1.90 per share for gross proceeds of $20.0 million. Underwriter discounts and commissions and other share issue costs totaled approximately $1.7 million.

2018 Equity Financing

On the SWK Closing Date, the Company entered into a Securities Purchase Agreement (the "First Tranche Securities Purchase Agreement") with EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P. (collectively, the "First Tranche Investors"), pursuant to which the Company offered and sold to the First Tranche Investors an aggregate of 8,606,324 shares of Common Stock at a purchase price of $1.10 per share (the "First Tranche Purchase Price") for aggregate gross proceeds of approximately $9.5 million (the "First Tranche Transaction").

On the SWK Closing Date, the Company entered into a Second Securities Purchase Agreement (the "Second Tranche Securities Purchase Agreement" and together with the First Tranche Securities Purchase Agreement, the "Securities Purchase Agreements") with the First Tranche Investors and certain other accredited investors (collectively, the "Second Tranche Investors"), pursuant to which the Company, subject to the approval of the Company's stockholders, would offer and sell to the Second Tranche Investors an aggregate of approximately $25.5 million of Units, with each Unit consisting of (a) one share of Common Stock and (b) one warrant to purchase a share of Common Stock (the "Second Tranche Transaction" and together with the First Tranche Transaction, the "Equity Transactions").

At a special meeting of stockholders held on June 22, 2018, the Company's stockholders approved the Second Tranche Transaction, following which, on June 25, 2018, the Company sold to the Second Tranche Investors an aggregate of 20,184,224 Units at a purchase price of $1.265 per Unit for gross proceeds of approximately $25.5 million, not including any proceeds that would be received from an exercise of the warrants (each a "Second Tranche Warrant", and collectively, the "Second Tranche Warrants"). In addition, the stockholders approved the adoption of an amendment to the Company's Certificate of Incorporation, as amended, to increase the number of authorized shares of Common Stock from 120,000,000 shares to 150,000,000 shares.

The Company determined that the shares of Common Stock issued in the First Tranche Transaction and the future obligation to issue Units in the Second Tranche Transaction were freestanding instruments. The Common Stock issued in the First Tranche Transaction was recorded as equity on the Company's balance sheet. The future obligation to issue Units in the Second Tranche Transaction was recorded as a liability on the Company's balance sheet, subject to remeasurement at fair value at each reporting period until settled.

The Company determined that the First Tranche Transaction and the Second Tranche Transaction should be accounted for as a single transaction. Accordingly, the total consideration received on the SWK Closing Date of $9.5 million was first allocated to the future obligation to issue Units in the Second Tranche Transaction at fair value as of the SWK Closing Date, with the residual amount allocated to the Common Stock issued in the First Tranche Transaction. Further, issuance costs of $343,000 were allocated to each of the freestanding instruments on the basis of relative fair value. A net amount of approximately $4.6 million was allocated to each of the Common Stock issued in the First Tranche Transaction and the future obligation to issue Units in the Second Tranche Transaction, respectively, as of the SWK Closing Date. As of March 31, 2018, the fair value of the Second Tranche Transaction derivative liability was approximately $6.9 million and the Company recorded the $2.2 million change in fair value for the quarter ended March 31, 2018.

The future obligation to issue Units in the second tranche transaction was revalued immediately prior to the Second Tranche Transaction on June 25, 2018 and resulted in a change in fair value of approximately $22.2 million. Upon consummation of the Second Tranche Transaction, the resulting derivative liability balance of approximately $29.1 million was reclassified to equity.

The Company determined that the Second Tranche Warrants were considered puttable warrants that represented an obligation that was indexed to the repurchase of the Company's shares and could require a transfer of assets that required classification as derivative liabilities. The initial valuation of the Second Tranche Warrants on June 25, 2018 of approximately $18.2 million was revalued at June 30, 2018 and then immediately prior to exercise and resulted in a change in fair value of $1.6 million and $18.9 million, respectively. The change in fair value immediately prior to exercise, in September 2018, was determined as the excess of the closing share price of the Company's Common Stock on the respective dates on which exercise notices were submitted by each of the Second Tranche Investors over the $1.43 exercise price. Upon exercise of the Second Tranche Warrants, the resulting derivative liability balance of $38.7 million was reclassified to equity.

Warrants to Purchase Common Shares

The following table provides a reconciliation of fixed price warrants to purchase shares of the Company's Common Stock for the year ended December 31, 2019 and the six months ended December 31, 2018:

	Year Ended December 31, 2019		Six Months Ended December 31, 2018	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of period	486,812	$ 1.23	486,812	$ 1.23
Expired	—	—	—	—
Balance and exercisable at end of period	486,812	$ 1.23	486,812	$ 1.23

In connection with the SWK Credit Agreement (see Note 10), the Company issued the SWK Warrant to purchase (i) 409,091 Initial Advance Warrant Shares on March 28, 2018 at an exercise price of $1.10 per share with a seven-year term and (ii) 77,721 Additional Advance Warrant Shares on June 26, 2018 at an exercise price of $1.93 per share with a seven-year term. At December 31, 2019, the weighted average remaining life of the warrants was approximately 5.28 years.

12. Share-Based Payment Awards

Equity Incentive Plans

The 2016 Long-Term Incentive Plan (the "2016 Plan"), approved by the Company's stockholders on December 12, 2016 (the "Adoption Date"), provides for the issuance of up to 3,000,000 shares of the Company's Common Stock reserved for issuance under the 2016 Plan plus any additional shares of the Company's Common Stock that were available for grant under the 2008 Incentive Plan (the "2008 Plan") at the Adoption Date or would otherwise become available for grant under the 2008 Plan as a result of subsequent termination or forfeiture of awards under the 2008 Plan. At the Company's Annual Meeting of Stockholders held on June 25, 2019, the Company's stockholders approved an amendment to the 2016 Plan to increase the number of shares authorized for issuance by 11,000,000 shares. At December 31, 2019, a total of 9,925,449 shares were available for new awards.

Certain inducement awards, although not awarded under the 2016 Plan or the 2008 Plan, are subject to and governed by the terms and conditions of the 2016 Plan or 2008 Plan, as applicable.

Stock Options

The following table provides a reconciliation of stock option activity under the Company's equity incentive plans and for inducement awards for the year ended December 31, 2019:

	Number of options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
			(in years)	(in thousands)
Outstanding at January 1, 2019	8,139,377	$ 2.83		
Granted	5,510,432	2.19		
Exercised	(223,426)	1.85		
Forfeited	(1,483,063)	2.49		
Expired	(1,033,520)	3.39		
Outstanding at December 31, 2019	10,909,800	$ 2.52	7.73	$ 539
Exercisable at December 31, 2019	4,718,213	$ 3.05	5.98	$ 46

In January 2019, the Company expanded the terms of its annual stock option grants to include vesting ratable monthly over four years, or with 25% vesting after one year followed by ratable monthly vesting over three years. Previously, the Company's option grants generally had ratable annual vesting over three years, or 1-year cliff vesting. Nonemployee awards are granted similar to the Company's employee awards. All option grants have a 10-year term. Options to purchase a total of 2,099,851 shares of the Company's Common Stock vested during the year ended December 31, 2019.

In determining the grant date fair value of option awards, the key assumptions used to apply the Black-Scholes option pricing model for options granted under the 2016 Plan during the year ended December 31, 2019, the six months ended December 31, 2018 and the years ended June 30, 2018 and 2017 were as follows:

	Year Ended December 31,	Six Months Ended December 31,	Year Ended June 30,	
	2019	2018	2018	2017
Option life (in years)	5.50 - 6.08	5.50 - 6.00	5.50 - 6.00	5.50 - 6.25
Stock volatility	60% - 65%	59% - 61%	59% - 64%	70% - 72%
Risk-free interest rate	1.37% - 2.63%	2.78% - 3.09%	2.18% - 2.89%	1.23% - 2.08%
Expected dividends	0.0%	0.0%	0.0%	0.0%

The following table summarizes information about employee, consultant and director stock options under the Company's equity incentive plans for the year ended December 31, 2019, the six months ended December 31, 2018 and the years ended June 30, 2018 and 2017 (in thousands except per share amounts):

	Year Ended December 31,	Six Months Ended December 31,	Year Ended June 30,	
	2019	2018	2018	2017
Weighted-average grant date fair value per share	$ 0.93	$ 1.37	$ 1.06	$ 1.95
Total cash received from exercise of stock options	414	219	503	99
Total intrinsic value of stock options exercised	84	284	152	53

Time-Vested Restricted Stock Units

Time-vested restricted stock units ("RSUs") issued to date under the 2016 Plan generally vest on a ratable annual basis over 3 years. The related stock-based compensation expense is recorded over the requisite service period, which is the vesting period. The fair value of all time-vested RSUs is based on the closing share price of the Common Stock on the date of grant.

The following table provides a reconciliation of RSU activity under the 2016 Plan for the year ended December 31, 2019:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2019	590,213	$ 1.86
Granted	587,761	1.90
Vested	(229,294)	1.81
Forfeited	(161,781)	2.19
Nonvested at December 31, 2019	786,899	$ 1.83

The weighted-average remaining vesting term of the RSUs at December 31, 2019 was 1.04 years.

Performance-Based Stock Units

Performance Stock Units ("PSUs") were previously awarded under the 2016 Plan to certain employees. The performance conditions associated with the PSU awards were as follows: (a) for one third of the PSUs, upon an FDA acceptance of the Company's NDA submission of YUTIQ for review on or before March 31, 2018 and (b) for two-thirds of the PSUs, upon an FDA approval of YUTIQ on or before March 31, 2019. For each performance criteria achieved, 50% of the PSUs associated with that performance condition vest at the achievement date and 50% vest on the first anniversary of such date, in each case subject to continued employment through such date. As a result of the achievement of the first performance condition on March 19, 2018, 48,332 PSUs vested at that date and the other 48,334 PSUs became subject only to a service-based condition with a vesting date of March 19, 2019. As a result of the achievement of the second performance condition on October 12, 2018, 96,668 PSUs vested at that date and the other 96,666 PSUs became subject only to a service-based condition with a vesting date of October 12, 2019.

In addition, there were 0 and 225,000 outstanding PSUs at December 31, 2019 and 2018, respectively, which were granted as inducement awards to the Company's former Chief Financial Officer in connection with his hire at August 1, 2018. The PSUs are subject to proportional vesting based on cumulative measurement over a 3-year period, with two-thirds of the award based upon the achievement of defined amounts of the Company's product revenues through June 30, 2021 and one-third of the award based upon the net present value of each applicable business development transaction, as defined, through August 1, 2021 measured as of the date that each such transaction is consummated by the Company. The Company's former Chief Financial Officer resigned from his position on July 8, 2019 and as a result, the award was cancelled and the performance metrics for vesting were not met.

The following table provides a reconciliation of PSU activity for the year ended December 31, 2019:

	Number of Performance Stock Units	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2019	370,000	$ 2.01
Vested	(115,000)	1.45
forfeited	(255,000)	2.26
Nonvested at December 31, 2019	—	$ —

Deferred Stock Units

There were 0 and 35,418 non-vested deferred stock units ("DSUs") issued and outstanding to the Company's non-executive directors at each of December 31, 2019 and 2018, respectively. Each DSU vests one year from the date of grant. Subsequent to vesting, the DSUs will be settled in shares of the Company's Common Stock upon the earliest to occur of (i) each director's termination of service on the Company's Board of Directors and (ii) the occurrence of a change of control as defined in the award agreement. At December 31, 2019, there were 71,251 vested DSUs that have not been settled in shares of the Company's Common Stock.

	Number of Deferred Stock Units	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2019	35,418	$ 1.95
Vested	(35,418)	1.95
Nonvested at December 31, 2019	—	$ —

Market-Based Restricted Stock Units

At December 31, 2019 and 2018, there were 0 and 500,000 market-based RSUs ("market-based RSUs") outstanding that were issued on September 15, 2016 as an inducement award to the Company's President and CEO in connection with her hire. Subject to a service condition through September 15, 2019, the number of shares underlying the market-based RSUs that will vest will be based upon the determination of the relative percentile rank of the 3-year change in the closing price of the Company's Common Stock compared to that of the companies that make up the Nasdaq Biotechnology Index over that same 3-year period. The weighted average grant date fair value of the market-based RSUs of $1.45 per share was determined using a Monte Carlo valuation model at the date of grant. Stock-based compensation has been recorded from the grant date on a straight-line basis. The performance metrics were not met for vesting through the measurement date.

Employee Stock Purchase Plan

On June 25, 2019, the Company's stockholders approved the adoption of the EyePoint Pharmaceuticals, Inc. 2019 Employee Stock Purchase Plan (the "ESPP") and authorized up to 1,100,000 shares of Common Stock reserved for issuance to participating employees. The ESPP allows qualified participants to purchase the Company's Common Stock twice a year at 85% of the lesser of the average of the high and low sales price of the Company's Common Stock on (i) the first trading day of the relevant offering period and (ii) the last trading day of the relevant offering period. The number of shares of the Company's Common Stock each employee may purchase under this plan, when combined with all other employee stock purchase plans, is limited to the lower of an aggregate fair market value of $25,000 during each calendar year, or 50,000 shares of the Company's Common Stock in any one offering period. The first six month offering period under the ESPP began on August 1, 2019 and will end on January 31, 2020. As of December 31, 2019, no shares of the Company's Common Stock were issued pursuant to the ESPP.

The Company estimated the fair value of the option component of the ESPP shares at the date of grant using a Black-Scholes valuation model. During the year ended December 31, 2019, the compensation expense from ESPP shares was immaterial.

Stock-Based Compensation Expense

The Company's statements of comprehensive loss included total compensation expense from stock-based payment awards as follows (in thousands):

	Year Ended December 31, 2019	Six Months Ended December 31, 2018	Year Ended June 30, 2018	Year Ended June 30, 2017
Compensation expense included in:				
Research and development	$ 1,073	$ 913	$ 1,252	$ 1,109
Sales and marketing	715	325	50	—
General and administrative	2,780	1,312	1,402	1,347
	$ 4,568	$ 2,550	$ 2,704	$ 2,456

In connection with termination benefits provided to the Company's former Chief Executive Officer, the vesting of certain options was accelerated in accordance with the terms of the options, the exercise period for all vested options was extended for one year through September 14, 2017, and all remaining non-vested options were forfeited. Additionally, in connection with the U.K. restructuring, the exercise period of all vested options held by the former U.K. employees was extended through June 30, 2017 and all non-vested options were forfeited. These option modifications and forfeitures were accounted for in the quarter ended September 30, 2016, the net effect of which resulted in an approximate $274,000 increase of stock-based compensation expense included in general and administrative expense and an approximate $35,000 reduction of stock-based compensation expense included in research and development expense for the year ended June 30, 2017 in the table above.

In connection with termination benefits provided to the Company's former Vice President, Corporate Affairs and General Counsel, the vesting of certain options was accelerated in accordance with the terms of the options, the exercise period for all vested options was extended for eighteen months through June 26, 2018, and all remaining non-vested options were forfeited. The option modification and forfeitures were accounted for in the quarter ended December 31, 2016, the net effect of which resulted in an approximate $104,000 reduction of stock-based compensation expense included in general and administrative expense for the year ended June 30, 2017 in the table above.

In connection with termination benefits provided to the Company's former EVP & GM, the vesting of certain options was accelerated in accordance with the terms of the options, with an exercise period through December 26, 2018. All remaining non-vested options were forfeited. The option modifications and forfeitures were accounted for in the quarter ended September 30, 2018, the net effect of which resulted in a $171,000 increase of stock-based compensation expense included in sales and marketing for the six months ended December 31, 2018 in the table above.

At December 31, 2019, there was approximately $4.1 million of unrecognized compensation expense related to outstanding equity awards under the 2016 Plan, the 2008 Plan, The inducement awards and the ESPP that is expected to be recognized as expense over a weighted-average period of approximately 1.45 years.

13. Fair Value Measurements

The following tables summarize the Company's assets carried at fair value measured on a recurring basis at December 31, 2019 and 2018, respectively, by valuation hierarchy (in thousands):

	December 31, 2019			
Description	**Total Carrying Value**	**Quoted prices in active markets (Level 1)**	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**
Assets:				
Cash equivalents	$ 19,976	$ 19,976	$ —	$ —
	$ 19,976	$ 19,976	$ —	$ —

	December 31, 2018			
Description	**Total Carrying Value**	**Quoted prices in active markets (Level 1)**	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**
Assets:				
Cash equivalents	$ 43,194	$ 43,194	$ —	$ —
	$ 43,194	$ 43,194	$ —	$ —

Financial instruments that potentially subject the Company to concentrations of credit risk have historically consisted principally of cash and cash equivalents. At December 31, 2019 and 2018, respectively, substantially all of the Company's interest-bearing cash equivalent balances were concentrated in one U.S. Government money market fund that has investments consisting primarily of U.S. Government Agency debt, U.S. Treasury debt, U.S. Treasury Repurchase Agreements and U.S. Government Agency Repurchase Agreements. These deposits may be redeemed upon demand and, therefore, generally have minimal risk. The Company's cash equivalents are classified within Level 1 on the basis of valuations using quoted market prices.

As described in Note 11, the Second Tranche Transaction was determined to be liability classified, which required that the liability be measured at fair value each period with changes in fair value being recorded as a component of net income (loss) in the statement of operations. The purchase price for each share of Common Stock issuable in the Second Tranche Transaction was defined as the lower of (a) $1.265 (which was a 15% premium to the First Tranche Purchase Price) and (b) a 20% discount to the volume weighted average price ("VWAP") of the shares of Common Stock on the Nasdaq Stock Market for the 20 trading days immediately prior to the closing of the Second Tranche Transaction; provided, however, that the purchase price could not be lower than $0.88, which was a 20% discount to the First Tranche Purchase Price.

The Second Tranche Warrants were exercisable any time on or after the closing of the Second Tranche Transaction until on or prior to the close of business on the 15th business day following the date on which the holders of the Second Tranche Warrants received written notice from the Company that CMS had announced that a new C-code had been established for DEXYCU. The exercise price of each Second Tranche Warrant was an amount equal to the lower of (a) $1.43 (a 30% premium to the First Tranche Purchase Price) and (b) a 20% discount to the VWAP of the shares of the Company's Common Stock on Nasdaq for the 20 trading days immediately prior to the exercise of a Second Tranche Warrant; provided, however, that the exercise price could not be lower than $0.88, which was a 20% discount to the First Tranche Purchase Price.

The valuation of the Second Tranche Transaction was determined to be a level 3 valuation because it included unobservable inputs. Changes in the valuation subsequent to the initial valuation were recorded as a component of non-operating expense in the consolidated statement of comprehensive loss. The Second Tranche Transaction liability was valued using a Monte Carlo simulation valuation model. This model incorporated several inputs, including the Common Stock price on the date of valuation, the historical volatility of the price of Common Stock, the risk-free interest rate and management's assessment of the probability and timing of the issuance of the Units occurring. A significant fluctuation in the Company's stock price or the Company's estimate of the number of Units to be issued could result in a material increase or decrease in the fair value of the Second Tranche liability. The Second Tranche Transaction liability was settled upon the closing of the Second Tranche Transaction in June 2018. The Company remeasured the Second Tranche Transaction liability to fair value immediately prior to settlement. This valuation at settlement was calculated as the excess of the sum of (i) the fair value of the Second Tranche Warrants and (ii) the fair value of the shares of Common Stock issued to settle the liability over the cash proceeds received by the Company for the Units. Significant assumptions used to value this liability were as follows:

	March 28, 2018 (Date of Issuance)	June 25, 2018 (Date of Settlement)
Volatility	54.20%	N/A
Risk free interest rate	1.70%	N/A
Estimated date of stockholder approval	June 2018	N/A
Estimated number of units issuable	26,900,000	20,184,224
Valuation date stock price	$ 1.07	$ 1.93

Upon the closing of the Second Tranche Transaction, the Company issued the Second Tranche Warrants, which were determined to be liability classified, which required that the liability be measured at fair value each period with changes in fair value being recorded as a component of non-operating expense in the consolidated statement of comprehensive loss. This valuation was determined to be a level 3 valuation because it included unobservable inputs. The Second Tranche Warrants were valued using a Monte Carlo simulation valuation model. This model incorporated several inputs, including the Common Stock price on the date of valuation, the historical volatility of the price of the Common Stock and the risk-free interest rate. The Second Tranche Investors delivered exercise notices covering all of the Second Tranche Warrants during the period from September 25 - 28, 2018 (see Note 11). The Company revalued the Second Tranche Warrants liability immediately prior to the respective exercise notice dates of the Second Tranche Investors, measured as the excess of the closing share price on the exercise notice date over the actual warrant exercise price of $1.43 per share times the number of shares purchased. The resulting liability balance was then reclassified to equity.

The following table sets forth a summary of changes in the fair value of the Company's derivative liability for which fair value was determined by Level 3 inputs (in thousands):

	Second Tranche Transaction Liability	Additional Advance Warrant Liability	Second Tranche Warrants Liability	Total
Balance at June 30, 2018	—	—	19,780	19,780
Change in fair value	—	—	18,886	18,886
Reclassification to equity	—	—	(38,666)	(38,666)
Balance at December 31, 2018	$ —	$ —	$ —	$ —

14. Retirement Plans

The Company operates a defined contribution plan intended to qualify under Section 401(k) of the U.S. Internal Revenue Code. Participating U.S. employees may contribute a portion of their pre-tax compensation, as defined, subject to statutory maximums. The Company matches employee contributions up to 5% of eligible compensation, subject to a stated calendar year Internal Revenue Service maximum.

The Company operated a defined contribution pension plan for U.K. employees pursuant to which the Company made contributions on behalf of employees plus a matching percentage of elective employee contributions. This pension plan was terminated in the quarter ending September 30, 2016 following termination of employment of all U.K. employees.

The Company contributed a total of $619,000 for the year ended December 31, 2019, $216,000 for the six months ended December 31, 2018, $220,000 for fiscal 2018 and $193,000 for fiscal 2017 in connection with these retirement plans.

15. Income Taxes

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

	Year Ended December 31, 2019	Six Months Ended December 31, 2018	Year Ended June 30, 2018	Year Ended June 30, 2017
U.S. operations	$ (56,866)	$ (44,804)	$ (53,000)	$ (17,566)
Non-U.S. operations	73	84	(171)	(919)
Loss before income taxes	$ (56,793)	$ (44,720)	$ (53,171)	$ (18,485)

On December 22, 2017, the *Tax Cuts and Jobs Act* (the "Tax Act") was signed into law, making significant changes to the federal tax law. Amongst other things, the Tax Act reduces the federal corporate tax rate from 34% to 21% effective for tax years beginning after December 31, 2017 and has resulted in a remeasurement of the Company's deferred tax assets included in the Company's fiscal 2018 rate reconciliation. The difference between the Company's expected income tax benefit, as computed by applying the blended statutory U.S. federal tax rate of 21% for the year ended December 31, 2019, 21% for the six months ended December 31, 2018, 27.5% for fiscal 2018 and 34% for fiscal 2017 to loss before income taxes, and actual income tax benefit is reconciled in the following table (in thousands):

	Year Ended December 31, 2019	Six Months Ended December 31, 2018	Year Ended June 30, 2018	Year Ended June 30, 2017
Income tax benefit at statutory rate	$ (11,927)	$ (9,391)	$ (14,622)	$ (6,284)
State income taxes, net of federal benefit	(3,685)	(1,657)	(1,552)	(928)
Non-U.S. income tax rate differential	374	186	(66)	(121)
Change in fair value of derivative	—	3,900	7,227	—
Change in federal tax rate	—	—	14,673	—
Research and development tax credits	(150)	(231)	(284)	(242)
Permanent items	55	—	(15)	(9)
Changes in valuation allowance	15,608	7,166	(5,385)	7,489
Other, net	(275)	27	24	95
Income tax benefit	$ —	$ —	$ —	$ —

For the year ended June 30, 2018, in addition to the $5.4 million change in valuation allowance in the above table, the Company recorded a deferred tax asset of $6.2 million and a valuation allowance of the same amount in connection with the Icon acquisition.

The significant components of deferred income taxes are as follows (in thousands):

	December 31, 2019	December 31, 2018
Deferred tax assets:		
Net operating loss carryforwards	$ 66,400	$ 53,259
Deferred revenue	8	70
Lease liability	923	0
Stock-based compensation	5,805	4,788
Tax credits	3,687	3,696
Other	1,473	682
Total deferred tax assets	78,296	62,495
Deferred tax liabilities:		
Intangible assets	7,559	8,207
Right-of-use assets	841	—
Total deferred tax liabilities	8,400	8,207
Deferred tax assets, net	69,896	54,288
Valuation allowance	69,896	54,288
Total deferred tax liability	$ —	$ —

The valuation allowance generally reflects limitations on the Company's ability to use the tax attributes and reduces the value of such attributes to the more-likely-than-not realizable amount. Management assessed the available positive and negative evidence to estimate if sufficient taxable income will be generated to use the existing net deferred tax assets. Based on a weighting of the objectively verifiable negative evidence in the form of cumulative operating losses over the three-year period ended June 30, 2018, management believes that it is not more likely than not that the deferred tax assets will be realized and, accordingly, a full valuation allowance has been established. The valuation allowance increased $15.6 million for the year ended December 31, 2019, $7.2 million for the six months ended December 31, 2018 and $765,000 and $7.5 million during the fiscal years ended June 30, 2018 and 2017, respectively, with such increases attributed to the re-measurement of the net deferred tax assets at the year-end dates. The valuation allowance decreased by $5.4 million from fiscal year 2018 activity, including the impact of the 2017 Tax Act, offset by an increase of $6.2 million related to the Icon acquisition.

The Company has tax net operating loss and tax credit carry forwards in its individual tax jurisdictions. Including approximately $49.3 million related to the Icon acquisition, at December 31, 2019 the Company had U.S. federal net operating loss carry forwards of approximately $236.6 million. The net operating losses consist of $151.8, which expire at various dates between calendar years 2023 and 2038. The utilization of certain of these loss and tax credit carry forwards may be limited by Sections 382 and 383 of the Internal Revenue Code as a result of historical or future changes in the Company's ownership. At December 31, 2019, the Company had state net operating loss carry forwards of approximately $190.1 million, which expire between 2033 and 2038, as well as U.S. federal and state research and development tax credit carry forwards of approximately $3.1 million, which expire at various dates between calendar years 2018 and 2038. In addition, at December 31, 2019 the Company had net operating loss carry forwards in the U.K. of £21.0 million (approximately $26.7 million), which are not subject to any expiration dates.

The Company's U.S. federal income tax returns for calendar years 2003 through 2017 remain subject to examination by the Internal Revenue Service. The Company's U.K. tax returns for fiscal years 2006 through 2017 remain subject to examination.

Through December 31, 2019, the Company had no unrecognized tax benefits in its consolidated statements of comprehensive loss and no unrecognized tax benefits in its consolidated balance sheets as of December 31, 2019 and 2018, respectively.

As of December 31, 2019 and 2018, the Company had no accrued penalties or interest related to uncertain tax positions.

16. Contingencies

Legal Proceedings

The Company is subject to various other routine legal proceedings and claims incidental to its business, which management believes will not have a material effect on the Company's financial position, results of operations or cash flows.

17. Segment and Geographic Area Information

Business Segment

The Company operates in one business segment, which is the business of developing and commercializing innovative ophthalmic products for the treatment of eye diseases. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. The chief operating decision maker made such decisions and assessed performance at the company level, as one segment.

Geographic Area Information

The following table summarizes the Company's revenues and long-lived assets, net by geographic area (in thousands):

	Revenues				Long-lived assets, net	
	Twelve Months Ended December 31, 2019	Six Months Ended December 31, 2018	Year Ended June 30, 2018	Year Ended June 30, 2017	At December 31, 2019	At December 31, 2018
U.S.	$ 19,144	$ 1,108	$ 2,861	$ 7,439	$ 357	$ 288
China	$ 1,121	1,720	—	—	—	—
U.K.	100	100	100	100	—	—
Consolidated	$ 20,365	$ 2,928	$ 2,961	$ 7,539	$ 357	$ 288

18. Subsequent Events

On February 25, 2020, the Company sold 15,000,000 shares of Common Stock in an underwritten public offering at a price of $1.45 per share for gross proceeds of $21.75 million. Underwriter discounts and other share issue costs are estimated to total approximately $1.75 million.

19. Quarterly Financial Data (unaudited)

The following tables summarize the quarterly results of operations for the year ended December 31, 2019, six months transition period ended December 31, 2018 and the year ended June 30, 2018 (in thousands except per share amounts):

	Year Ended December 31, 2019				
	First Quarter Ended March 31, 2019	Second Quarter Ended June 30, 2019	Third Quarter Ended September 30, 2019	Fourth Quarter Ended December 31, 2019	Year Ended December 31, 2019
Total revenues	$ 2,012	$ 7,210	$ 2,509	$ 8,634	$ 20,365
Operating loss	(14,651)	(10,165)	(14,060)	(8,985)	(47,861)
Net loss	(19,238)	(11,498)	(15,647)	(10,410)	(56,793)
Net loss per share - basic and diluted	$ (0.20)	$ (0.11)	$ (0.15)	$ (0.10)	$ (0.54)
Weighted average common shares - basic and diluted	95,452	106,238	106,938	106,680	104,307

	Six Months Ended December 31, 2018		
	Quarter Ended September 30, 2018 (1)	Quarter Ended December 31, 2018	Six Months Ended December 31, 2018
Total revenues	$ 486	$ 2,442	$ 2,928
Operating loss	(13,554)	(11,005)	(24,559)
Net loss	(33,126)	(11,594)	(44,720)
Net loss per share - basic and diluted	$ (0.44)	$ (0.12)	$ (0.53)
Weighted average common shares - basic and diluted	75,170	94,494	85,057

	Fiscal Year 2018				
	First Quarter Ended September 30, 2017	Second Quarter Ended December 31, 2017	Third Quarter Ended March 31, 2018 (1)	Fourth Quarter Ended June 30, 2018 (1)	Year Ended June 30, 2018
Total revenues	$ 385	$ 933	$ 928	$ 715	$ 2,961
Operating loss	(6,006)	(5,808)	(4,678)	(9,782)	(26,274)
Net loss	(5,983)	(5,782)	(6,978)	(34,428)	(53,171)
Net loss per share - basic and diluted	$ (0.15)	$ (0.13)	$ (0.15)	$ (0.62)	$ (1.15)
Weighted average common shares - basic and diluted	39,430	44,530	45,644	55,387	46,226

(1) Results for the quarter ended September 30, 2018 and each of the third and fourth quarters of fiscal 2018 included $18.9 million, $2.3 million and $24.0 million, respectively, of change in fair value of derivative liability in connection with the Second Tranche Transaction (see Notes 11 and 13). The fourth quarter of fiscal 2018 includes an out-of-period expense of $1.2 million reflecting the increase in the fair value of the Company's derivative liability which occurred, but was not recorded, in the third quarter of fiscal 2018.

20. Stub Period Comparative Data (Unaudited)

The condensed consolidated statements of operations for the year ended December 31, 2018 and the six months ended December 31, 2017 is as follows (in thousands except per share amounts):

	Year Ended December 31, 2018	Six Months Ended December 31, 2017
Revenues:		
Collaborative research and development	$ 2,625	$ 601
Royalty income	1,946	717
Total revenues	4,571	1,318
Operating expenses:		
Research and development	18,502	8,088
Sales and marketing	9,658	—
General and administrative	15,430	5,044
Total operating expenses	43,590	13,132
Loss from operations	(39,019)	(11,814)
Interest and other income	420	49
Interest expense	(2,362)	—
Change in fair value of derivative liability	(45,164)	—
Net loss	$ (86,125)	$ (11,765)
Net loss per common share - basic and diluted	$ (1.27)	$ (0.28)
Weighted average common shares - basic and diluted	67,942	41,980

Exhibit 4.5

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of the date of the Annual Report on Form 10-K of which this exhibit forms a part, the only class of securities of EyePoint Pharmaceuticals, Inc. ("we," "us" and "our") registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is our common stock, $0.001 par value per share.

COMMON STOCK

The following description of our common stock summarizes provisions of our certificate of incorporation, as amended, our by-laws, as amended, and the Delaware General Corporation Law. For a complete description, refer to our certificate of incorporation, our by-laws and the amendments thereto, which are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this exhibit is a part, and to the applicable provisions of the Delaware General Corporation Law.

Our certificate of incorporation authorizes us to issue up to 150,000,000 shares of common stock with a par value of $0.001 per share. The shares of common stock currently outstanding are fully paid and nonassessable.

Rights

Voting Rights. Holders of shares of our common stock are entitled to one vote for each share held of record on all matters to be voted on by stockholders, including the election of directors. When a quorum is present at any meeting, a plurality of the votes properly cast for election to any office shall elect to such office and a majority of the votes properly cast upon any question other than an election to an office shall decide the question, except when a larger vote is required by law, by our certificate of incorporation or by our by-laws.

Our certificate of incorporation and by-laws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends. Subject to the preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

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

Other Rights and Preferences. The terms of our common stock do not include any preemptive, conversion or subscription rights, nor any redemption or sinking fund provisions. The common stock is not subject to future calls or assessments by us.

Preferred Stock. Our board of directors is authorized to issue up to 5,000,000 shares of preferred stock in one or more series, with such rights, preferences and privileges as shall be determined by our board of directors. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of shares of any series of our preferred stock that we may classify and issue in the future.

Registration Rights. On March 28, 2018, we entered into (i) a Securities Purchase Agreement, or the First Tranche Securities Purchase Agreement, with EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P., or the First Tranche Investors, pursuant to which we offered and sold to such investors an aggregate of 8,606,324 shares of our common stock, or the First Tranche Transaction, and (ii) a Second Securities Purchase Agreement, or

the Second Tranche Securities Purchase Agreement, with the First Tranche Investors and certain other accredited investors signatory thereto, or the Second Tranche Investors, pursuant to which we agreed to offer and sell, subject to the approval of our stockholders, an aggregate of up to approximately $25.5 million of units, with each unit consisting of (a) one share of our common stock and (b) one warrant to purchase a share of our common stock, or the Second Tranche Transaction. In connection with the First Tranche Transaction, we entered into a Registration Rights Agreement with the First Tranche Investors with respect to the shares issued to the First Tranche Investors. In connection with the closing of the Second Tranche Transaction, we entered into a Second Registration Rights Agreement with the Second Tranche Investors with respect to the shares of common stock underlying the units. In addition, pursuant to the terms of the SWK Warrant, we granted the Agent certain registration rights with respect to the Initial Advance Warrant Shares and the Additional Advance Warrant Shares. A registration statement relating to such shares was filed with the SEC on July 25, 2018 and declared effective by the SEC on November 1, 2018.

Director Nomination Rights. Per the terms of the First Tranche Securities Purchase Agreement, the First Tranche Investors have the right, subject to certain customary limitations and restrictions, to nominate one individual to our board of directors for so long as they beneficially own shares of our common stock. Mr. Eastman, a Managing Director of EW Healthcare Partners, which is an affiliate of both of the First Tranche Investors was appointed to our board of directors as the designee of the First Tranche Investors pursuant to the First Tranche Securities Purchase Agreement. Per the terms of the Second Tranche Securities Purchase Agreement, the First Tranche Investors have the right, subject to certain customary limitations and restrictions, to nominate one individual to our board of directors for so long as they beneficially own shares of our common stock. Dr. Ando, Senior Advisor to EW Healthcare Partners, which is an affiliate of both of the First Tranche Investors, was appointed to our board of directors as the designee of the First Tranche Investors pursuant to the Second Tranche Securities Purchase Agreement.

Anti-Takeover Effects of Our Certificate of Incorporation and By-laws and Delaware Law

Certificate of Incorporation and By-laws. Provisions of our certificate of incorporation and by-laws may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Among other things, our certificate of incorporation and our by-laws:

- permit our board of directors to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as it may designate, which issuance could result in the loss of voting control by other stockholders;
- provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled only by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that, stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and
- provide that special meetings of our stockholders may be called only by the (i) the chairperson of the board; (ii) the president of our company; or (iii) a majority of the members of our board of directors then in office.

Section 203 of the Delaware General Corporation Law. We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the consummation of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Listing

Our shares of common stock are listed for trading on the Nasdaq Global Market under the symbol “EYPT.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

EXHIBIT 10.32

Portions of this exhibit indicated by bracketed asterisks have been omitted because they are not material and would likely cause competitive harm to EyePoint Pharmaceuticals, Inc. if publicly disclosed.

EXCLUSIVE LICENSE AGREEMENT

by and between

EYEPOINT PHARMACEUTICALS, INC.

and

EQUINOX SCIENCE, LLC

FEBRUARY 3, 2020

EXCLUSIVE LICENSE AGREEMENT

This **EXCLUSIVE LICENSE AGREEMENT** (this "**Agreement**") is entered into as of the 3rd day of February, 2020 (the "**Effective Date**"), by and between EyePoint Pharmaceuticals, Inc., a Delaware corporation having offices at 480 Pleasant Street, Watertown, MA 02472 ("**EyePoint**"), and Equinox Science, LLC, a Delaware limited liability company having offices at 11780 U.S. Hwy One, Suite 202, Palm Beach Gardens, FL 33408 ("**Equinox**"). EyePoint and Equinox are each referred to herein by name or as a "**Party**" or, collectively, as "**Parties**."

RECITALS

WHEREAS, Equinox owns or Controls (as defined below) certain rights to patents and other intellectual property related to the Compound (as defined below); and

WHEREAS, EyePoint desires to exclusively license from Equinox those intellectual property rights, and to develop, manufacture, use and distribute Licensed Products based upon those intellectual property rights in the Field in the Territory (as such terms are defined below), and Equinox desires to grant this exclusive license to EyePoint, in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1

DEFINITIONS

As used in this Agreement, the following terms shall have the meanings set forth in this Article 1:

1.1 "**AAA**" has the meaning assigned to such term in Section 10.2(b).

1.2 "**Action**" has the meaning assigned to such term in Section 5.2(b).

1.3 **"Additional Indication**" means the prevention or treatment of any human disease or disorder of the eye that is outside the Field using EyePoint's localized delivery technologies such as Durasert and Verisome [***].

1.4 "**Additional Indication Option**" has the meaning assigned to such term in Section 2.4.

1.5 "**Affiliate**" means any Person that directly or indirectly through one (1) or more intermediaries controls, is controlled by or is under common control with a Party. For purposes of this definition, a Person shall be deemed to "control" another Person if it (a) owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a Person in a particular jurisdiction) of such other Person, or has other comparable ownership interest with

respect to any Person other than a corporation, or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the Person.

1.6 "**Agreement**" has the meaning assigned to such term in the Preamble.

1.7 "**Annual Net Sales**" means, with respect to all Licensed Products, aggregate Net Sales in the Territory in a particular Calendar Year for all Licensed Products.

1.8 "**Applicable Laws**" means individually and collectively, any federal, state, local, national and supra-national laws, treaties, statutes, ordinances, rules and regulations, including any rules, regulations, guidance, guidelines or requirements having the binding effect of law of national securities exchanges, automated quotation systems or securities listing organizations, Regulatory Authorities, courts, tribunals, agencies other than Regulatory Authorities, legislative bodies and commissions that are in effect from time to time during the Term and applicable to a particular activity hereunder.

1.9 "**Arbitration Request**" has the meaning assigned to such term in Section 10.2.

1.10 "**Bankruptcy Code**" has the meaning assigned to such term in Section 9.4.

1.11 "**Breaching Party**" has the meaning assigned to such term in Section 9.2(a).

1.12 "**Business Day**" means a day other than a Saturday or a Sunday on which banking institutions in Boston, Massachusetts are open for business.

1.13 "**Calendar Quarter**" means a period of three (3) consecutive months ending on the last day of March, June, September, or December, respectively.

1.14 "**Calendar Year**" means a period of twelve (12) consecutive months beginning on January 1 and ending on December 31.

1.15 "**CDA**" has the meaning assigned to such term in Section 6.4.

1.16 "**Claims**" has the meaning assigned to such term in Section 8.1.

1.17 "**Commercially Reasonable Efforts**" means, with respect to a Party, efforts that are consistent with the efforts and resources commonly used in the pharmaceutical industry by a company of comparable size in connection with the research, development and commercialization of a pharmaceutical product owned by it or to which it has exclusive rights, with similar product characteristics, which is of similar market potential at a similar stage in its development or product life, taking into account issues of patent coverage, safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the potential or actual profitability of the applicable product (including pricing and reimbursement status achieved or to be achieved) and other relevant factors, including technical, legal, scientific and/or medical factors.

1.18 "**Completion**" means, with respect to a Phase II Clinical Trial for the Compound or a Licensed Product for a particular indication, that all of the primary endpoints set forth in the

protocol for such Clinical Trial have been achieved and the database for such Clinical Trial has been locked, or if, irrespective of the Phase II study outcome, a Phase III Clinical Trial for the Compound or a Licensed Product for the same indication commences, then the date that such Phase III Clinical Trial commences.

1.19 "**Compound**" means vorolanib (X-82), as well as any solvates or hydrates, polymorphs, prodrugs, metabolites, isomers, anhydrates and pharmaceutically acceptable salts thereof.

1.20 "**Confidential Information**" has the meaning assigned to such term in Section 6.1.

1.21 "**Control**," "**Controls**," or "**Controlled**" means possession of the ability to grant the licenses or sublicenses as provided herein without violating the terms of any agreement or other arrangement with any Third Party. A Party shall be deemed to Control certain specified Patents or Know-How to the extent of its individual or joint interest therein, as applicable.

1.22 "**Disclosing Party**" has the meaning assigned to such term in Section 6.1.

1.23 "**Dollars**" or "**$**" means the legal tender of the U.S.

1.24 "**Effective Date**" has the meaning assigned to such term in the Preamble.

1.25 "**EMA**" means the European Medicines Agency for the Evaluation of Medicinal Products of the European Union, or any successor agency thereto.

1.26 "**Equinox**" has the meaning assigned to such term in the Preamble.

1.27 "**Equinox Know-How**" means any Know-How Controlled by Equinox or its Affiliates, as of the Effective Date or after the Effective Date during the Term, to the extent necessary to practice the Equinox Patents or potentially useful to develop the Compound in the Field.

1.28 "**Equinox Patents**" means any Patents that are Controlled by Equinox, as of the Effective Date or after the Effective Date during the Term, that claim or cover the making, having made, using, selling, offering for sale or importation of the Compound. The Equinox Patents in existence as of the Effective Date are set forth on **Exhibit A** hereto, which Exhibit shall be updated as needed from time to time during the Term.

1.29 "**European Union**" means all countries that are officially recognized as member states of the European Union at any particular time during the Term.

1.30 "**Exclusive License**" has the meaning assigned to such term in Section 2.1.

1.31 "**Executive Officer**" means (a) with respect to EyePoint, the Chief Executive Officer of EyePoint, or any other person that such officer designates from time to time, and (b) with respect to Equinox, the Chief Operating Officer of Equinox, or any other person that such officer designates from time to time.

1.32 "**Expanded License**" has the meaning assigned to such term in Section 2.4.

1.33 "**EyePoint**" has the meaning assigned to such term in the Preamble.

1.34 "**FDA**" means the U.S. Food and Drug Administration, or any successor entity thereto.

1.35 "**Field**" means (a) the prevention or treatment of age-related macular degeneration (AMD), retinal vein occlusion (RVO) and diabetic retinopathy (DR) using EyePoint's proprietary localized delivery technologies such as Durasert, Verisome, [***], and (b) any Additional Indication for which the parties have entered into an Expanded License pursuant to Section 2.4 herein.

1.36 "**First Commercial Sale**" means, with respect to any Licensed Product, the first sale for which revenue has been recognized by EyePoint for use or consumption by the general public of such Licensed Product in any country in the Territory after all Regulatory Approvals have been granted in such country.

1.37 "**Force Majeure**" has the meaning set forth in Section 10.6.

1.38 "**GAAP**" means U.S. generally accepted accounting principles, consistently applied.

1.39 "**Generic Product**" means, with respect to any Licensed Product and any country in the Territory, any finished drug product that (a) is marketed for sale by a Third Party not authorized by EyePoint, and (b) receives Regulatory Approval in such country in reliance on the Regulatory Approval of such Licensed Product and is determined by a Regulatory Authority to be therapeutically equivalent to, interchangeable with, or substitutable for, such Licensed Product. By way of example, in the United States this would include a product that is submitted to FDA under an Abbreviated New Drug Application under Section 355(j) of Title 21 of the United States Code, as may be amended from time to time, or under an NDA under Section 355(b)(2) of Title 21 of the United States Code, as may be amended from time to time, for which the Licensed Product is the reference listed drug, and that is determined to be therapeutically equivalent to the Licensed Product.

1.40 "**GLP**" means current Good Laboratory Practices as defined in Part 58 of Title 21 of the U.S. Code of Federal Regulations, as may be amended from time to time, or any successor thereto and foreign equivalents thereof.

1.41 "**GMP**" means current Good Manufacturing Practices as defined in Parts 210 and 211 of Title 21 of the U.S. Code of Federal Regulations, as may be amended from time to time, or any successor thereto and foreign equivalents thereof.

1.42 "**IND**" means any investigational new drug application filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations prior to beginning clinical trials in humans in the United States or any comparable application filed with any Regulatory Authority outside of the United States.

1.43 "**Indemnitee**" has the meaning assigned to such term in Section 8.3.

1.44 "**Infringement**" has the meaning assigned to such term in Section 5.2(a).

1.45 "**Know-How**" means any proprietary data, results, material(s), technology, and nonpublic information of any type whatsoever, in any tangible or intangible form, including: (a) information, techniques, technology, practices, trade secrets, discoveries, developments, inventions (whether patentable or not), methods, knowledge, know-how, skill, experience, data, results (including assay development, compound screening, chemical, pharmacological, toxicological, preclinical and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms, reports and study reports; and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material.

1.46 "**Licensed Product**" means any pharmaceutical product comprising the Compound, [***]

1.47 "**Losses**" has the meaning assigned to such term in Section 8.1.

1.48 "**Manufacturing Know-How**" has the meaning assigned to such term in Section 3.9(b).

1.49 "**MTA**" has the meaning assigned to such term in Section 6.4.

1.50 "**NDA**" means a New Drug Application seeking Regulatory Approval of a Licensed Product and all amendments and supplements thereto filed with the FDA, or any comparable application filed with any Regulatory Authority outside the United States.

1.51 "**Negotiation Period**" has the meaning assigned to such term in Section 2.4(b).

1.52 "**Net Sales**" means, with respect to any Licensed Product, the gross invoiced sales price of such Licensed Product sold by EyePoint, its Affiliates or Sublicensees (the "**Selling Party**"), in finished product form, packaged and labelled for sale in arm's-length transactions to Third Parties, less deductions allowed to the Third Party customer by the Selling Party, to the extent actually taken by such Third Party customer, on such sales for:

(a) transportation charges relating to the Licensed Product, including handling charges and insurance premiums relating thereto;

(b) sales taxes, excise taxes, use taxes, VAT and duties paid by the Selling Party in relation to the Licensed Product and any other equivalent governmental charges imposed upon the importation, use or sale of the Licensed Product;

(c) government-mandated and other rebates (such as those in respect of any state or federal Medicare, Medicaid or similar programs);

(d) customary trade, quantity and cash discounts allowed on the Licensed Product;

(e) allowances or credits to customers on account of retrospective price reductions affecting the Licensed Product;

(f) customary rebates and charge-backs including those granted to managed care entities;

(g) bad debt and uncollectable invoiced amounts actually written off in accordance with the standard practices of the Selling Entity; and

(h) that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended), that EyePoint, its Affiliates, or its or their Sublicensees, as applicable, allocate to sales of the Licensed Product in accordance with their respective standard policies and procedures consistently applied across their respective products; and

(i) fees for distribution paid to wholesalers, distributors, specialty pharmacies, etc., but not commissions on sales.

If a sale, transfer or other disposition with respect to a Licensed Product involves consideration other than cash or is not at arm's length, the Net Sales from such sale, transfer, or other disposition will be calculated on the average Net Sales price of the Licensed Product in arm's length sales for cash in the relevant country during the same Calendar Quarter as such sale, transfer or other disposition or in the absence of such sales, the fair market value of the Licensed Product as mutually determined by the Parties.

Where a Licensed Product is sold in combination with other active ingredients (collectively, "**Combination Components**"), then the Parties shall discuss an appropriate allocation for the fair market value of the Licensed Product and the Combination Components with which the Licensed Product is combined to mutually determine Net Sales for the relevant transactions based on an equitable method of determining the same that takes into account variations in potency, the relative contribution of each therapeutically active ingredient or other component, and the relative value to the end user of each therapeutically active ingredient or other component.

Notwithstanding the foregoing to the contrary, sales of Licensed Product between EyePoint and its Affiliates or Sublicensees shall be excluded from the computation of Net Sales and no payments shall be payable on such sales except where such Affiliates or Sublicensees are end users.

1.53 "**Non-Breaching Party**" has the meaning assigned to such term in Section 9.2(a).

1.54 "**Notice of Exercise**" has the meaning assigned to such term in Section 2.4(b).

1.55 "**Option Notice**" has the meaning assigned to such term in Section 2.4(a).

1.56 "**Party**" or "**Parties**" has the meaning assigned to such term in the Preamble.

1.57 "**Patent**" means (a) all patents and patent applications in any country or supranational jurisdiction in the Territory, and (b) any substitutions, divisions, continuations, continuations-in-part, provisional applications, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like of any such patents or patent applications.

1.58 "**Person**" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

1.59 "**Pharmacovigilance Agreement**" has the meaning assigned to such term in Section 3.6**Error! Reference source not found.**.

1.60 "**Phase II Clinical Trial**" means a human clinical trial of a compound or product for an indication, the principal purpose of which is a determination of safety and efficacy for such indication in a target patient population over a range of doses, as more fully defined in 21 C.F.R. §312.21(b), or its successor regulation, or the equivalent in any foreign country.

1.61 "**Phase III Clinical Trial**" means a human clinical trial of a compound or product for an indication on a sufficient number of subjects that is designed to establish that the compound or product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with the compound or product in the dosage range to be prescribed, and to support Regulatory Approval of the compound or product for such indication, as more fully defined in 21 C.F.R. §312.21(c), or its successor regulation, or the equivalent in any foreign country.

1.62 "**Product Information**" has the meaning assigned to such term in Section 7.2(i).

1.63 "**Receiving Party**" has the meaning assigned to such term in Section 6.1.

1.64 "**Regulatory Approval**" means all approvals, licenses, registrations, or authorizations of any country, federal, supra-national, state or local regulatory agency, department, bureau or other government entity that are necessary for the manufacture, use, storage, import, transport and/or sale of a particular Licensed Product in the applicable jurisdiction.

1.65 "**Regulatory Authority**" means the FDA, and any health regulatory authority in any country in the Territory that is a counterpart to the FDA and holds responsibility for granting regulatory marketing approval for a Licensed Product in such country, and any successor(s) thereto.

1.66 "**Regulatory Materials**" means, with respect to a Licensed Product in the Field, regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority that are necessary to obtain marketing authorization for or to develop, manufacture or commercialize such Licensed Product in the Field, for or in a particular country or regulatory jurisdiction. Regulatory Materials include NDAs, INDs, presentations, responses, and applications for Regulatory Approvals other than NDAs.

1.67 "**Royalty Term**" has the meaning assigned to such term in Section 4.3(b).

1.68 "**Sublicensee**" means, with respect to a particular Licensed Product, a Third Party to whom EyePoint has granted a sublicense, license, or other transfer of rights under any Equinox Patents and Equinox Know-How, but excluding distributors.

1.69 "**Term**" has the meaning assigned to such term in Section 9.1.

1.70 "**Territory**" means the entire world except The People's Republic of China, Hong Kong, Taiwan, and Macau.

1.71 "**Third Party**" means any Person other than Equinox or EyePoint or an Affiliate of Equinox or EyePoint.

1.72 "**Third Party License**" means any license or other agreement between a Third Party and EyePoint or its Affiliate or Sublicensee, pursuant to which EyePoint or its Affiliate or Sublicensee (as applicable) is granted a license to Patents owned or Controlled by a Third Party, where such license is necessary or useful, in EyePoint's sole discretion, for the development, manufacture or commercialization of the Compound or Licensed Products in the Field.

1.73 "**United States**" or "**U.S.**" means the United States of America, including its territories and possessions.

1.74 "**Valid Claim**" means a claim of (a) an issued and unexpired Patent within the Equinox Patents, or (b) an application within the Equinox Patents that has been pending approval for no more than seven (7) years after the initial date of filing, and that (in each case, as applicable) has not been held invalid or unenforceable by a court or other government agency of competent jurisdiction from which no appeal can be or has been taken and has not been held or admitted to be invalid or unenforceable through reexamination or disclaimer, opposition procedure, nullity suit or otherwise.

1.75 "**VAT**" means the tax imposed by Council Directive 2006/112/EC of the European Community and any national legislation implementing that directive together with legislation supplemental thereto and in particular, in relation to the United Kingdom, the tax imposed by the Value Added Tax Act of 1994 or other tax of a similar nature imposed elsewhere instead of or in addition to value added tax.

ARTICLE 2

GRANT OF RIGHTS

2.1 **License**

s. Subject to the terms and conditions of this Agreement, Equinox hereby grants to EyePoint an exclusive (even as to Equinox and its Affiliates), royalty-bearing right and license, with the right to grant sublicenses (including through multiple tiers of sublicensees), under the Equinox Patents to research, develop, make, have made, use, sell, offer for sale and import the Compound and Licensed Products in the Field in the Territory (the "**Exclusive License**"). Subject to the terms and conditions of this Agreement, Equinox hereby grants to EyePoint a non-exclusive

royalty-bearing right and license, with the right to grant sublicenses (including through multiple tiers of Sublicensees), under the Equinox Know-How as necessary to practice the Equinox Patents or potentially useful to develop the Compound in the Field in the Territory (the "Know-How License").

2.2 Sublicenses

. The Exclusive License may be sublicensed, in full or part, by EyePoint to its Affiliates or Third Parties, provided that (a) any such sublicense shall be in writing and consistent with and subject to the terms and conditions of this Agreement, (b) EyePoint shall continue to be responsible for the performance of its obligations under this Agreement and will be responsible for all actions of its Sublicensees as if such Sublicensees were EyePoint hereunder, and (c) EyePoint shall provide Equinox with a full and complete copy of each sublicense within thirty (30) days after execution, subject to EyePoint's right to redact provisions of such sublicense that are not necessary to verify compliance with this Agreement.

2.3 No Implied Rights

. Except as expressly stated herein, EyePoint shall have no other right to use, or interest in, the Equinox Patents or the Equinox Know-How. Additionally, EyePoint shall not have any interest in any other Patents or other intellectual property owned, licensed, developed or Controlled by Equinox, other than as expressly provided in this Agreement or other valid written agreements. Equinox makes no grant of intellectual property rights by implication.

2.4 Option for Additional Indications

. Equinox hereby grants to EyePoint an exclusive option (the "**Additional Indication Option**") to acquire an exclusive license in the Territory under the Equinox Patents and a non-exclusive license under the Equinox Know-How to research, develop, make, have made, use, sell, offer for sale and import the Compound and Licensed Products in the Territory for Additional Indications in the field of ophthalmology on the terms and conditions set forth in this Section 2.4 (the "**Expanded License**").

(a) If at any time during the Term, Equinox (i) has a bona fide plan to develop or commercialize by itself or through any Affiliate, (ii) desires to enter into discussions or negotiations with any Third Party to develop or commercialize, or (iii) receives from a Third Party a set of written terms to develop or commercialize the Compound for any Additional Indication in the Territory in the field of ophthalmology, then Equinox shall provide EyePoint with written notice of such intention, along with a copy of the bona fide plan in the event that such development or commercialization is pursuant to (i) above or the written terms from the Third Party in the event that such development or commercialization is pursuant to (iii) above (the "**Option Notice**"). For clarity, Equinox's obligations under this Section 2.4(a) apply each and every time that the conditions set forth in subsections (i), (ii) or (iii) exist, even if one or more of such conditions occur with respect to the same Additional Indication, and further, Equinox shall not collaborate with any Third Party for the development or commercialization of a localized delivery technology for the prevention or treatment of age-related macular degeneration (AMD), retinal vein occlusion (RVO) and diabetic retinopathy (DR) in the Territory.

(b) EyePoint shall have the right to exercise the Additional Indication Option by delivery to Equinox of written notice of exercise (the "**Notice of Exercise**") within sixty (60) days after the date it receives the Option Notice. If Equinox has received from a Third Party a set of written terms to develop or commercialize the Compound for any Additional Indication in the Territory in the field of ophthalmology, then during the ninety (90) day period following the date

of the Notice of Exercise (the "**Negotiation Period**") EyePoint and Equinox shall negotiate in good faith to enter into an amendment to this Agreement on the terms described in the Option Notice. In all other cases, if EyePoint exercises the Additional Indication Option by delivery to Equinox of a Notice of Exercise, then during the Negotiation Period, the Parties shall negotiate in good faith to enter into an amendment to this Agreement to (i) provide for the grant by Equinox to EyePoint of the Expanded License in exchange for the payment of incremental consideration based on the value of the Expanded License as mutually agreed by the Parties, and (ii) revise and clarify any other provisions of this Agreement necessary or appropriate in view of the grant of the Expanded License.

(c) If (i) EyePoint has not delivered a Notice of Exercise to Equinox within the sixty (60) day period referenced in Section 2.4(b) above, or (ii) the Parties are unable to reach agreement on the economic or other terms for the Expanded License prior to the expiration of the Negotiation Period, then Equinox shall have the right to develop and commercialize by itself or through any Affiliate, or to license to a Third Party, such Additional Indication; provided, that if Equinox does not commence development by itself within ninety (90) days or sign a license with a Third Party within one (1) year of the applicable date referenced in (i) and (ii) above, then EyePoint's rights with respect to such Additional Indication under this Section 2.4 shall reset.

2.5 Equinox License Outside the Territory. Prior to or promptly after the Effective Date, the Parties shall negotiate in good faith the terms and conditions of (i) an exclusive license agreement pursuant to which Equinox or its Affiliates or sublicensees shall have the exclusive right to develop, seek regulatory approval and commercialize Licensed Products outside of the Territory and (ii) a supply agreement (and related quality agreement) pursuant to which EyePoint will manufacture and supply Equinox or its Affiliates or sublicensees with Licensed Products that are finished products ready for development and sale outside of the Territory. If the Parties are unable to execute a definitive exclusive license agreement and supply agreement within one hundred eighty (180) days after the Effective Date, then at the request of either Party the matter shall be referred to dispute resolution under Section 10.1. These agreements will include the following terms:

(a)In full consideration of the exclusive license to sell Licensed Products outside the Territory, Equinox will not make any upfront payment to EyePoint, but shall pay Eyepoint a tiered royalty on annual net sales as follows:

Annual Net Sales	**Royalty Rate**
The portion of annual net sales of Licensed Products outside the Territory up to and including [***]	[***]%
The portion of annual net sales for Licensed Products outside the Territory exceeding [***]	[***]%

(b) Eyepoint will supply all required finished product to Equinox (subject to customary forecasts and collars) at EyePoint's actual manufacturing cost including overhead and administrative costs ("**Manufacturing Cost**"), it being understood and agreed that the Manufacturing Cost charged to Equinox shall not exceed an amount to be mutually agreed upon in the supply agreement.

ARTICLE 3

COVENANTS

3.1 **EyePoint Development and Commercialization.** EyePoint, either itself and/or by and through its Affiliates or Sublicensees, shall be solely responsible for and shall have full control and authority with respect to, all development, registration, manufacturing, marketing, advertising, promotional, launch and sales activities in connection with the Compound and the Licensed Products in the Field in the Territory. All costs associated with such activities shall be borne solely by EyePoint. EyePoint shall prepare, own and maintain all Regulatory Materials, including all applications for Regulatory Approval and Regulatory Approvals obtained from Regulatory Authorities in the Field in the Territory in connection with the Compound and Licensed Products.

3.2 **Initial Transfer of Data and Regulatory Materials.** Promptly after the Effective Date, Equinox shall disclose and transfer to EyePoint the IND and the data corresponding to the Phase I Clinical Trial using the Compound for the treatment of age-related macular degeneration conducted by or on behalf of Equinox prior to the Effective Date.

3.3 **Exchange of Regulatory Materials.** During the Term, at the request of a Party, the other Party shall disclose and transfer a copy of Regulatory Materials that are Controlled by such Party, which materials shall be the Confidential Information of the disclosing party. The receiving party may use such information in its development of any product comprising the Compound and may disclose such information to Regulatory Authorities as reasonably necessary to advance the development of any product comprising the Compound. This covenant shall extend to Affiliates and Sublicensees of a Party.

3.4 **Right to Cross-Reference.** Each Party shall have the right to reference Regulatory Materials of any product comprising the Compound to the extent that such Regulatory Materials are Controlled by the other Party for purposes relating to obtaining Regulatory Approval for a product comprising the Compound. This covenant shall extend to Affiliates and Sublicensees of a Party.

3.5 **Cooperation.** Each Party agrees to cooperate with the other Party on matters relating to obtaining Regulatory Approval for any product comprising the Compound. Eyepoint shall notify not less frequently than once per calendar quarter about the preparation and submission of material Regulatory Materials, activities under the Pharmacovigilance Agreement, allowing Equinox to review and comment within thirty (30) days on Regulatory Materials prior to submission (to the extent that such Regulatory Materials may impact the development of a product under development by the other Party), and generally taking no actions that would violate

Applicable Laws or compromise patient safety or which could have a material adverse effect on the development of the Licensed Product. Equinox and its Affiliates and Sublicensees shall keep Eyepoint regularly informed of the preparation, Regulatory Authority review and approval of submissions and communications with Regulatory Authorities with respect to a Licensed Product. In addition, upon Eyepoint's request, Equinox and its Affiliates and Sublicensees shall provide Eyepoint with, in their original language and summaries thereof in English (if their original language is not English), all Regulatory Materials related to Licensed Products. This covenant shall extend to Affiliates and Sublicensees of a Party.

3.6 **Safety Data Exchange and Global Safety Database.** Within ninety (90) days of the Effective Date, but in any event prior to commencement of any clinical trials with the Compound or a Licensed Product in the Field in the Territory by or on behalf of EyePoint or its Affiliates or Sublicensees, the Parties will in good faith negotiate and finalize a separate safety data exchange agreement (the "**Pharmacovigilance Agreement**"), the terms of which shall set forth the obligations, procedures and timelines for exchanging information (such as the occurrence of adverse events and serious adverse events) observed in connection with the Compound in order to enable each Party to comply with its safety reporting obligations to Regulatory Authorities. Prior to the execution of the Pharmacovigilance Agreement, each Party shall promptly notify the other Party of any information observed in connection with the Compound necessary to enable such Party to comply with its safety reporting obligations to Regulatory Authorities. Equinox shall be responsible for maintaining a global safety database with respect to the Compound. EyePoint shall be responsible for reporting all adverse drug reaction experiences related to the Compound in connection with the activities of EyePoint under this Agreement to the applicable Regulatory Authorities in accordance with all Applicable Laws.

3.7 **Restrictions.** Equinox shall not, by itself or through its Affiliates or Third Parties, develop, or license a third party to develop, a Licensed Product in the Field in the Territory during the Term of this Agreement. Equinox further agrees not to commercialize, or license a third party to commercialize, a Licensed Product in the Field and in the Territory during the Term of this Agreement. Notwithstanding the foregoing, the prohibitions under this Section 3.7 and the licenses and transfers of Equinox Patent Rights and Equinox Know-How required under this Agreement shall not apply to the development and commercialization activities of a third party acquiree or transferor, or a third party merger or consolidation partner, of or with Equinox, or a third party acquiror or transferee of substantially all of the assets or stock of Equinox's ophthalmics business, provided that such acquiror, acquiree, transferor, transferee, or a merger or consolidation partner does not use in such development or commercialization activities for a Licensed Product in the Field any (i) Equinox Patent or (ii) Equinox Know-How that was previously owned by Control Delivery Systems, Inc., and shall not include Patents and Know-How of a third party acquiree or transferor, or a third party merger or consolidation partner, of or with Equinox or a third party acquiror or transferee of substantially all of the assets or stock of Equinox's ophthalmics business. Notwithstanding the foregoing, for the avoidance of doubt, during the Term, in partial consideration for the amounts payable to Equinox under this Agreement, Equinox shall not, by itself or through its Affiliates or Third Parties, sell, offer for sale or market the Compound or any product comprising the Compound in the Territory for (a) the prevention or treatment of age-related macular degeneration (AMD), retinal vein occlusion (RVO) and diabetic retinopathy

(DR) using any localized delivery technology, or (b) any Additional Indication for which the parties have entered into an Expanded License pursuant to Section 2.4 herein.

3.8 EyePoint Diligence

. EyePoint, either by itself or through its Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to develop, seek Regulatory Approval for and commercialize one Licensed Product in the Field in the Territory. Additionally, EyePoint shall develop and share with Equinox a detailed clinical development plan with commercially and clinically reasonable clinical and developmental milestones and a commercially reasonable timeline to achieve those milestones, including the anticipated cumulative number of years to start each development phase based on EyePoint's then-current assumptions regarding the clinical development process. On a semi-annual basis (every six months), EyePoint shall disclose, via written report to Equinox, progress relating to the clinical development plan. Equinox shall receive the first clinical development plan within ninety (90) days of the Effective Date.

Prior to the end of each of the first and third Calendar Quarters of each Calendar Year occurring during the Term, EyePoint shall deliver to Equinox a written report summarizing at a high-level the development and commercialization activities undertaken by or on behalf of EyePoint and its Affiliates and Sublicensees with respect to the Compound and Licensed Products in the Field in the Territory during the prior Calendar Year.

Failure by either Party to comply with the provisions of this Section, as may be amended subsequent to the Effective Date, shall constitute a material breach of this Agreement by such Party.

3.9 Manufacturing and Transfer of Equinox Know-How

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(a) *Initial Technology Transfer*. Equinox represents and warrants, and subject to such representation and warranty EyePoint acknowledges and agrees that, prior to the Effective Date, Equinox has transferred and delivered to EyePoint all tangible embodiments of the Equinox Know-How (other than Regulatory Materials and the Manufacturing Know-How) in its possession or in existence on or prior to the Effective Date, including clinical data arising from Equinox's development activities prior to the Effective Date. For a period of twelve (12) months after the Effective Date, Equinox shall use Commercially Reasonable Efforts, at EyePoint's reasonable request and expense, to provide technical assistance to enable the use of the transferred Equinox Know-How, and any updates to the Equinox Know-How that may occur up to twelve (12) months after the Effective Date.

(b) *Manufacturing Know-How*. At any time after the Effective Date, in the event that Equinox repeated and materially fails to supply the API (as defined below) to EyePoint as required under the applicable Supply Agreement, and Equinox does not correct the failure in accordance with the terms of the Supply Agreement, then EyePoint shall have the right to request that Equinox commence a technology transfer to EyePoint or its designated contract manufacturing organization, at the expense of EyePoint, of any tangible embodiments of Equinox Know-How or other information or technology Controlled by Equinox and reasonably necessary for the clinical and/or commercial manufacture of the Compound (the "**Manufacturing Know-How**"). The Parties shall reasonably cooperate to develop and complete a technology transfer plan for the Manufacturing Know-How within thirty (30) days of EyePoint's request to Equinox to complete

such technology transfer; provided, that such technology transfer shall be conducted in accordance with the schedule agreed in such technology transfer plan. For a period of twelve (12) months after the completion of the transfer above, Equinox shall use Commercially Reasonable Efforts, at EyePoint's reasonable request and expense, to provide technical assistance to enable the use of all Manufacturing Know-How.

(c) *Supply Agreement.* Promptly after the Effective Date, EyePoint and Equinox shall negotiate in good faith the terms of a supply agreement (the "**Supply Agreement**") and related quality agreement (the "**Quality Agreement**") pursuant to which Equinox shall supply to EyePoint, directly or through a Third Party, quantities of active pharmaceutical ingredient for the Compound ("**API**") to support the development of the Licensed Products in the Field in the Territory. For clarity, EyePoint shall be responsible for manufacturing Licensed Product using the API supplied by Equinox. The API will be supplied to EyePoint at Equinox's manufacturing cost including overhead and administrative costs ("**API Manufacturing Cost**"), it being understood and agreed that API Manufacturing Cost charged to EyePoint shall not exceed an amount to be mutually agreed upon in the Supply Agreement. The Supply Agreement shall contain terms customary and reasonable for such an agreement. At the request of EyePoint, EyePoint and Equinox shall negotiate in good faith the terms of a commercial supply agreement ("**Commercial Supply Agreement**") and related quality agreement pursuant to which Equinox shall supply to EyePoint, directly or through a Third Party quantities of API to support the commercial sale of the Licensed Products in the Field in the Territory.

ARTICLE 4

FINANCIAL PROVISIONS

4.1 Upfront Payment

. In partial consideration for the rights granted to EyePoint under this Agreement, EyePoint shall pay to Equinox a one-time, non-refundable, non-creditable upfront payment of One Million Dollars ($1,000,000) within ten (10) Business Days of the Effective Date.

4.2 Development Milestone Events

. Subject to the terms and conditions set forth in the remainder of this Section 4.2, EyePoint shall make each of the one-time milestone payments to Equinox that are set forth below upon the first achievement of the corresponding milestone event with respect to the Compound or a Licensed Product by or on behalf of EyePoint or its Affiliate or Sublicensee. Each milestone payment under this Section 4.2 shall be paid only once with respect to the first time such milestone is achieved, and no more than Fifty Million Dollars ($50,000,000) in milestone payments shall be payable under this Section 4.2 no matter how many times the milestone events are achieved.

Milestone Number	Milestone Event	Milestone Payment ($)
1	Completion of a Phase II Clinical Trial for the Compound or a Licensed Product	[***]
2	Filing of an NDA or equivalent for the Compound or a Licensed Product in the US or European Union or United Kingdom	[***]
3	Regulatory Approval of the Compound or a Licensed Product in the US or European Union or United Kingdom	[***]

EyePoint shall notify Equinox in writing promptly, but in no event later than ten (10) Business Days, after the achievement of each milestone event. EyePoint shall pay all such milestone payments due in Dollars within thirty (30) days following the achievement of the corresponding milestone event.

4.3 Royalties

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(a) *Licensed Product Royalty from EyePoint*. Subject to the remainder of Section 4.3, EyePoint shall pay to Equinox the following tiered royalties on Annual Net Sales of Licensed Products in the Territory:

Annual Net Sales	Royalty Rate
The portion of Annual Net Sales of Licensed Products in the Territory up to and including [***]	[***]%
The portion of Annual Net Sales for Licensed Products in the Territory exceeding [***]	[***]%

(b) *Royalty Term*. EyePoint's obligation to pay royalties with respect to a Licensed Product in a particular country in the Territory, even if reduced as provided below in this Section 4.3, shall commence upon the First Commercial Sale of such Licensed Product in such country and shall expire on a country-by-country and Licensed Product-by-Licensed Product basis on the later of (i) the date that is twelve (12) years after First Commercial Sale of such Licensed Product in such country, and (ii) the first day of the month following the month in which a Generic Product corresponding to such Licensed Product is launched in a particular country (the "**Royalty Term**").

(c) *Existence and Expiry of Valid Claims.* If, on a country-by-country and Licensed Product-by-Licensed Product basis, there is no Valid Claim that covers the Licensed Product, and there is no other Patent that is Controlled by EyePoint which covers such Licensed

Product, either at the time of First Commercial Sale or anytime thereafter during the Royalty Term, then EyePoint shall have no obligation to pay royalties on Net Sales of such Licensed Product in such country at the royalty rates set forth in Section 4.3(a), but rather, EyePoint shall pay to Equinox a Know-How royalty on Net Sales of such Licensed Product in such country at a royalty rate equal to [***] of the applicable royalty rate as set forth in Section 4.3(a) during the Royalty Term.

(d) *Third Party Licenses.* EyePoint shall pay all amounts due under Third Party Licenses. Such payments under Third Party Licenses are not creditable against any payments due to Equinox under this Agreement.

4.4 Reports; Royalty Payments

. Until the expiration of all applicable Royalty Terms, EyePoint shall make written reports and Calendar Quarterly payments to Equinox within sixty (60) calendar days after the end of each Calendar Quarter covering Net Sales of Licensed Products in the Territory by EyePoint, its Affiliates and Sublicensees during the preceding Calendar Quarter, each such written report in reasonable detail as available stating (a) gross sales of the Licensed Product sold by EyePoint, its Affiliates and Sublicensees, in local currency and U.S. Dollars, (b) calculation of Net Sales of the Licensed Product including all deductions and currency conversions, and (c) a calculation of the royalties due to Equinox. Concurrent with the delivery of each such report, EyePoint shall make the royalty payment due to Equinox for the Calendar Quarter covered by such report.

4.5 Method of Payments

. All payments due from EyePoint to Equinox under this Agreement shall be paid in Dollars by wire transfer to a bank account designated in writing by Equinox at least five (5) Business Days before such payment is due.

4.6 Audit

. EyePoint and its Affiliates and Sublicensees shall keep and maintain for five (5) years complete and accurate records of sales of Licensed Products in sufficient detail to allow Equinox to confirm the accuracy of royalties paid and/or payable under Section 4.3 hereunder. Equinox shall have the right during such five (5) year period to appoint at its expense an independent certified public accountant reasonably acceptable to EyePoint to audit all relevant records for the purpose of verifying reports provided by EyePoint under Section 4.4. EyePoint and its Affiliates and Sublicensees shall make such records available for audit by such independent certified public accountant during regular business hours at such place or places where such records are customarily kept, upon thirty (30) days written notice from Equinox. Such audit right shall not be exercised by Equinox more than once in any Calendar Year and the records for a twelve (12) month period may not be audited more than once. All records made available for audit shall be deemed to be Confidential Information of EyePoint and, upon the request of EyePoint, the independent certified public accountant selected by Equinox shall enter into a confidentiality agreement with EyePoint in a form reasonably acceptable to EyePoint regarding the use and disclosure of such Confidential Information. The results of each audit, if any, shall be binding on both Parties absent manifest error. Equinox shall bear the full cost of such audit, except in the event that the results of the audit reveal an underpayment of royalties to Equinox under Section 4.3 of [***] or more over the period being audited, in which case documented and reasonable audit fees for such examination shall be paid by EyePoint. If such audit reveals an underpayment of royalties, EyePoint shall pay any unpaid royalties within thirty (30) days of the completion of the audit. If such audit reveals an overpayment of royalties, then at EyePoint's election, Equinox shall

either pay any overpaid royalties to EyePoint within thirty (30) days of the completion of the audit or EyePoint shall have the right to credit such overpayment against future amounts payable to Equinox under this Agreement.

4.7 Taxes

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(a) *Withholding*. Any tax paid or required to be withheld by EyePoint for the benefit of Equinox on account of any royalties or other payments payable to Equinox under this Agreement shall be deducted from the amount of royalties or other payments otherwise due. EyePoint shall secure and send to Equinox proof of any such taxes withheld and paid by EyePoint for the benefit of Equinox, and will, at Equinox's request, provide reasonable assistance to Equinox in recovering such taxes.

(b) *VAT*. All amounts in this Agreement are stated exclusive of VAT and other applicable indirect taxes or duties. The Parties agree that, where appropriate, they will provide each other with a valid tax invoice, and against the production of such invoice, the Parties shall pay the amount of any such tax to the other Party. If such taxes are subsequently refunded by the applicable fiscal authority, the Party receiving the refund will immediately notify the other Party and refund such amount within thirty (30) days of receipt.

4.8 Currency

. With respect to sales of the Licensed Product invoiced in Dollars, the Net Sales and the amounts due hereunder will be expressed in Dollars. With respect to sales of the Licensed Product invoiced in a currency other than Dollars, the Net Sales and amounts due hereunder will be reported in Dollars, calculated using the exchange rates on the last day of the applicable Calendar Quarter as published in the *Wall Street Journal*.

ARTICLE 5

INTELLECTUAL PROPERTY RIGHTS

5.1 Prosecution and Maintenance of Equinox Patents

. Equinox shall have the first right, but not the obligation, in a commercially reasonable and expeditious manner, to prepare, file, prosecute, and maintain each of the Equinox Patents throughout the Territory at Equinox's cost; provided, that Equinox shall notify EyePoint of each such Equinox Patent, and EyePoint shall reimburse Equinox for [***] of all of Equinox's costs in the preparation, filing, prosecution, and maintenance of each such Equinox Patent. Upon request, Equinox shall promptly furnish or have furnished to EyePoint copies of all patents, patent applications, substantive patent office actions, and substantive responses received or filed in connection with such applications for the Equinox Patents at least thirty (30) days before filing or mailing, as the case may be, and, if requested, use reasonable efforts to solicit EyePoint's advice and review of Equinox Patents and material prosecution matters related thereto in reasonable time prior to filing thereof, and Equinox shall consider in good faith Eyepoint's reasonable comments and suggestions related thereto; provided, that nothing herein shall obligate Equinox to adopt or follow such comments or suggestions. If, during the Term, Equinox intends to allow any Equinox Patent to expire or intends to otherwise abandon any such Equinox Patent, Equinox shall notify EyePoint of such intention or decision at least fifteen (15) days (or as soon as possible if less than thirty (30) days) prior to any filing or payment due date, or any other date that requires action, in connection with such Equinox Patent,

and EyePoint shall thereupon have the right, but not the obligation, to assume responsibility for the preparation, filing, prosecution or maintenance thereof in the Territory at its sole cost and expense, in the name of Equinox. Each Party agrees to reasonably cooperate with the other Party to execute all lawful papers and instruments and to provide consultation and assistance as may be reasonably necessary in the prosecution and maintenance of the Equinox Patents in a manner consistent with this Section 5.1.

5.2 Third Party Infringement

.

(a) *Notice*. If either Party becomes aware of any suspected infringement or misappropriation by a Third Party of any Equinox Patents or Equinox Know-How, then that Party shall promptly notify the other Party and provide it with all material details of such activities (each, an "**Infringement**") of which it is aware.

(b) *EyePoint Right to Enforce*. EyePoint shall have the first right, but not the obligation, to address such Infringement in the Field in the Territory and to defend against any related declaratory judgement action, by taking reasonable steps, which may include the institution of legal proceedings or other actions (an "**Action**"), and to compromise or settle such Action; provided, that (i) EyePoint shall keep Equinox reasonably informed about such Action and shall consult with Equinox about the Action so that Equinox can advise EyePoint about potential impacts of the Action outside of the Field, (ii) Equinox shall provide all reasonable cooperation to EyePoint in connection with such Action, (iii) EyePoint shall not take any position with respect to such Action in any way that is reasonably likely to directly and adversely affect the scope, validity or enforceability of the Equinox Patents or Equinox Know-How, or compromise or settle any such Action, without the prior consent of Equinox, which consent shall not be unreasonably withheld, and (iv) if EyePoint does not intend to prosecute or defend an Action, or ceases to diligently pursue such an Action, it shall promptly inform Equinox in such a manner that such Action will not be prejudiced and Section 5.2(c) shall apply.

(c) *Equinox Right to Enforce*. In the event of an Infringement described in Section 5.2(a) or a declaratory judgement action relating to such Infringement, if (i) EyePoint informs Equinox that it does not intend to prosecute an Action in respect of the Equinox Patents or the Equinox Know-How, (ii) within sixty (60) days after notice of Infringement EyePoint has not commenced any such Action, or (iii) if EyePoint thereafter ceases to pursue such Action, then Equinox shall have the right, at its own expense, upon notice to EyePoint to take appropriate action to address such Infringement, including by initiating its own Action or taking over prosecution of any Action initiated by EyePoint. In such event, Equinox shall keep EyePoint fully informed about such Action and EyePoint shall provide all reasonable cooperation to Equinox in connection with such Action.

(d) *Right to Representation*. Each Party shall have the right to participate and be represented by counsel that it selects, in any Action instituted under Section 5.2(b) or 5.2(c) by the other Party. If a Party with the right to initiate an Action to eliminate an Infringement or defend against a declaratory judgement action lacks standing to do so and the other Party has standing to initiate such Action, then the Party with the right to initiate an Action may name the other Party as plaintiff in such Action or may require the Party with standing to initiate such Action at the expense of the other Party.

(e) *Cooperation*. In any Action instituted under this Section 5.2, the Parties shall cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party instituting such Action, the other Party shall join such Action and shall be represented using counsel of its own choice, at the requesting Party's expense; provided, that if EyePoint has informed Equinox that it would not proceed with such Action on the opinion of competent counsel, Equinox may not require EyePoint to join such Action.

(f) *Share of Recoveries.* Except as otherwise provided, the costs and expenses of the Party bringing suit under this Section 5.2 shall be borne by such Party, and any damages or other monetary awards recovered shall be shared as follows: (i) the amount of such recovery actually received by the Party controlling such action shall first be applied to the out-of-pocket costs of each Party in connection with such action; (ii) if EyePoint is the Party controlling such action, then any proceeds that are lost profits damages or a reasonable royalty shall be treated as the equivalent of Annual Net Sales in the Calendar Year in which the recovery is paid (i.e., shall be allocated to EyePoint with Equinox receiving a royalty on the recovery proceeds in accordance with the provisions of Section 4.3), and any remaining proceeds shall be retained by EyePoint; or (iii) if Equinox is the Party controlling such action, then any remaining proceeds shall be retained by Equinox. A settlement or consent judgment or other voluntary final disposition of a suit under this Section 5.2 may not be entered into without the consent of the Party not bringing the suit, which consent shall not be unreasonably withheld.

5.3 Defense of Claims Brought by Third Parties

. In the event that any action, suit or proceeding is brought against either Party or an Affiliate or sublicensee of either Party alleging the infringement of the Know-How or Patents of a Third Party by the making, having made, use, sale, offering for sale or importation of the Compound or a Licensed Product in the Field in the Territory, such Party shall notify the other Party within five (5) days of the earlier of (a) receipt of service of process in such action, suit or proceeding, or (b) the date such Party becomes aware that such action, suit or proceeding has been instituted, and the Parties shall meet as soon as possible to discuss the overall strategy for defense of such matter. EyePoint shall have the right, but not the obligation, to defend such action, suit or proceeding in the Territory at its sole cost and expense. Equinox shall have the right to separate counsel at its own expense in any such action, suit or proceeding, and the Parties shall cooperate with each other in all reasonable respects in any such action, suit or proceeding. Each Party shall promptly furnish the other Party with a copy of each communication relating to the alleged infringement that is received by such Party including all documents filed in any litigation.

5.4 Patent Listing

and Marking. EyePoint will have sole decision-making authority with respect to the determination of which Equinox Patents to list in the FDA's Orange Book with respect to the Licensed Products. EyePoint shall mark all Licensed Products with the relevant Equinox Patent Rights to the extent permitted under Applicable Law.

ARTICLE 6

CONFIDENTIALITY

6.1 Confidentiality; Exceptions

. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that the receiving Party (the

"**Receiving Party**") shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any Know-How or other confidential and proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which is disclosed to it by the other Party (the "**Disclosing Party**") or otherwise received or accessed by a Receiving Party in the course of performing its obligations or exercising its rights under this Agreement (collectively, "**Confidential Information**"), except to the extent that it can be established by the Receiving Party that such Confidential Information:

(a) was in the lawful knowledge and possession of the Receiving Party prior to the time it was disclosed to, or learned by, the Receiving Party, or was otherwise developed independently by the Receiving Party, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual knowledge by the Receiving Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement; or

(d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others.

6.2 Authorized Disclosure

. Except as otherwise provided in this Agreement, a Receiving Party may use and disclose Confidential Information of the Disclosing Party as follows:

(a) under appropriate confidentiality provisions similar to those in this Agreement, in connection with the performance of its obligations or exercise of rights granted or reserved in this Agreement;

(b) to the extent such disclosure is reasonably necessary in filing or prosecuting patent, copyright and trademark applications, prosecuting or defending litigation, complying with applicable governmental regulations, obtaining Regulatory Approval, conducting pre-clinical activities or clinical trials, marketing Licensed Products or otherwise required by Applicable Laws or the rules of a securities exchange or securities listing organization; provided, that if a Receiving Party is required by Applicable Laws to make any such disclosure of a Disclosing Party's Confidential Information it shall, except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure requirement and, except to the extent inappropriate in the case of patent applications, shall use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed;

(c) to existing or prospective advisors, investors, collaborators, (sub)licensees, partners or joint venturers, in each case under appropriate confidentiality provisions substantially equivalent to those of this Agreement;

(d) as reasonably required under the circumstances, to a Third Party in connection with (i) a merger, consolidation or similar transaction by such Party, or (ii) the sale of all or substantially all of the assets of such Party to which this Agreement relates, in each case under appropriate confidentiality provisions substantially equivalent to those of this Agreement, or (iii) to the extent mutually agreed in writing by the Parties.

In each of the above authorized disclosures, the Receiving Party shall remain responsible for any failure by any Person who receives the Confidential Information pursuant to this Section 6.2 to treat such Confidential Information as required under this Article 6.

6.3 Press Release; Disclosure of Agreement

. On or promptly after the Effective Date, the Parties shall issue a public announcement of the execution of this Agreement in the form mutually agreed by the Parties. Except to the extent required by Applicable Laws or the rules of a securities exchange or securities listing organization, neither Party shall issue any other press release or other public disclosure concerning this Agreement, the subject matter hereof or the Parties' activities hereunder, or any results or data arising hereunder, except with the other Party's prior written consent. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of any such press releases and disclosures prior to the issuance thereof, and a Party may not unreasonably withhold consent to such releases and disclosures, and shall give due consideration to any reasonable comments by the non-filing Party relating to such releases and disclosures, including where applicable subject matter for which confidential treatment may be sought. A Party may publicly disclose without regard to the preceding requirements of this Section 6.3 any information that was previously publicly disclosed pursuant to this Section 6.3; provided that such disclosure does not materially alter the meaning of the information disclosed previously.

6.4 Termination of Prior Agreements

. As of the Effective Date, this Agreement supersedes all prior agreements between the Parties, including but not limited to, the Mutual Confidential Disclosure Agreement executed by Equinox and EyePoint and dated December 8, 2017 (the "**CDA**") and the Material Transfer & Evaluation Agreement executed by Equinox and EyePoint and dated October 29, 2019 (the "**MTA**"). All information exchanged between the Parties prior to the Effective Date and/or under the CDA and the MTA shall be deemed Confidential Information hereunder and shall be subject to the terms of this Article 6.

6.5 Remedies

. Each Party shall be entitled to seek, in addition to any other right or remedy it may have, at law or in equity, a temporary injunction, without the posting of any bond or other security, enjoining or restraining the other Party from any violation or threatened violation of this Article 6.

6.6 Clinical Trial Register

. EyePoint shall have the right to publish the results or summaries of results of all clinical trials (including meta-analysis or observational studies) conducted by or on behalf of EyePoint with respect to the Compound or Licensed Products in any clinical trial register maintained by EyePoint or its Affiliates and the protocols of clinical trials relating to the Compound or Licensed Products on www.ClinicalTrials.gov (and/or in each case publish the results, summaries and/or protocols of clinical trials on such other websites and/or repositories as required by Applicable Laws or EyePoint's or its Affiliates' policies). Each such

publication made in accordance with this Section 6.6 shall not be a breach of the confidentiality obligations provided in this Article 6.

6.7 Return of Confidential Information

. Except as otherwise provided in Article 9 of this Agreement, upon termination of this Agreement, each Party hereto and its Affiliates shall use Commercially Reasonable Efforts to return all Confidential Information of the other Party in its possession to the other Party; provided, that each Party may retain: (a) a single archival copy of the Confidential Information of the other Party; and (b) any portion of the Confidential Information of the other Party which is contained in laboratory notebooks or other electronic systems, the deletion from which would not be practicable; in either case, solely for the purpose of determining the extent of disclosure of Confidential Information hereunder, assuring compliance with the surviving provisions of this Agreement, relevant document retention policies of the Party and Applicable Laws.

6.8 Survival

. This Article 6 shall survive the expiration or termination of this Agreement for a period of ten (10) years.

ARTICLE 7

REPRESENTATIONS, WARRANTIES AND COVENANTS

7.1 Representations and Warranties of Both Parties

. Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:

(a) such Party is duly organized, validly existing and in good standing under Applicable Laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) such Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

(c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof, except as enforcement may be affected by bankruptcy, insolvency or other similar laws and by general principles of equity;

(d) the execution, delivery and performance of this Agreement by such Party does not conflict with any material agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party; and

(e) no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Laws currently in effect, is necessary for the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith.

7.2 Representations and Warranties of Equinox

. Equinox hereby represents, warrants, and covenants to EyePoint, as of the Effective Date, that:

(a) Equinox Controls the Equinox Know-How and Equinox Patents existing as of the Effective Date;

(b) Equinox has the right to grant all rights and licenses it purports to grant to EyePoint with respect to the Equinox Know-How and Equinox Patents under this Agreement;

(c) Equinox has no present knowledge that any settled, pending or threatened claim or lawsuit or legal proceeding of a Third Party against Equinox alleging that the Equinox Know-How or Equinox Patents misappropriates or infringes, in part or in whole, the intellectual property or intellectual property rights of any Third Party;

(d) To the knowledge of Equinox, the Equinox Patents do not infringe, in part or in whole, the intellectual property or intellectual property rights of any Third Party;

(e) The Equinox Know-How does not misappropriate or otherwise infringe, in part or in whole, the intellectual property or intellectual property rights of any Third Party;

(f) Equinox has not granted any right or license to any Third Party relating to any of the Equinox Know-How or Equinox Patents that would conflict or interfere with any of the rights or licenses granted to EyePoint hereunder;

(g) **Exhibit A** sets forth a complete and accurate list of the Equinox Patents as of the Effective Date. Equinox has disclosed to EyePoint all material information received by Equinox concerning the institution of any interference, opposition, reexamination, reissue, revocation, nullification or any official proceeding involving any Equinox Patent anywhere in the Territory;

(h) To its knowledge, Equinox has not employed (or use any subcontractor or consultant that employs) any individual or entity debarred by the FDA (or subject to a similar sanction of the EMA), or any individual who or entity which is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA), in the research and development of the Compound prior to the Effective Date; and

(i) Equinox acknowledges that, in entering into this Agreement, EyePoint has relied upon information supplied by Equinox and information which Equinox has caused to be supplied to EyePoint by Equinox's agents and/or representatives, pursuant to the CDA (all of such information being hereinafter referred to collectively as "**Product Information**"). Equinox represents and warrants to EyePoint that, to Equinox's knowledge, the Product Information included in the online data room maintained by Equinox in connection with this Agreement is accurate in all material respects. Equinox further warrants and represents to EyePoint that it has not, as of the Effective Date, intentionally omitted to furnish EyePoint with any material information known to Equinox concerning the Compound or the transactions contemplated by this Agreement, which would reasonably be considered to be material to EyePoint's decision to enter into this Agreement and to undertake the commitments and obligations set forth herein.

7.3 Mutual Covenants

. Each Party hereby covenants to the other Party that:

(a) such Party shall, to the extent applicable, perform its activities pursuant to this Agreement in material compliance with Applicable Laws, including GLP, GMP and good clinical practices; and

(b) such Party shall notify the other Party in writing promptly in the event that it has actual knowledge of the material breach of any covenant under this Section 7.3 or the material breach of any representation or warranty provided by either Party under Section 7.1 or by Equinox under Section 7.2.

7.4 Equinox Covenants

. During the Term, Equinox shall not grant any right or license to any Third Party relating to any of the intellectual property rights it Controls which would conflict or interfere with any of the rights or licenses granted to EyePoint hereunder.

7.5 Disclaimer

. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE OR THAT THEIR EXERCISE DOES NOT INFRINGE ANY PATENT RIGHTS OF THIRD PARTIES AND EXPRESSLY DISCLAIMS ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, EACH PARTY DISCLAIMS ANY WARRANTIES WITH RESPECT TO (A) THE SAFETY OR USEFULNESS FOR ANY PURPOSE OF THE COMPOUND, AND ALL PRODUCTS IT PROVIDES OR DISCOVERS UNDER THIS AGREEMENT, AND (B) THE VALIDITY, ENFORCEABILITY, OR NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OR TECHNOLOGY IT PROVIDES OR LICENSES TO THE OTHER PARTY UNDER THIS AGREEMENT.

7.6 LIMITATION OF LIABILITY

. EXCEPT FOR A BREACH OF ARTICLE 6 OR FOR ACTS OF GROSS NEGLIGENCE OR WRONGFUL INTENTIONAL ACTS OR OMISSIONS, NEITHER EQUINOX NOR EYEPOINT, NOR ANY OF THEIR AFFILIATES OR SUBLICENSEES SHALL BE LIABLE TO THE OTHER PARTY, ITS AFFILIATES OR ANY OF THEIR SUBLICENSEES FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, RELIANCE OR PUNITIVE DAMAGES OR LOST OR IMPUTED PROFITS, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE; PROVIDED, THAT THIS LIMITATION WILL NOT LIMIT THE INDEMNIFICATION OBLIGATION OF A PARTY UNDER THE PROVISIONS OF ARTICLE 8 FOR SUCH DAMAGES CLAIMED BY A THIRD PARTY.

ARTICLE 8

INDEMNIFICATION

8.1 Indemnification by EyePoint

. EyePoint shall indemnify, defend and hold harmless Equinox, and its Affiliates, and its or their respective directors, officers, employees and agents, from and against any and all liabilities, damages, losses, costs and expenses including the reasonable fees of attorneys and other professionals (collectively, "**Losses**"), arising out of or resulting from any and all Third Party suits, claims, actions, proceedings or demands ("**Claims**") based upon:

(a) the gross negligence or wrongful intentional acts or omissions of EyePoint and/or its Affiliates and/or its or their respective directors, officers, employees and agents, in connection with EyePoint's performance of its obligations or exercise of its rights under this Agreement;

(b) any breach of any representation or warranty or express covenant made by EyePoint under Article 7 or any other provision under this Agreement; or

(c) the research, development and commercialization activities conducted by or on behalf of EyePoint, its Affiliates, subcontractors or Sublicensees of the Compound or Licensed Products;

except, in each case of 8.1(a) through 8.1(c) (inclusive), to the extent Equinox is obligated to indemnify EyePoint with respect to such Losses under Section 8.2.

8.2 Indemnification by Equinox

. Equinox shall indemnify, defend and hold harmless EyePoint and its Affiliates, and its or their respective directors, officers, employees and agents, from and against any and all Losses, arising out of or resulting from any and all Third Party Claims based upon:

(a) the gross negligence or wrongful intentional acts or omissions of Equinox and/or its Affiliates and/or its or their respective directors, officers, employees and agents, in connection with Equinox's performance of its obligations or exercise of its rights under this Agreement;

(b) any breach of any representation or warranty or express covenant made by Equinox under Article 7 or any other provision under this Agreement;

(c) the research, development and commercialization activities conducted by or on behalf of Equinox, its Affiliates, subcontractors or sublicensees of the Compound;

except, in each case of 8.2(a) through 8.2(c) (inclusive), to the extent EyePoint is obligated to indemnify Equinox with respect to such Losses under Section 8.1.

8.3 Procedure

. In the event that any person (an "**Indemnitee**") entitled to indemnification under Section 8.1 or Section 8.2 is seeking such indemnification, such Indemnitee shall (a) inform, in writing, the indemnifying Party of the Claim as soon as reasonably practicable

after such Indemnitee receives notice of such Claim, (b) permit the indemnifying Party to assume direction and control of the defense of the Claim (provided, that the indemnifying Party may not settle the Claim without the prior consent of the Indemnitee, not to be unreasonably withheld), (c) cooperate as reasonably requested (at the expense of the indemnifying Party) in the defense of the Claim, and (d) undertake all reasonable steps to mitigate any loss, damage or expense with respect to the Claim(s). Without limiting the foregoing, any Indemnitee will be entitled to participate in the defense of a Claim for which it has sought indemnification hereunder and to employ counsel of its choice for such purpose; provided, that such employment will be at the Indemnitee's own expense unless (i) the employment thereof has been specifically authorized by the indemnifying Party in writing, or (ii) the indemnifying Party has failed to assume the defense (or continue to defend such Claim in good faith) and employ counsel in accordance with this Section 8.3, in which case the indemnified Party will be allowed to control the defense.

ARTICLE 9

TERM AND TERMINATION

9.1 Term; Expiration

. The term of this Agreement (the "**Term**") shall begin on the Effective Date and, unless earlier terminated pursuant to the other provisions of this Article 9, shall expire on a Licensed Product-by-Licensed Product and country-by-country basis on the date of the expiration of all applicable Royalty Terms under Article 4 of this Agreement. Upon expiration of the Term, EyePoint shall have a fully paid-up, non-exclusive, perpetual license to use the applicable Equinox Patents and Equinox Know-How to research, develop, make, have made, use, sell, offer for sale and import the applicable Licensed Product in the Field in the applicable country.

9.2 Termination for Cause

.

(a) *Termination for Material Breach*. Either Party (the "**Non-Breaching Party**") may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in the event the other Party (the "**Breaching Party**") shall have materially breached or defaulted in the performance of its obligations under this Agreement and such default shall have continued for ninety (90) calendar days after written notice thereof was provided to the Breaching Party by the Non-Breaching Party, such notice describing with particularity and in detail the alleged material breach. Any such termination of this Agreement under this Section 9.2(a) shall become effective at the end of such ninety (90) calendar day period, unless the Breaching Party has either (i) cured any such breach or default prior to the expiration of such ninety (90) calendar day period, or (ii) if such breach is not susceptible to cure within such ninety (90) calendar day period, the Breaching Party has, within thirty (30) calendar days from notice of such breach or default, provided to the Non-Breaching Party a written plan to effect a cure that the Non-Breaching Party notifies the Breaching Party is reasonably satisfactory to the Non-Breaching Party. If the Non-Breaching Party rejects this plan, then the Breaching Party may either (a) seek dispute resolution pursuant to Section 9.2(b) herein, or (b) allow the Non-Breaching Party to terminate the Agreement without further action. In the event that the Non-Breaching Party has accepted any plan in accordance with the preceding sentences, the Non-Breaching Party may terminate this Agreement immediately upon written notice to the Breaching Party if the Breaching Party subsequently fails to carry out such plan. The right of either Party to terminate this

Agreement as provided in this Section 9.2(a) shall not be affected in any way by such Party's waiver or failure to take action with respect to any previous default.

(b) *Disagreement.* If the Parties reasonably and in good faith disagree as to whether there has been a material breach, the Party which seeks to dispute that there has been a material breach may contest the allegation in accordance with Sections 10.1 and 10.2.

9.3 EyePoint Unilateral Termination Right

. EyePoint shall have the right, at its sole discretion and without any penalty or liability, exercisable at any time during the Term, to terminate this Agreement for any reason or no reason at all upon ninety (90) calendar days' prior written notice to Equinox.

9.4 Termination for Insolvency

. In the event that either Party makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act in any state or country or has any such petition filed against it which is not discharged within sixty (60) calendar days of the filing thereof, then the other Party may thereafter terminate this Agreement effective immediately upon written notice to such Party. In connection therewith, all rights and licenses granted under or pursuant to any section of this Agreement are and shall otherwise be deemed to be for purposes of Section 365(n) of Title 11, United States Code (the "**Bankruptcy Code**") licenses of rights to "intellectual property" as defined in Section 101(56) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of Equinox, EyePoint shall further be entitled to a complete duplicate of, or complete access to, any such intellectual property, and such, if not already in its possession, shall be promptly delivered EyePoint, unless Equinox elects to continue, and continues, to perform all of its obligations under this Agreement.

9.5 Effects of Termination

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(a) *Upon Unilateral Termination by EyePoint; Termination by Equinox for Cause or Insolvency*. In the event of (1) termination of this Agreement by EyePoint pursuant to Section 9.3, or (2) termination of this Agreement by Equinox pursuant to Sections 9.2 or 9.4, the following terms shall apply:

(i) all rights and licenses granted to EyePoint by Equinox under this Agreement shall terminate; and

(ii) the Parties shall have no further obligation to perform any activities under this Agreement other than as provided for or referenced in this Section 9.5 or in Section 9.6, and EyePoint shall cease any and all development and commercialization activities relating to the Compound and Licensed Products;

(iii) EyePoint shall comply with its obligations pursuant to Sections 6.7 and 9.6;

(iv) with respect to any ongoing clinical trials of the Compound conducted by EyePoint, (1) EyePoint shall wind down the conduct of such clinical trials as

soon as reasonably practicable, subject to requirements of Applicable Law, and (2) until such time as the conduct of such clinical trials has been successfully terminated, EyePoint shall continue such clinical trials at its sole cost; and

(v) subject to Section 6.7, EyePoint shall promptly return to Equinox, at no cost to Equinox, all tangible Equinox Know-How and Confidential Information of Equinox and shall transfer and assign to Equinox all Patent Rights and Know-How (including without limitation regulatory filings and clinical trial results) relating to the Compound or any Licensed Product, but only to the extent such Patent Rights and Know-How consist of or are derived from Equinox Know-How or Confidential Information. For purposes of clarity, this subsection (v) does not require EyePoint to transfer any of EyePoint's Know-How or Patent Rights to Equinox, and any proposed transfer of EyePoint's Know-How or Patent Rights will be subject to separate negotiation and definitive agreement.

(b) *Upon Termination by EyePoint for Cause or Insolvency.* In the event of a termination of this Agreement by EyePoint pursuant to Section 9.2 or Section 9.4, the following terms shall apply:

(i) the Parties shall have no further obligation to perform any activities under this Agreement other than as provided for or referenced in this Section 9.5(b) or in Section 9.6;

(ii) At EyePoint's option, (1) Equinox shall grant to EyePoint a perpetual, exclusive, irrevocable license, with the right to grant sublicenses (including through multiple tiers of sublicensees), under the Equinox Patents and Equinox Know-How that are necessary to permit EyePoint to continue to conduct further research, development, manufacturing and commercialization of the Compound and Licensed Products in the Field in the Territory, (2) if not completed at the time of termination, the Parties shall complete the technology transfer of Equinox Know-How to EyePoint in accordance with Section 3.9, and (3) in consideration of the license granted under subsection (1) above, EyePoint shall make milestone payments to Equinox under Section 4.2 at [***], when and if they become due, and shall pay Equinox royalties in accordance with Section 4.3 at [***].

9.6 Accrued Rights; Surviving Provisions of this Agreement

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(a) Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration and any and all damages arising from any breach hereunder. Such termination or expiration shall not relieve any Party from obligations which are expressly indicated to survive termination of this Agreement.

(b) The following provisions shall survive the termination or expiration of this Agreement for any reason, in accordance with their respective terms and conditions, and for the duration stated, and where no duration is stated, shall survive for so long as required to give effect

to the subject matter of the provision: Section 3.6, Article 6, Sections 7.5, 7.6, Articles 8, 9 and 10, as well as any applicable definitions in Article 1 and any other provisions which are expressed to survive termination or expiration or which are required to give effect to such termination or expiration.

ARTICLE 10

MISCELLANEOUS

10.1 Dispute Resolution

. Unless otherwise set forth in this Agreement, in the event of a dispute arising under this Agreement between the Parties, either Party shall have a right to refer such dispute to the respective Executive Officers, and such Executive Officers shall attempt in good faith to resolve such dispute. If the Parties are unable to resolve a given dispute pursuant to this Section 10.1 within thirty (30) calendar days of referring such dispute to the Executive Officers, either Party may have the dispute settled by binding arbitration pursuant to Section 10.2.

10.2 Arbitration Request

. A Party intending to commence an arbitration proceeding to resolve a dispute must first provide written notice (the "**Arbitration Request**") to the other Party of such intention, setting forth the issues for resolution, not less than ten (10) calendar days prior to submitting the dispute to arbitration in accordance with this Section 10.2. From the date of the Arbitration Request until such time as the dispute has become finally settled, the time period during which a Breaching Party must cure an alleged breach that is the subject matter of the dispute shall be suspended.

(a) *No Arbitration of Patent/Confidentiality Issues*. Unless otherwise agreed by the Parties, disputes to the extent relating to Patents and Know-How and non-disclosure, non-use and maintenance of Confidential Information shall not be subject to arbitration, and shall be submitted to a court of competent jurisdiction.

(b) *Arbitration Procedure*. The arbitration shall be held in Boston, Massachusetts, United States under the commercial arbitration rules of the American Arbitration Association ("**AAA**"). The arbitration shall be conducted by one (1) arbitrator who shall (a) be a lawyer of not less than fifteen (15) years' standing who is knowledgeable in the law concerning the subject matter at issue in the dispute, (b) not be or have been an employee, consultant, officer, director or stockholder of either Party or any Affiliate of either Party, and (c) not have a conflict of interest under any applicable rules of ethics. The arbitrator shall be selected by mutual agreement of the Parties, provided that if the Parties cannot agree on the arbitrator within ten (10) Business Days of the submission of the dispute to arbitration, the arbitrator shall be selected by the Boston office of the AAA. The arbitrator may proceed to an award, notwithstanding the failure of either Party to participate in the proceedings. The arbitrator shall, within fifteen (15) calendar days after the conclusion of the arbitration hearing, issue a written award. The arbitrator shall be authorized to award compensatory damages, but shall not be authorized to award non-economic damages or punitive, special, consequential, or any other similar form of damages. The arbitrator also shall be authorized to grant any temporary, preliminary or permanent equitable remedy or relief the arbitrator deems just and equitable and within the scope of this Agreement, including an injunction or order for specific performance, but is not authorized to reform, modify or materially change this Agreement. The award of the arbitrator shall be the sole and exclusive remedy of the

Parties (except for those remedies set forth in this Agreement), the Parties hereby expressly agree to waive the right to appeal from the decisions of the arbitrator, and there shall be no appeal to any court or other authority (government or private) from the decision of the arbitrator. Judgment on the award rendered by the arbitrator may be enforced in any court having competent jurisdiction thereof, subject only to it being vacated on grounds of fraud or clear bias on the part of the arbitrator, as demonstrated by clear and convincing evidence. Notwithstanding anything contained in this Section 10.2 to the contrary, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through or under such other Party, in order to vacate or confirm an award of the arbitrator, to enforce the instituting Party's rights hereunder through specific performance, injunction or other equitable relief, or to collect any monetary award of the arbitrator.

(c) *Costs*. Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators.

(d) *Preliminary Injunctions*. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrators on the ultimate merits of any dispute.

(e) *Confidentiality*. All proceedings and decisions of the arbitrators shall be deemed Confidential Information of each of the Parties, and shall be subject to Article 6.

10.3 Governing Law

. This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the laws of the State of Delaware without reference to conflicts of laws principles which would direct the application of the laws of another jurisdiction.

10.4 Assignment

. Neither this Agreement nor any obligation of a Party hereunder may be assigned by either Party without the consent of the other which shall not be unreasonably withheld, except that each Party may assign this Agreement and the rights, obligations and interests of such Party, in whole or in part, to any of its Affiliates, to any purchaser of all or substantially all of its assets or all or substantially all of its assets to which this Agreement relates, or to any successor corporation resulting from any merger, consolidation, share exchange or other similar transaction; provided, that in each instance the assignee or resulting entity in such transaction (if not the Party) expressly assumes all obligations imposed on the assigning Party by this Agreement in writing. This Agreement shall bind and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. Any purported assignment in violation of this Section 10.4 shall be null and void.

10.5 Performance Warranty

. Each Party hereby acknowledges and agrees that it shall be responsible for the full and timely performance as and when due under, and observance of all the covenants, terms, conditions and agreements set forth in, this Agreement by its Affiliate(s) and, as applicable, sublicensees.

10.6 Force Majeure

. Neither EyePoint nor Equinox shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to any occurrence beyond the reasonable control of a Party that (a) prevents or substantially interferes with the performance by such Party of any of its obligations hereunder, and (b) occurs by reason of any act of God, flood, fire, explosion, earthquake, strike, lockout, labor dispute, casualty or accident, or war, revolution, civil commotion, act of terrorism, blockage or embargo, or any injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government or of any subdivision, authority or representative of any such government (a "**Force Majeure**"). In event of such Force Majeure, the Party affected shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

10.7 Notices

. Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), overnight express courier service (signature required), prepaid, or by email (with a duplicate copy by another method of notice) to the Party for which such notice is intended, at the address set forth for such Party below:

If to Equinox, addressed to:

11780 U.S. Hwy One, Suite 202
Palm Beach Gardens, FL 33408
Attn: Chief Operating Officer
Email: kevin.sang@xcovery.com

If to EyePoint, addressed to:

EyePoint Pharmaceuticals, Inc.
480 Pleasant Street
Watertown, MA 02472
Attention: Ron Honig
Facsimile: 617-926-5050
Email: rhonig@eyepointpharma.com

or to such other address for such Party as it shall have specified by like notice to the other Parties, provided, that notices of a change of address shall be effective only upon receipt thereof. If delivered personally or by confirmed facsimile or email transmission, the date of delivery shall be deemed to be the date on which such notice or request was given. Notwithstanding the foregoing, any notice delivered outside normal business hours (which shall for these purposes mean in the country of the recipient of the notice) then delivery shall be deemed to occur on the Business Day following such delivery. If sent by overnight express courier service, the date of delivery shall be deemed to be the next Business Day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery shall be deemed to be the third (3rd) Business Day after such notice or request was deposited with the U.S. Postal Service.

10.8 Waiver

. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term.

10.9 Severability

. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

10.10 Independent Contractors

. Nothing herein shall be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. The Parties shall not have the authority to bind or obligate the other Party and neither Party shall represent that it has such authority.

10.11 Headings; Interpretation

. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. Further, in this Agreement: (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression; (b) the singular shall include the plural and vice versa; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable. A Party includes its permitted assignees and/or the respective successors in title to substantially the whole of its undertaking. A statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended, restated, modified, supplemented, or re-enacted. The Exhibits and other attachments form part of the operative provisions of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the recitals and the Exhibits and attachments. References to pharmaceutical products, preparations, ingredients, and the like, include biologics and biopharmaceuticals, as applicable.

10.12 Further Actions

. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be reasonably necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.

10.13 Construction of Agreement

. The terms and provisions of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms and provisions of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereto hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of law to the effect that ambiguous

or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement.

10.14 Supremacy

. In the event of any express conflict or inconsistency between this Agreement and any Exhibit hereto, the terms of this Agreement shall control. The Parties understand and agree that the Exhibits hereto are to be updated from time to time during the Term, as appropriate, and in accordance with the provisions of this Agreement.

10.15 Counterparts

. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

10.16 Entire Agreement

. This Agreement, together with the Exhibits hereto, sets forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and supersedes and terminates all prior agreements and understandings between the Parties, including the CDA and the MTA. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.

* - * - * - *

IN WITNESS WHEREOF, the Parties have caused this Exclusive License Agreement to be executed by their duly authorized representatives as of the Effective Date.

EYEPOINT PHARMACEUTICALS, INC.

By: /s/ Nancy Lurker
Name: Nancy Lurker
Title: President and CEO

EQUINOX SCIENCE, LLC

By: /s/ Kevin Sang
Name: Kevin Sang
Title: COO

EXHIBIT A

EQUINOX PATENTS

[***]

Exhibit 21.1

List of Subsidiaries of EyePoint Pharmaceuticals, Inc.

Subsidiary Name	Jurisdiction of Incorporation
EyePoint Pharmaceuticals US, Inc.	Delaware
pSiMedica Limited	United Kingdom
EyePoint Pharmaceuticals Securities Corporation	Massachusetts
Icon Bioscience, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-152146, 333-163208 and 333-216166, 333-227525 and 333-233137 on Form S-8 and Registration Nos. 333-226341 and 333-228581 on Form S-3 of our reports dated March 13, 2020, relating to the financial statements of EyePoint Pharmaceuticals, Inc. and subsidiaries (which report expresses an unqualified opinion and includes explanatory paragraphs relating to a change in accounting principle and going concern), and the effectiveness of Eyepoint Pharmaceutical Inc. and subsidiaries' internal control over financial reporting, appearing in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 13, 2020

Exhibit 31.1

Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.

CERTIFICATIONS

I, **Nancy Lurker**, certify that:

1. I have reviewed this Annual Report on Form 10-K of **EYEPOINT 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 13, 2020

/s/ Nancy Lurker
Name: Nancy Lurker
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.

CERTIFICATIONS

I, **George Elston**, certify that:

1. I have reviewed this Annual Report on Form 10-K of **EYEPOINT 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 13, 2020

/s/ George Elston
Name: George Elston
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 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.

In connection with the Annual Report of EyePoint Pharmaceuticals, Inc. (the "Company") on Form 10-K for the twelve months ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nancy Lurker, President and Chief Executive Officer of the Company, certify that to the best of my knowledge:

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

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

Date: March 13, 2020

/s/ Nancy Lurker

Name: Nancy Lurker
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

In connection with the Annual Report of EyePoint Pharmaceuticals, Inc. (the "Company") on Form 10-K for the twelve months ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George Elston, Chief Financial Officer of the Company, certify that to the best of my knowledge:

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

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

Date: March 13, 2020

/s/ George Elston

Name: George Elston
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)