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

or

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

For the transition period from July 1, 2018 to December 31, 2018

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	**Name of each exchange on which registered**
Common Stock, $.001 par value per share	**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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 29, 2018, the last trading day of the registrant's most recently completed second fiscal quarter, was approximately $101,471,000.

There were 95,374,236 shares of the registrant's common stock, $0.001 par value, outstanding as of March 13, 2019.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Transition Report on Form 10-K incorporates certain information by reference from the registrant's proxy statement for the 2019 annual meeting of stockholders to be filed no later than 120 days after the end of the transition period ended December 31, 2018.

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Preliminary Note Regarding Forward-Looking Statements

Various statements made in this Transition 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 commercialization of DEXYCU and YUTIQ;
- our expectations regarding the timing of release of 36-month patient follow-up data for YUTIQ;
- our expectations regarding the timing of a line extension application for approval of our YUTIQ next-generation, shorter-duration treatment for non-infectious posterior segment uveitis (“NIPU”);
- 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 borrowing availability under our February 2019 term loan facility with CRG to fund our operations through calendar year 2019;
- 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 ability to establish or maintain collaborations and obtain milestone, royalty and/or other payments from any such collaborators;
- the ability of Alimera Sciences, Inc., or Alimera, to obtain regulatory approval of and commercialize ILUVIEN® for the treatment of NIPU in Europe, the Middle East and Africa;
- 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 expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for DEXYCU, YUTIQ 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; 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: our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; our ability to successfully produce commercial supply of YUTIQ and DEXYCU and successfully commercialize YUTIQ and DEXYCU in the U.S.; our ability to successfully build a commercial infrastructure and enter into and maintain commercial agreements for the launch of YUTIQ and DEXYCU; the successful release of our YUTIQ line extension shorter-acting treatment for NIPU; potential off-label sales of ILUVIEN for NIPU;

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 ("DME"); Alimera's ability to obtain additional marketing approvals and the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; Alimera's ability to obtain marketing approval for ILUVIEN in its licensed territories for NIPU; potential declines in Retisert® royalties; our ability to market and sell products; the success of current and future license agreements; termination or breach of current license agreements; 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 stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. 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 Transition 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.

We have received Notices of Allowance from the U.S. Patent and Trademark Office, or the USPTO, for trademarks DEXYCU™, YUTIQ™, DELIVERING INNOVATION TO THE EYE™ and Durasert™ in the U.S. 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, or the SEC, including this Transition 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

Transition Period

On November 1, 2018, our Board of Directors approved a change in our fiscal year end from June 30 to December 31, effective immediately. The reporting period for this Transition Report on Form 10-K is for the six months ended December 31, 2018. In this Transition Report, our fiscal years are identified according to the calendar year in which they historically ended (e.g., the fiscal year ended June 30, 2018 is referred to as "fiscal 2018", June 30, 2017 is referred to as "fiscal 2017" and June 30, 2016 is referred to as "fiscal 2016", as if we had not changed our fiscal year to a calendar year on November 1, 2018. References in this Transition Report to "fiscal 2019" refer to the year ending December 31, 2019.

Overview

We are a specialty biopharmaceutical 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 have been launched directly in the U.S. during the first quarter of 2019.

YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg for intravitreal injection, was approved by the FDA in October 2018 and we launched YUTIQ 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 ("NIPU"). YUTIQ is a non-bioerodible intravitreal implant in a drug delivery system 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 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. 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. In the U.S., NIPU affects between 55,000 to 120,000 people each year, causes approximately 30,000 new cases of blindness every year and is the third leading cause of blindness. NIPU is typically treated by retina and uveitis specialists. The standard of care treatment for NIPU involves the use of corticosteroids to reduce uveitic flares and then additional treatments of sustained release, lower dose steroids to reduce the risk of further flares. Prior to the launch of YUTIQ, the standard of care treatment involving steroids provided sustained release of steroids over a period of 3 to 4 months. In contrast, YUTIQ is designed to release FA continuously, for up to 36 months. We launched YUTIQ initially with 10 dedicated key account managers ("KAMs") hired through a contract sales organization ("CSO"), which are led by our internal sales management team and supported by our market access, marketing and commercial sales operations teams.

DEXYCU™ (dexamethasone intraocular suspension) 9%, for intraocular administration, was approved by the FDA in February 2018 for the treatment of post-operative ocular inflammation. 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 platform, which allows for a single intraocular injection that releases dexamethasone, a corticosteroid, for up to 22 days. We launched DEXYCU in March 2019 with a primary focus on its use immediately following cataract surgery. There are approximately 4.8 million cataract surgeries performed annually in the U.S., growing at an estimated annual rate of approximately 8%. Prior to the launch of DEXYCU, the standard of care for post-operative treatment of cataract surgery for the reduction of inflammation and pain has been a combination of steroid, antibiotic and non-steroidal eye drops administered several times each day over a period of several weeks. DEXYCU was launched initially with 34 dedicated KAMs hired through our CSO, which are supported by our market access, marketing and commercial sales management teams. Effective October 2018, DEXYCU was granted "pass through status" by the Centers for Medicare & Medicaid Services ("CMS") that provides for reimbursement separate from the cataract procedure for a 3-year period. The 3-year period commences in the quarter that the first claim for reimbursement for DEXYCU is made with CMS. 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.

We own the worldwide rights to all indications for DEXYCU. We own the rights for YUTIQ in the U.S. and all foreign jurisdictions and have licensed these rights as described below in Europe, the Middle East and Africa ("EMEA") and the greater China territory. 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. This may be accomplished through our internal discovery efforts, our 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.

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 subject to EMEA regulatory approval, ILUVIEN for NIPU, licensed to Alimera Sciences, Inc. ("Alimera") and (ii) Retisert® for the treatment of posterior segment uveitis licensed to Bausch & Lomb.

We also earn collaborative research and development revenues from other arrangements, including upfront fees, research funding and development, regulatory and/or sales milestones. 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) an exclusive license agreement with Ocumension Therapeutics ("Ocumension") for the development and commercialization of our Durasert three-year treatment of posterior segment uveitis in the greater China territory. We also undertake feasibility study agreements which generally include formulation and other pre-clinical studies designed to evaluate the use of our Durasert technology platform, or 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, or AMD, diabetic retinopathy, DME and NIPU. 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 are not an effective means of delivering a steady state dose to the site of disease.

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. Injecting drugs in solution directly into the back of the eye can achieve effective, but often transient, dosage levels in the eye, requiring repeated injections. In addition to the issues of inconvenience, cost and noncompliance, repeated intravitreal injections have medical risks, including intraocular infection, perforated sclera and vitreous hemorrhage.

Ophthalmic drugs, whether drops, injections or oral dosage forms, are often not administered on the optimal schedule or at all, because patients do not self-administer as prescribed or do not get medical professional administration as required. 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.

Due to the drawbacks of traditional delivery, we believe the development of methods to deliver drugs to patients in a more precise, controlled fashion over sustained periods of time satisfies an unmet medical need by assuring compliance to the prescribed treatment regimen. Our DEXYCU and YUTIQ products are intended to address diseases of both the anterior and posterior segments of the eye, respectively, through long-acting and sustained delivery technologies.

Strategy

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

- **Launch and maximize the commercial potential of DEXYCU for post-operative inflammation.** In February 2018, the FDA approved DEXYCU for the treatment of postoperative inflammation following ocular surgery. DEXYCU is the first long-acting intraocular product approved by the FDA for the treatment of postoperative inflammation. We launched DEXYCU in the U.S. in early March 2019.
- **Launch and maximize the commercial potential of YUTIQ for NIPU.** In October 2018, the FDA approved YUTIQ for the treatment of NIPU. NIPU is a high unmet need area with limited treatment options and the third leading cause of blindness in the U.S. We launched YUTIQ in the U.S. in February 2019.
- **Acquire or in-license ophthalmology products or product candidates developed by third parties.** We plan to expand our commercial portfolio of treatments for eye disease by evaluating for acquisition and/or in-licensing approved ophthalmology products or product candidates in late stage clinical development.
- **Leverage our Durasert and Verisome technologies.** We plan to use our proprietary Durasert and Verisome drug delivery technology platforms to independently develop new drug delivery products that use already-approved drugs to treat ophthalmic and other diseases, while continuing to leverage our technology platforms through collaborations and 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. We believe that our proven track record of five approved products, all providing sustained release of previously approved drugs, reflects the benefits of this strategy.

- **Develop Sustained Delivery of Off-Patent Drugs.** Many drugs are now, or will soon be, off-patent. It is estimated that over the next several years, patent coverage will end on products with world-wide sales aggregating billions of dollars annually. We are using our technology platforms to evaluate potential product candidates that deliver off-patent drugs, primarily focused on ocular diseases with significant market opportunities, where less frequent dosing through sustained delivery and/or targeted delivery at the treatment site would materially improve the effectiveness, safety or convenience of the original drug. By focusing on delivery of already-approved drugs, particularly those requiring potentially shorter clinical development programs, we believe we may be able to reduce the substantial risks and financial investment required for product approval.
- **Continue Partnering with Leading Biopharmaceutical and Pharmaceutical Companies.** We intend to continue to partner with leading biopharmaceutical and pharmaceutical companies, institutions and others, where patent protection, development and regulatory costs, expertise and/or other factors make it desirable for us to have a partner. For example, drugs that might be more effectively delivered by our technology platforms or may have extended patent protection could make collaborations with the patent holders attractive. We may also seek to partner the development of product candidates that could materially benefit from sustained delivery but would require expensive clinical trials or are in treatment areas outside of our technical expertise. We may also seek to partner with companies with drugs coming off patent where our drug delivery technologies could offer an improved product and effectively extend patent protection.

Our Products and Product Candidates

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

Product	Disease	Approved Products	Partner
DEXYCU	Ocular post-surgical inflammation	FDA-approved; U.S. product launch in March 2019	None
YUTIQ	NIPU	FDA-approved; U.S. product launch in February 2019	None
ILUVIEN	DME	Approved in the U.S. and 17 EU countries; direct commercialization in the U.S., U.K., Germany, Portugal, Ireland and Austria; distribution rights through sublicense partners in Spain, Italy, France, Canada and various countries in the Middle East	Alimera
RETISERT	NIPU	FDA-approved; commercialized in the U.S. since 2005	Bausch & Lomb
VITRASERT	CMV retinitis	FDA-approved; commercialized from 1996 through 2012 (patent expiration)	Bausch & Lomb
Line Extension Candidate	**Disease**	**Stage of Development**	**Partner**
YUTIQ short-acting	NIPU	Nonclinical bioequivalence and safety studies	None
Product Candidate	**Disease**	**Stage of Development**	**Partner**
ILUVIEN	NIPU	Type II variation accepted for review in the 17 EU countries previously approved for ILUVIEN for DME	For EMEA: regulatory, reimbursement and distribution licensed to Alimera
Durasert FA	NIPU	Pending clinical trials	For greater China territory: development, regulatory, reimbursement and distribution licensed to Ocumension
Durasert TKI	Wet AMD	Pre-clinical	None

DEXYCU

DEXYCU was approved by the FDA in February 2018.

DEXYCU is the first long-acting intraocular product approved by the FDA for the treatment of post-operative ocular inflammation such as treatment following cataract surgery. Cataract surgery is one of the most frequent surgical procedures performed in the U.S., with approximately 4.8 million procedures performed annually. However, patients can experience post-operative ocular inflammation. Under the current standard of care for inflammation associated with cataract surgery, patients, many of whom are elderly, must self-administer medicated eye drops several times a day over a period of several weeks. DEXYCU, administered as a single intraocular injection at the conclusion of surgery, utilizes our Verisome technology to dispense a biodegradable extended-release formulation of dexamethasone, a corticosteroid, in the chamber of the anterior segment, directly behind the iris. We believe that a single administration of a corticosteroid at the site of inflammation may benefit patients by eliminating non-compliance and dosing errors associated with the current practice of dispensing multiple daily self-administered eye drops following cataract surgery over a period of several weeks.

DEXYCU Phase 3 Clinical Trial

The efficacy of DEXYCU was 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, or 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, or 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.

The FDA-approved dosage of DEXYCU is 0.005 milliliters, or 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 a steady release of dexamethasone for up to 22 days post-injection.

DEXYCU Market Opportunity

DEXYCU is approved for ocular post-surgical inflammation. The primary indication we will focus on for DEXYCU is post-operative inflammation associated with cataract surgery. Approximately 4.8 million cataract surgeries are performed annually in the U.S. The current standard of care in the U.S. for treating post-operative inflammation is primarily a combination of steroid, antibiotic and non-steroidal eye drops. The steroid eye drop requires a tapered treatment regimen that can last up to four weeks. This eye drop treatment regimen is complicated and can result in up to 100 eye drops being administered over time. 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. Many patients schedule cataract surgery in their second eye within a few weeks after the first and, as such, this tapered dosing schedule applies differently to each eye. 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 failing to administer eye drops according to the prescribed schedule, or administering an eye drop but failing to have it go into the eye, and/or not finishing the treatment regimen. In addition, patients often call their physician’s office multiple times to have them re-explain the treatment regimen. We believe DEXYCU addresses many of these issues and potentially eliminates the need for post-surgical steroid eye drops by providing one injection immediately post-surgery into the same incision site where the new intraocular lens has been placed. We believe physicians will react positively to this single injection because the full steroid dose will be placed at the surgical site where inflammation can occur post-surgery.

Claims 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 ambulatory surgical center, 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.

DEXYCU qualified for Medicare transitional pass-through payment and we subsequently received a J-code from CMS, which became effective on January 1, 2019. We have established a Wholesale Acquisition Cost, or WAC, at a level that we believe is sufficient to ensure that we will continue to qualify for pass-through status after including normal industry discounts and rebates associated with arriving at an Average Sales Price, or ASP. Based upon our anticipated ASP and the number of cataract surgeries performed each year, we believe the total addressable market for DEXYCU is in excess of $2.4 billion.

DEXYCU Intellectual Property

Our DEXYCU U.S. patent portfolio includes two issued patents 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.

YUTIQ is based on our Durasert technology platform and consists of an injectable, sustained-release micro-insert approved by the FDA for the treatment of NIPU. YUTIQ, is designed to provide sustained release of a total of 0.18 mg of the off-patent corticosteroid FA at a controlled rate directly to the back of the eye for up to 36 months from a single administration performed in an office visit. 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 China, Hong Kong, Macau and Taiwan (the “greater China territory”).

NIPU is a chronic, non-infectious 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., NIPU is estimated to affect approximately 55,000—120,000 people, resulting in approximately 30,000 cases of blindness and making it the third leading cause of blindness in the U.S. Patients with NIPU 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 NIPU market in the U.S. is relatively modest in size, with an estimated patient prevalence for NIPU of approximately 55,000 to 120,000 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 will be reimbursed using a previously issued J Code. We have applied for a specific J-code relating to YUTIQ which, if granted, would be effective January 1, 2020. Based upon our anticipated ASP and the approximate number of patients requiring treatment we estimate the total addressable market for YUTIQ to be in excess of $550 million.

Outside of the U.S., we expanded our 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 reported that it plans to commercialize the NIPU EMEA indication under its ILUVIEN trademark.

In November 2018, we out-licensed to Ocumension the clinical development, regulatory, reimbursement and distribution rights for Durasert FA in the greater China territory. Clinical trial requirements have not yet been determined with the Chinese regulatory authorities. Assuming a three-year patient follow-up requirement for enrolled patients, it will likely take several years for Ocumension to complete clinical trials and obtain regulatory approval for Durasert FA in their licensed territory. 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, especially those affecting the hard 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 Sciences, Inc., or 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, YUTIQ and our YUTIQ short duration line extension candidate are designed to be injected at the target site in an office visit. Currently, the Durasert technology platform utilizes a miniaturized, injectable, sustained-release insert for small molecules that can deliver a drug for up to three years. Other than for the YUTIQ shorter acting line extension candidate, this insert is only 3.5 mm in length with an external diameter of just 0.37 mm. The insert can be administered in an office setting through a needle as small as 25-gauge. In these products and product candidate, a drug core is surrounded with one or more polymer layers, and the permeability of those layers and other design aspects of the product or product candidate 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.

Our Durasert technology platform is designed to address the issue of sustained delivery for ophthalmic diseases and conditions. Specifically, our Durasert platform features:

- *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 studies 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 is scheduled to be completed for 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 24 months of follow up ($p < 0.001$, intent to treat analysis; recurrence of 59.8% for YUTIQ versus 97.6% for control). YUTIQ was generally well tolerated through 24 months of follow-up. 16.1% of YUTIQ treated eyes needed the assistance of adjunctive intraocular / periocular injection medication for uveitic inflammation compared to 66.7% for sham treated eyes. Intraocular (“IOP”) lowering drops were used in 41.4% of YUTIQ treated eyes and 33.3% of sham treated eyes, with IOP lowering surgeries performed in 4.6% of YUTIQ treated eyes and 7.1% of sham treated eyes. Cataracts were extracted from 64.3% of patients administered YUTIQ with phakic eyes (42) and 14.3% 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). As in the first Phase 3 trial, YUTIQ was generally well tolerated through 6 months, and 12-month follow-up efficacy and safety data was consistent with the 12-month data from our first Phase 3 trial.

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.

Data from all these studies of YUTIQ over twelve months indicate that 56% of studied subjects developed cataracts as an adverse reaction.

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 NIPU 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 expects that it will obtain approval for its application in the first half of calendar 2019.

Manufacturing

Manufacturing of pharmaceutical products is subject to extensive regulations that impose various procedural and documentation requirements, and which govern record-keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among other activities. Our systems and our contractors are required to comply with these regulations, and we assess this compliance regularly through monitoring of performance and a formal audit program.

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 within our Watertown, MA facility.

DEXYCU

We currently use a contract manufacturer for the commercial supply of DEXYCU. A second contract manufacturer provides kitting and packaging of the finished product, and other third parties provide sterilization, testing and storage services for DEXYCU. 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 of our other pre-clinical study and clinical trial supplies for products and product candidates that utilize our Durasert technology platform, including YUTIQ, have been, and will continue to be, manufactured 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 calendar 2019 utilizing a model whereby we hired sales leadership professionals (including our National Sales Director and Regional Managers) during 2018 and we contracted with a CSO to recruit experienced ophthalmology KAMs, who are specifically designated to either YUTIQ or DEXYCU. We believe this flexible sales model provides less execution risk to us, because CSOs can leverage costs across multiple clients and thus are able to cost-effectively build the necessary infrastructure to support sales activities using varied, industry-wide experience to provide the most impactful solutions. In addition, we are able to utilize the 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. For YUTIQ, we have a defined footprint of approximately 10 territories that could expand over time. For DEXYCU, we have a defined footprint of approximately 35 territories that could also expand over time. We have recruited, hired and trained three Regional Sales Managers with an average of approximately 12 years of ophthalmology sales leadership experience. In partnership with our CSO, we have recruited and trained 44 KAMs to address sales opportunities in these territories. 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.

Outside of the U.S., we have already out-licensed our Durasert three-year uveitis product (trade named YUTIQ in the U.S.) to Alimera for the EMEA and to Ocumension for the greater China territory and would expect to seek further out-licenses for other geographical territories. We have not yet identified our out-licensing strategy for DEXYCU but anticipate that we will assess this further in 2019.

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 and Government Affairs, 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 an existing J code 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. We have applied for a specific J code for YUTIQ which, if approved, would become effective on January 1, 2020.

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 an exclusive 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. The ILUVIEN micro-insert is substantially the same micro-insert as YUTIQ. 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 17 EU 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.

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 NIPU, 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) on January 1, 2020, another $5 million will be cancelled, provided, however, that such date of cancellation may be extended under certain circumstances related to Alimera's regulatory approval process for ILUVIEN for the treatment of NIPU, with such extension, if any, subject to mutual agreement by the parties; 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 NIPU. 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 expects that it will obtain approval for its application in the first half of calendar 2019. If the variation is approved, 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 NIPU

Retisert is a sustained-release implant based on our Durasert technology platform for the treatment of NIPU. 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. Approved in the U.S., Bausch & Lomb sells the product and pays sales-based royalties to us.

Vitrasert for CMV Retinitis

Vitrasert is a sustained-release implant based on our Durasert technology platform for the treatment of cytomegalovirus retinitis, a blinding eye disease that occurs in individuals with advanced acquired immune deficiency syndrome. Surgically implanted, Vitrasert provided sustained delivery of the anti-viral drug ganciclovir for six to eight months. Approved in the U.S. and EU, Vitrasert was licensed to Bausch & Lomb, which discontinued payment of sales-based royalties at the end of calendar year 2011 following patent expiration.

Line Extension Candidate

Shorter Duration YUTIQ

We are completing nonclinical bioequivalence and safety studies for a next-generation, shorter-duration treatment for NIPU, using the same Durasert technology and drug (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 both 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.

Development Product Candidate

Tyrosine Kinase Inhibitor Insert for Wet AMD

We are investigating the development of an injectable, bioerodible, sustained-release Durasert insert delivering a tyrosine kinase inhibitor, or TKI, for treatment of wet age-related macular degeneration, or AMD. AMD, the leading cause of vision loss in people over 65, is most commonly treated with intravitreal injections of biologics that block vascular endothelial growth factor, or VEGF. FDA-approved Lucentis® and EYLEA® and off-label use of anti-cancer drug Avastin® are the leading treatments for wet AMD. These biologics must be injected into the eye as frequently as monthly and typically can lose efficacy over time, resulting in vision loss and return of the disease. TKIs may exhibit the same efficacy as anti-VEGF drugs like LUCENTIS and EYLEA as some of them also block the VEGF receptor.

In cancer therapy, TKIs are taken orally but their toxicity prevents their systemic use to treat AMD. Using our Durasert technology, we plan to develop an implant to deliver a TKI directly to the back of the eye with a total dose that is significantly lower than what is customarily used in a course of cancer therapy.

Our development goal is to provide sustained treatment of wet AMD for six months with a single injection of a TKI-based product, targeting VEGF while avoiding or reducing the toxic systemic side effects of TKIs and the frequent injections of current wet AMD anti-VEGF biologics. Using a model TKI, we have generated pre-clinical data that demonstrate that a TKI delivered by a sustained release insert was comparably efficacious to a commercially available biologic indicated for wet AMD delivered by injection, both in preventing choroidal neovascularization and in reducing vascular leakage. On the basis of these data, we are currently evaluating other, potentially patentable TKIs for sustained release over several months and with comparable therapeutic effects.

Feasibility Study Agreements

From time to time we have entered into feasibility study agreements funded by third parties to evaluate our Durasert technology platform for the treatment of ophthalmic and other diseases. There are no such funded studies currently ongoing. We intend to continue to identify other companies with compounds that could be successfully delivered with our Durasert and Verisome technology platforms and, through appropriate agreements, seek to generate non-dilutive operating capital.

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.

Alimera

In February 2005, as amended and restated in March 2008, we granted Alimera an exclusive worldwide license to manufacture, develop, market and sell ILUVIEN for the treatment and prevention of human eye diseases other than uveitis (the "Prior Alimera Agreement"). We also granted Alimera a worldwide non-exclusive license to manufacture, develop, market and sell certain additional Durasert-based products (1) to deliver a corticosteroid and no other active ingredient by a direct delivery method to the back of the eye solely for the treatment and prevention of eye diseases in humans other than uveitis and (2) to treat DME in humans by delivering a compound by a direct delivery method through an incision no smaller than that required for a 25-gauge or larger needle. The non-exclusive license is limited to those products that, among other things, (i) have a drug core within a polymer layer (with certain limitations regarding chemically bonded combinations of active agents) and (ii) are approved, or designed to be approved, to deliver a corticosteroid and no other active ingredient by a direct delivery to the posterior portion of the eye, or to treat DME by delivering a compound by a direct delivery through an incision required for a 25-gauge or larger needle. We are not permitted to use or grant a license to any third party to use the licensed technologies to make or sell any products that are or would be subject to the non-exclusive license granted to Alimera.

In October 2014, Alimera paid us a $25.0 million milestone upon FDA approval of ILUVIEN as provided in in the Prior Alimera Agreement.

In July 2017, we entered into the Amended Alimera Agreement to (i) expand the license to Alimera for our proprietary Durasert sustained-release drug delivery technology platform to include uveitis, including NIPU, in the EMEA and (ii) convert the previous net profit share arrangement on a country-by-country basis to sales-based royalties for ILUVIEN for DME, NIPU and any other ILUVIEN indications that obtain regulatory approval in various jurisdictions in the future, provided that certain amounts of Alimera's previous ILUVIEN net commercialization losses can be offset against earned sales-based royalties (as described below). Under the Amended Alimera Agreement, we are entitled to a 2% sales-based royalty within 60 days following the end of each quarterly period through calendar year 2018. Commencing December 12, 2018, the sales-based royalty increased to 6% on aggregate calendar year net sales up to $75 million and 8% on any calendar year sales in excess of $75 million. Alimera's share of accumulated ILUVIEN commercialization losses under the original net profit share arrangement (as set forth in the Prior Alimera Agreement), was capped at $25 million. Under the Amended Alimera Agreement, these recoverable losses are to be reduced as follows: (i) $10 million was cancelled in lieu of any 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% of net sales will be offset against the quarterly royalty payments due from Alimera; (iii) on January 1, 2020 (or earlier under certain circumstances), another $5 million of the accumulated commercialization losses will be cancelled, provided, however, that such date of cancellation may be extended further under certain circumstances related to Alimera's regulatory approval process for ILUVIEN for the treatment of NIPU, with such extension, if any, subject to mutual agreement by the parties; and (iv) commencing in calendar year 2021, 20% of earned sales-based royalties in excess of 2% of net sales will be offset against the quarterly royalty payments due from Alimera until such time as the remaining balance of the original $25 million of commercialization losses has been recouped by Alimera.

Bausch & Lomb

Under a 2003 amended license agreement, Bausch & Lomb has a worldwide exclusive license to make and sell Retisert and other first-generation products defined in the agreement in return for royalties based on sales. This agreement also covered Vitrasert prior to patent expiration. Bausch & Lomb can terminate its agreement with us without penalty at any time upon 90 days' written notice.

OncoSil Medical Ltd.

Our December 2012 license agreement, amended and restated in March 2013, with Enigma Therapeutics Limited, currently a wholly-owned subsidiary of OncoSil Medical Ltd, or OncoSil Medical, provides OncoSil Medical with an exclusive, worldwide, royalty-bearing license for the development of BrachySil (now named OncoSil™), a product candidate for the treatment of pancreatic and other cancers. We received an upfront fee of $100,000 and are entitled to an 8% sales-based royalty, 20% of sublicense consideration and milestones based on aggregate product sales. To date, OncoSil Medical has not received regulatory approval for OncoSil in any jurisdiction although a CE Mark application is pending. OncoSil Medical is obligated to pay an annual license maintenance fee of $100,000, creditable during each ensuing twelve-month period against reimbursable patent maintenance costs and sales-based royalties. Annual license maintenance fees of $100,000 were paid during each calendar year from 2013 through 2018. OncoSil Medical has the right to terminate this license upon 60 days' prior written notice.

Ocumension Therapeutics

In November 2018, we entered into an exclusive license agreement for the development and commercialization in the greater China territory of our Durasert three-year treatment for NIPU. Under the terms of the license agreement, we received a one-time upfront payment of $1.75 million from Ocumension and will be eligible to receive up to an additional $10.25 million if certain future prespecified development, regulatory and commercial sales milestones are achieved by Ocumension. In exchange, Ocumension has exclusive rights to develop the product in the Greater China Region, at its own cost and expense with us supplying product for clinical trials.

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 marked expires in March 2019. The last expiring patent covering Retisert expires in April 2020. 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 two additional patents have issued in the U.S. that will cover DEXYCU until at least 2034.

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 March 1, 2019:

Technology	United States Patents	United States Applications	Foreign Patents	Foreign Applications	Patent Families
Durasert	11	5	45	14	5
Verisome	10	5	33	24	8
Other	10	7	32	40	11
Total	31	17	110	78	24

Employees

We had 55 employees on March 1, 2019. 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, YUTIQ or, if approved, ILUVIEN for NIPU. Some of these products and potential products 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.

Ocular Therapeutix™ Inc. (“Ocular”) has developed DEXTENZA®, 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. More recently, Ocular has filed a supplemental New Drug Application (“sNDA”) intended to expand the current indication to include the treatment of ocular inflammation following ophthalmic surgery. The FDA review is expected to be completed in the second half of 2019.

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. On the other hand, since 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®, which is 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. As with DME, the several-month 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 NIPU. 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.

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 diabetic retinopathy. 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, retinal vein occlusion 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.

Wet AMD, 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 wet AMD. 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 is currently developing an antibody fragment, brolucizumab, 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. Novartis had announced applying for approval with the FDA at the end of calendar year 2018.

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. Allergan expects to file abicipar pegol with the FDA in the first half of 2019.

The port delivery system with ranibizumab, or PDS, is a refillable reservoir system being developed by Genentech and is designed to gradually release LUCENTIS (ranibizumab). The drug is released using a diffusion-control mechanism and 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.

In cancer therapy, TKIs are taken orally, but their toxicity prevents their systemic use to treat AMD. Graybug Vision, Inc.’s, or Graybug Vision’s, lead product, GB-102, is an intravitreal injectable depot formulation of a tyrosine kinase inhibitor, sunitinib malate, that blocks multiple angiogenesis pathways. In 2017, Graybug Vision launched the first clinical trial of GB-102 given every 6 months in patients with wet AMD. 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 study of GB-102, is expected to begin enrollment in 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 wet AMD. The trial is a multi-center, open-label study testing the safety, durability, and tolerability of OTX-TKI delivered by intravitreal injection.

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 European Medicines Agency, or 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 quality and safety of the product. Certain animal studies must be performed in compliance with the FDA's Good Laboratory Practice, or 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 investigational new drug, or 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. 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. 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 with one another:

- Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human patients, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to determine the 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 safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile, and to provide a basis for physician labeling. 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 for new formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) 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 listed drug, or RLD, 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 RLD.

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. 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 has followed such recommendations.

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 current Good Manufacturing Practice, or 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, the FDA may decide to not approve the application or may issue a complete response letter, or CRL, outlining the deficiencies in the submission. The CRL also may request additional information, including additional pre-clinical or clinical data. 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.

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, products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met, or if safety 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 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 seek sanctions, including fines, 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 commercially 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 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, if a product is similar, but not identical, to an already approved product, it may 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 the FDA's finding that the RLD is safe and effective 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 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, 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 2020. 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 marketing authorization application, or 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 28 EU Member States and three of the four European Free Trade Association, or EFTA 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.

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. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, 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 (pre- and post-marketing), 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 European Medicines Agency, or 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, or SPCs, is granted.

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

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 and expansion of the Medicaid program. This law substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacts 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's 340B drug pricing discount program, or 340B program, fraud and abuse, and enforcement. These changes 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.

Some of the provisions of the Affordable Care Act have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump Administration to repeal or replace certain aspects of the Affordable Care Act and to alter the implementation of the Affordable Care Act and related laws. 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 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 negotiates 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 average sales price, or 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 ("MDRP"). 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 recomputed each quarter based on our report to CMS of current quarterly AMP and Best Price for our drug. The terms of our participation in the program would impose a requirement for us 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 MDRP 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 average sales price 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 Transition 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. Significant civil monetary penalties can be applied if we are found to have knowingly submitted any false price information to the government or fail to submit the required price data on a timely basis. 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. 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'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 laws and regulations covering data privacy and the protection of health-related and other personal information. 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. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that could negatively affect our business. In addition, healthcare providers who prescribe our products and research institutions we collaborate with are subject to privacy and security requirements under HIPAA.

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 Transition Report on Form 10-K. Copies of this transition 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, or the Exchange Act, 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 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. As of December 31, 2018, our cash and cash equivalents totaled $45.3 million. In addition, on February 13, 2019 (the "Loan Closing Date"), we entered into a Term Loan Agreement, or the Loan Agreement, with CRG Servicing LLC, as agent, or CRG, and the lenders party thereto, collectively referred to herein as the Lenders, providing for a senior secured term loan of up to $60 million, or the Loan. On the Loan Closing Date, $35 million of the Loan, or the Initial Advance, was advanced to us, resulting in incremental net proceeds of approximately $11.4 million after repayment of (i) approximately $22.7 million under a prior term loan agreement with SWK Funding LLC (consisting of $20.0 million of loan principal and $2.7 million of fees and a make whole interest provision) and (ii) $875,000 of CRG loan origination fees and expenses. In addition, we have the right to draw an additional $15.0 million of proceeds, or the Second Advance, under the CRG term loan facility on or before June 30, 2019. We believe that our existing capital resources, together with the net proceeds from the Initial Advance, the right to the Second Advance and expected amounts to be received from commercial sales of YUTIQ and DEXYCU and from our existing collaboration agreements should enable us to fund our operations as currently planned through calendar 2019. However, changing circumstances may cause us to consume capital faster than we currently anticipate, and we may need to spend more money than currently expected because of such circumstances. Our ability to fund our planned operations beyond that time, including the continued U.S. commercialization of YUTIQ and DEXYCU, and continuing our research and development program for our other product candidates, will require additional capital. In particular, the continued commercialization of YUTIQ and DEXYCU in the U.S. has required and will continue to require significant operating cost investment related to product manufacturing, marketing, sales, distribution and other commercialization costs. Under the Loan Agreement, subject to achievement of $25 million of combined YUTIQ and DEXYCU product sales during any three-month period on or before March 31, 2020, we have the right to borrow an additional $10.0 million under the CRG Loan.

To meet our further capital needs, we are considering multiple alternatives, including but not limited to, equity financings, additional debt financings, corporate collaborations, partnerships and other strategic transactions and funding opportunities. However, there can be no assurance that we will be able to complete any one or more of such other transactions on acceptable terms or otherwise. 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 transition period ended December 31, 2018 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; 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 research, development and other expenses related to our ongoing operations, including the commercialization of YUTIQ and DEXYCU and the completion of clinical development of YUTIQ. For the fiscal 2018 and for the six months ended December 31, 2018, we had losses from operations of $26.3 million and $24.6 million, respectively, and net losses of $53.2 million and $44.7 million, respectively, and we had a total accumulated deficit of $408.5 million at December 31, 2018.

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 DEXYCU and YUTIQ and further scale up our manufacturing and distribution capabilities to commercialize 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 commercialization 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. 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 income from our collaboration partners. 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 have only recently begun to commercialize DEXYCU and YUTIQ in the U.S during the first quarter of 2019 and we do not know the extent to which DEXYCU or YUTIQ, or any of our other product candidates, if approved, will generate 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 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 recent commercial launch 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 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 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 amount of revenues we earn from commercial sales of DEXYCU and YUTIQ;
- the amount of future revenues we receive with respect to the commercialization of ILUVIEN for DME and, if approved in the EMEA, ILUVIEN for NIPU;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- the amount of Retisert royalties and other payments we receive under 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;
- timely and successful development, regulatory approval and commercialization of other potential product candidates;
- 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 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, ILUVIEN or Retisert. If we seek to sell our equity securities under our at-the-market, or 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, or 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, or the Icon Closing Date, we and our wholly-owned subsidiary, Merger Sub, 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 commercialization 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 commercialization 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 expect to pay 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.

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 the Loan Closing Date, we, as the borrower, and EyePoint Pharmaceuticals US, Inc. and Icon Bioscience, Inc., as Guarantors, entered into the Loan Agreement with CRG and the Lenders, providing for a senior secured term loan of up to $60 million. 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 intend to use the net proceeds from the Additional Advances for general working capital and corporate purposes. 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 on or prior to December 31, 2019, an amount equal to 10% of the aggregate outstanding principal amount of the 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 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. 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 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, 2018, including pre-acquisition amounts related to Icon , we had U.S. net operating loss ("NOL") carryforwards of approximately $185.9 million for U.S. federal income tax and approximately $144.3 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 $3.1 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;
- 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.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

The Tax Act, which was passed on December 22, 2017, introduced significant changes to the U.S. tax laws. The Tax Act, among other things, contains significant changes to corporate taxation, including but not limited to the reduction of the corporate tax rate from a top rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income in respect of losses arising in taxable years beginning after 2017 and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). Any federal net operating loss carryovers for taxable years beginning after 2017 will be carried forward indefinitely pursuant to the Tax Act. The Tax Act also limits deductions for compensation in excess of $1 million, which could impact our ability to deduct such corporate expenses. We continue to examine the impact the Tax Act may have on our business. Notwithstanding the reduction in the federal corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected.

RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS AND PRODUCT CANDIDATES

We have no history of commercializing products ourselves, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been largely focused on raising capital and developing Retisert, ILUVIEN, YUTIQ and our other product candidates, including undertaking pre-clinical studies and conducting clinical trials. Bausch & Lomb and Alimera were responsible for completing the clinical development of, obtaining regulatory approval for, and initiating the commercial launch of Retisert and ILUVIEN, respectively, under our license agreements with each of them. Icon completed the clinical development of, and obtained regulatory approval for, DEXYCU. YUTIQ represents the first product for which we have demonstrated our ability to successfully complete clinical development through the submission and attainment of marketing approvals for any product candidate. We have not yet demonstrated our ability to manufacture products at commercial scale, or, with the exception of Retisert and ILUVIEN, arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer history of successfully developing and commercializing products.

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 ability to commercialize any products successfully will also depend 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 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 the reimbursement price and, therefore, 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 recomputed each quarter based on our report to CMS of current quarterly AMP and Best Price for our drug. The terms of our participation in the program would impose a requirement for us 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.

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 also may not be able to obtain a permanent "J" code for YUTIQ, thereby limiting our ability to obtain reimbursement from Medicare and making it more difficult for us to obtain reimbursement from commercial or Medicare Advantage plans.

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, 340B program, and 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. For example, if we are found to have knowingly submitted false AMP, ASP, Best Price, or Non-FAMP information to the government, or fail to timely submit such information, we may be liable for significant civil monetary penalties. The foregoing also could be grounds for other sanctions, such as termination from the Medicaid Drug Rebate Program. 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 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 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, 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 last year, as required. We have identified clinical sites and are currently commencing 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, 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 or the manufacturing facility, 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, as amended by the Health Information Technology and Clinical Health Act, or HITECH 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 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.
- 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.

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 were to become the subject of problems related to its safety, 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 will increase from 50% to 70% beginning in 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'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.

Some of the provisions of the Affordable Care Act have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump Administration to repeal or replace certain aspects of the Affordable Care Act and to alter the implementation of the Affordable Care Act and related laws. 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 health care programs such as Medicare and Medicaid and state health care programs. 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 NIPU.

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 NIPU 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 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 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.

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.

Other than completion of patient follow-up in our second YUTIQ Phase 3 clinical trial, 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 Durasert technology platform to develop proprietary sustained-release pharmaceutical products for the treatment of posterior uveitis and other 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, 2019, we had 141 patents or granted applications and 95 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 Notices of Allowance for DEXYCU™, YUTIQ™, DELIVERING INNOVATION TO THE EYE™ and Durasert™. ILUVIEN® is Alimera's trademark. Retisert® and Vitrasert® are Bausch & Lomb's trademarks. Verisome® is exclusively licensed to us by Ramscor, Inc. Our and our licensees' trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We have negotiated a co-existence agreement with Sun Pharma. 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

If we encounter difficulties in negotiating long-term commercial manufacturing and supply agreements with our third-party manufacturers and suppliers of DEXYCU, our ability to commercialize DEXYCU would be impaired.

We currently rely, and expect to continue to rely, on a limited number of CMOs and suppliers who assist in the production, assembly, test, supply, storage and distribution of DEXYCU, and we control only some of the aspects of their activities. We currently have an arrangement for a limited number of batches of commercial supply of DEXYCU. We are in the process of negotiating a long-term supply arrangement with respect to DEXYCU but we may not be able to obtain terms that are favorable to us or enter into a long-term supply agreement at all. If we are unable to enter into such agreement on commercially reasonable terms, our ability to commercialize DEXYCU would be impaired, and our business, financial condition and results of operations would be materially adversely affected.

If we encounter issues with our contract manufacturers 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 contract manufacturers and suppliers for DEXYCU. We are currently obtaining commercial supply of DEXYCU from one CMO. Although we could obtain the drug product for DEXYCU from other third-party suppliers, we would need to qualify and obtain FDA approval for another contract manufacturer or supplier as an alternative source for the drug product, 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 and supply 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 or supplier, as applicable, as an alternate manufacturer or source for the drug product before any drug product manufactured by such manufacturer or by such supplier could be sold or used.

Any production shortfall that impairs the supply of DEXYCU could have a material adverse effect on our business, financial condition and results of operations and adversely affect our ability to satisfy demand for DEXYCU, which could adversely affect our product sales and operating results materially.

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 previously manufactured products only for clinical and testing purposes in this facility and we have recently begun to manufacture products for commercial use, having obtained FDA approval of our manufacturing process and passed a pre-approval FDA inspection of our manufacturing facility in advance of our YUTIQ FDA approval in October 2018. 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 NIPU 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 NIPU 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 NIPU, in the EMEA (under the ILUVIEN trademark) and subsequently withdrew our YUTIQ MAA and orphan drug designation for NIPU. 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 NIPU 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 NIPU. In December 2017, Alimera submitted a Type II variation for ILUVIEN to add the indication of recurrent and persistent NIPU 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 and expects it will obtain approval for its application in the first half of calendar 2019. Obtaining approval of an MAA by the EMA is uncertain and Alimera may fail to obtain the approval. The MAA review processes, and the processes of other regulatory authorities, are extensive, lengthy, expensive, and uncertain, and such regulatory authorities may delay, limit, or deny approval 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 NIPU 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 NIPU in the EMEA for any reason, or does not succeed in securing market acceptance of ILUVIEN for NIPU in the EMEA, or elects for any reason to discontinue development of ILUVIEN for NIPU, 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 and Bausch & Lomb. While Bausch & Lomb has significant experience in the ophthalmic field and substantial resources, there is no assurance whether, and to what extent, that experience and those resources will be devoted to Retisert, and we do not expect revenues from Retisert to increase, and they may decline further. 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, and ILUVIEN for DME is currently Alimera's first and only commercial product. Alimera has reported that its negative cash flows from operations and accumulated deficit may 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 for DME 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 for DME is a significant undertaking by Alimera, and ILUVIEN for DME is Alimera's first and only commercial product. 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 for DME. 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 for DME, it would adversely affect our business, operating results and financial condition.

There is no assurance our Retisert royalty income will continue at current levels or at all.

Our Retisert royalty income, which had ranged between $1.2 million and $1.4 million from fiscal 2012 through fiscal 2016, decreased to $970,000 for fiscal 2017, totaled approximately $1.0 million for fiscal 2018 and $456,000 for the six months ended December 31, 2018. We do not expect Retisert royalty income to increase materially, if at all, and it may decline further or cease. Bausch & Lomb's obligation to pay a royalty terminates on a licensed product by licensed product basis and country by country basis upon the date that the last to expire patent expires. The patent with which Retisert is marketed expires in March 2019. The latest patent covering Retisert expires in April 2020, and we will not receive any Retisert royalty income after that time. Bausch & Lomb previously discontinued sales of Vitrasert, our product previously licensed to Bausch & Lomb, on its patent expiration.

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 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, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act) govern the collection, use, disclosure, and protection of health-related and other personal information. 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. 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.

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, 2019, we had outstanding options to acquire approximately 9.1 million shares of our common stock, outstanding restricted stock units to acquire approximately 1.3 million shares of our common stock, outstanding performance stock units to acquire approximately 370,000 shares of our common stock, outstanding deferred stock units to acquire 35,418 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 10.5% 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 43.9% of our total outstanding common stock as of March 13, 2019. 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. We are entitled to base rent abatement for the aggregate space for the four months ending January 9, 2019. 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 8, 2019, we had approximately 100 holders of record of our common stock and, according to our estimates, approximately 6,300 beneficial owners of our common stock.

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 Transition 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 six months ended December 31, 2018.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected historical financial data set forth below as of December 31, 2018 and for the six months then ended and as of June 30, 2018, 2017, 2016, 2015 and 2014 and for each of the years then ended have been derived from our audited consolidated financial statements, of which the financial statements as of December 31, 2018, June 30, 2018 and 2017 and for the six months ended December 31, 2018 and for each of the years ended June 30, 2018, 2017 and 2016 are included elsewhere in this Transition Report on Form 10-K.

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.

	Six Months Ended December 31, 2018	Year Ended June 30, 2018	2017	2016	2015	2014
		(In thousands except per share data)				
Consolidated Statements of Operations Data:						
Revenues:						
Collaborative research and development (1)	$ 1,883	$ 1,343	$ 6,569	$ 398	$25,411	$ 2,155
Royalty income (2)	1,045	1,618	970	1,222	1,154	1,318
Total revenues	2,928	2,961	7,539	1,620	26,565	3,473
Operating expenses:						
Research and development	10,412	16,178	14,880	14,381	12,088	9,573
Sales and marketing	8,174	1,512	—	—	—	—
General and administrative	8,901	11,545	11,235	9,013	8,056	7,468
Gain on sale of property and equipment	—	—	—	—	—	(78)
Total operating expenses	27,487	29,235	26,115	23,394	20,144	16,963
Operating (loss) income	(24,559)	(26,274)	(18,576)	(21,774)	6,421	(13,490)
Interest and other income, net	367	101	91	72	22	5
Interest expense	(1,642)	(720)	—	—	—	—
Change in fair value of derivative liability	(18,886)	(26,278)	—	—	—	—
(Loss) income before income taxes	(44,720)	(53,171)	(18,485)	(21,702)	6,443	(13,485)
Income tax benefit (expense)	—	—	—	155	(96)	130
Net (loss) income	$ (44,720)	$(53,171)	$(18,485)	$(21,547)	$ 6,347	$(13,355)
Net (loss) income per share:						
Basic	$ (0.53)	$ (1.15)	$ (0.52)	$ (0.68)	$ 0.22	$ (0.49)
Diluted	$ (0.53)	$ (1.15)	$ (0.52)	$ (0.68)	$ 0.21	$ (0.49)
Weighted average common shares outstanding:						
Basic	85,057	46,226	35,344	31,623	29,378	27,444
Diluted	85,057	46,226	35,344	31,623	30,584	27,444

	As of December 31, 2018	As of June 30, 2018	2017	2016	2015	2014
				(In thousands)		
Consolidated Balance Sheet Data:						
Cash and cash equivalents	$ 45,261	$ 38,776	$ 16,898	$ 15,313	$19,121	$ 15,334
Marketable securities	—	—	—	13,679	9,414	2,944
Intangible assets, net	30,129	31,358	364	1,102	1,925	2,765
Total assets	78,168	71,670	18,677	31,619	32,367	22,671
Long-term debt	17,621	17,309	—	—	—	—
Derivative liability	—	19,780	—	—	—	—
Total deferred revenue-current and long-term	30	—	50	5,732	5,629	5,722
Total stockholders' equity	37,633	11,687	13,336	20,881	23,368	14,924

(1) Includes the following: from our license agreement with Ocumension: $1.7 million in the six months ended December 31, 2018; from our Prior Alimera Agreement (including patent reimbursement costs): $148,000 in fiscal 2018, $659,000 in fiscal 2017, $233,000 in fiscal 2016, $25.1 million in fiscal 2015 and $114,000 in fiscal 2014; from our Restated Pfizer Agreement: $5.6 million in fiscal 2017 and $7,000 in fiscal 2014; from feasibility study agreements: $1.1 million in fiscal 2018, $211,000 in fiscal 2017, $33,000 in fiscal 2016, $144,000 in fiscal 2015 and $1.9 million in fiscal 2014; from our license agreement with OncoSil Medical: $100,000 in the six months ended December 31, 2018, $100,000 in fiscal 2018, $100,000 in fiscal 2017, $100,000 in fiscal 2016, $100,000 in fiscal 2015 and $102,000 in fiscal 2014. See Note 4 in the accompanying Notes to the Consolidated Financial Statements contained in this Transition Report on Form 10-K for additional information.

(2) Includes the following: from our Amended Alimera Agreement; $588,000 in the six months ended December 31, 2018 and $575,000 in fiscal 2018; from our license agreement with Bausch & Lomb: $456,000 in the six months ended December 31, 2018, $1.0 million in fiscal 2018, $970,000 in fiscal 2017, $1.2 million in fiscal 2016, $1.2 million in fiscal 2015 and $1.3 million in fiscal 2014.

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 Transition 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.

On November 1, 2018, our Board of Directors approved a change in our fiscal year end from June 30 to December 31, effective immediately. The reporting period for this Transition Report on Form 10-K is for the six months ended December 31, 2018. In this Transition Report our fiscal years are identified according to the calendar year in which they historically ended (e.g. the fiscal years ended June 30, 2018 is referred to as "fiscal 2018", June 30, 2017 is referred to as "fiscal 2017" and June 30, 2016 is referred to as "fiscal 2016", as if we had not changed our fiscal year to a calendar year) on November 1, 2018. References in this Transition Report to "fiscal 2019" refer to the year ending December 31, 2019.

The following Management's Discussion and Analysis ("MD&A") provides a narrative of our results of operations for the transition period ended December 31, 2018 and the comparable period ended December 31, 2017, and the fiscal years ended June 30, 2018, 2017, and 2016, respectively, and our financial position as of December 31, 2018, June 30, 2017, and June 30, 2016, respectively. The MD&A should be read together with our consolidated financial statements and related notes included on pages F-1 through F-41 of this Transition Report on Form 10-K.

Overview

We are a specialty biopharmaceutical 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 have been launched directly in the U.S. during the first quarter of 2019.

YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg for intravitreal injection, was approved by the FDA in October 2018 and we launched YUTIQ 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 ("NIPU"). YUTIQ is a non-bioerodible intravitreal implant in a drug delivery system 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 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. 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. In the U.S., NIPU affects between 55,000 to 120,000 people each year, causes approximately 30,000 new cases of blindness every year and is the third leading cause of blindness. NIPU is typically treated by retina and uveitis specialists. The standard of care treatment for NIPU involves the use of corticosteroids to reduce uveitic flares and then additional treatments of sustained release, lower dose steroids to reduce the risk of further flares. Prior to the launch of YUTIQ, the standard of care treatment provided sustained release of steroids over a period of 3 to 4 months. In contrast, YUTIQ is designed to release FA continuously, for 36 months. We launched YUTIQ initially with 10 dedicated key account managers ("KAMs") hired through a contract sales organization ("CSO"), which are led by our internal sales management team and supported by our market access, marketing and commercial sales operations teams.

DEXYCU™ (dexamethasone intraocular suspension) 9%, for intraocular administration, was approved by the FDA in February 2018 for the treatment of post-operative ocular inflammation. 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 platform, which allows for a single intraocular injection that releases dexamethasone, a corticosteroid, for up to 22 days. We launched DEXYCU in March 2019 with a primary focus on its use immediately following cataract surgery. There are approximately 4.8 million cataract surgeries performed annually in the U.S., growing at an estimated annual rate of approximately 8%. Prior to the launch of DEXYCU, the standard of care for post-operative treatment of cataract surgery for the reduction of inflammation and pain has been a combination of steroid, antibiotic and non-steroidal eye drops administered several times each day over a period of several weeks. DEXYCU was launched initially with 34 dedicated KAMs hired through our CSO, which are supported by our market access, marketing and commercial sales management teams. Effective October 2018, DEXYCU was granted “pass through status” by the Centers for Medicare & Medicaid Services (“CMS”) that provides for reimbursement separate from the cataract procedure for a 3-year period. The 3-year period commences in the quarter that the first claim for reimbursement for DEXYCU is made with CMS. 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.

We own the worldwide rights to all indications for DEXYCU. We own the rights for YUTIQ in the U.S. and all foreign jurisdictions and have licensed these rights as described below in Europe, the Middle East and Africa (“EMEA”) and the greater China territory. 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. This may be accomplished through our internal discovery efforts, our 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.

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 subject to EMEA regulatory approval, ILUVIEN for NIPU, licensed to Alimera Sciences, Inc. (“Alimera”) and (ii) Retisert® for the treatment of posterior segment uveitis licensed to Bausch & Lomb.

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

Six Month Transition Period Ended December 31, 2018 Overview

The six-month transition period ended December 31, 2018 was highlighted by the following events:

- We substantially completed recruitment of field-based regional sales, market access and medical science liaison personnel in preparation for the launch of YUTIQ and DEXYCU;
- We added key members of our senior management team, including our Chief Financial Officer, SVP of Regulatory & Quality and SVP, General Counsel and Company Secretary;
- On October 12, 2018, we received FDA approval for YUTIQ;

- In July 2018, we began implementing an exclusive agreement with a contract sales organization ("CSO") for the recruitment and training of field-based key account managers in preparation for the commercial launch of YUTIQ and DEXYCU.
- In November 2018, we entered into an exclusive license agreement with Ocumension Therapeutics for the development and commercialization of our Durasert three-year treatment of posterior segment uveitis in the greater China territory and received an upfront license fee of $1.75 million.

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, or 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 Transition 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

Historically we have derived revenue from two sources (i) collaborative research and development activities, and (ii) royalties. In the future we will derive revenue from product sales. The terms of our collaborative research and development arrangements typically include multiple deliverables by us (such as granting of license rights, providing research and development services, manufacturing of clinical materials and participating on joint research committees) in exchange for consideration to us of some combination of one or more of non-refundable license fees, funding of research and development activities, payments based upon achievement of clinical development, regulatory and sales milestones and/or royalties in the form of a designated percentage of product sales or participation in profits.

Revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and based on the selling price of the deliverables. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price method using management's best estimate of the standalone selling price of deliverables when vendor-specific objective evidence or third-party evidence of selling price is not available. Allocated consideration is recognized as revenue upon application of the appropriate revenue recognition principles to each unit.

The assessment of multiple deliverable arrangements requires judgment in order to determine the appropriate units of accounting, the estimated selling price of each unit of accounting, and the points in time that, or periods over which, revenue should be recognized.

We adopted Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers*, 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 Transition Report on Form 10-K). The adoption of ASC 606 represents a change in accounting principle that will more closely align revenue recognition with the delivery of our services and will provide 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.

For the six months ended December 31, 2018 and for the years ended June 30, 2018 and 2017, we reported $1.9 million, $1.3 million and $6.6 million, respectively, of collaborative research and development revenue. Of the total for fiscal 2017, $5.6 million represented non-cash revenue recognized upon the termination of our Restated Pfizer Agreement (see Note 4 in the accompanying Notes to the Consolidated Financial Statements contained in this Transition Report on Form 10-K for more information). Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured.

Recognition of Expense in Outsourced Clinical Trial Agreements

We recognize research and development expense with respect to outsourced agreements for clinical trials with 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. Our financial obligations under the agreements are determined by the services that we request from time to time under the agreements. The actual amounts owed under the agreements and the timing of those obligations will depend on various factors, including changes to the protocols and/or services requested, the number of patients to be enrolled and the rate of patient enrollment, achievement of pre-defined direct cost milestone events and other factors relating to the clinical trials. As of December 31, 2018, our CRO agreements provided for the completion of two Phase 3 clinical trials of YUTIQ at an aggregate remaining cost of approximately $2.0 million, excluding any potential remaining contract change orders. We can terminate the agreements at any time without penalty, and if terminated, we would be liable only for services through the termination date plus non-cancellable CRO obligations to third parties.

During the six months ended December 31, 2018 and for fiscal 2018, we recognized approximately $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

Six Months Ended December 31, 2018 and 2017

	Six Months Ended December 31,		Change	
	2018	2017 (unaudited)	Amounts	%
	(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	na
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)	na
Change in fair value of derivative liability	(18,886)	—	(18,886)	na
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 (see Notes 2 and 4 in the accompanying Notes to the Consolidated Financial Statements contained in this Transition Report on Form 10-K), 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).

We expect to report revenues from the net sales of YUTIQ and DEXYCU commencing in the first quarter of calendar 2019.

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. We expect increases in sales and marketing costs during fiscal year 2019, primarily consisting of costs associated with contract sales organization operations and personnel, managed markets and sales operations activities.

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. With the commercial launch of DEXYCU and YUTIQ, we expect a modest increase in calendar year 2019 expense, including salary, benefits and other personnel costs for recent and prospective headcount additions, higher professional fees and increased insurance premiums.

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. Under the terms of the CRG debt facility, we have the option for a second borrowing of up to $15 million on or before June 30, 2019. We expect to incur interest expense during calendar 2019 in the range of approximately $4.2 million to $5.2 million depending upon the timing and amount of this second borrowing option. In addition, we also will record an as yet undetermined amount of amortization of debt discount, a non-cash expense, during calendar 2019.

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 (see Note 13 in the accompanying Notes to the Consolidated Financial Statements contained in this Transition Report on Form 10-K). The resulting Second Tranche Warrants derivative liability balance of $38.7 million was reclassified to equity upon exercise of these warrants.

Years Ended June 30, 2018 and 2017

	Year Ended June 30,		Change	
	2018	2017	Amounts	%
	(In thousands except percentages)			
Revenues:				
Collaborative research and development	$ 1,343	$ 6,569	$ (5,226)	(80)%
Royalty income	1,618	970	648	67%
Total revenues	2,961	7,539	(4,578)	(61)%
Operating expenses:				
Research and development	16,178	14,880	1,298	9%
Sales and marketing	1,512	—	1,512	na
General and administrative	11,545	11,235	310	3%
Total operating expenses	29,235	26,115	3,120	12%
Operating loss	(26,274)	(18,576)	(7,698)	(41)%
Interest income and other, net	101	91	10	11%
Interest expense	(720)	—	(720)	na
Change in fair value of derivative liability	(26,278)	—	(26,278)	na
Net loss	$(53,171)	$(18,485)	$(34,686)	(188)%

Revenues

Collaborative research and development revenue totaled $1.3 million in fiscal 2018, a decrease of $5.2 million, or 80%, compared to $6.6 million in fiscal 2017. This decrease was attributable primarily to $5.6 million of revenue recognized upon the termination of the Restated Pfizer Agreement in December 2016 and a $535,000 reduction of revenues attributable to the Prior Alimera Agreement, which included $136,000 of revenue recognized from a May 2017 arbitration settlement of Alimera's calendar year 2014 reporting of ILUVIEN net profits, partially offset by an $879,000 increase in revenues derived from feasibility study agreements.

In July 2017, we entered into the Amended Alimera Agreement, pursuant to which we (i) expanded the license to Alimera for our proprietary Durasert drug delivery technology platform to include uveitis, including NIPU, in the 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. We expect this conversion to result in increased revenues from Alimera over time, as well as better predictability and consistency of revenues to be recognized from Alimera. Based on 60-day payment terms from Alimera following the end of each calendar quarter, sales-based royalties earned from Alimera are being recognized as revenues one quarter in arrears. Commencing in calendar 2019, the royalty rate on net sales of ILUVIEN will increase 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). See Note 4 in the accompanying Notes to the Consolidated Financial Statements contained in this Annual Report on Form 10-K for more information related to the Alimera collaboration agreement and to the settlement of a dispute relating to the computation of ILUVIEN net profits for calendar year 2014

Royalty income totaled $1.6 million for fiscal 2018, an increase of $648,000, or 67%, compared to $970,000 in fiscal 2017. Royalty income attributable to the Amended Alimera Agreement totaled $575,000 in fiscal 2018. Retisert royalty income increased by $73,000, or 8%, to approximately $1.0 million in fiscal 2018 compared to $970,000 in fiscal 2017. We expect Retisert royalty income to remain flat or to decline somewhat in the next fiscal year.

Research and Development

Research and development expenses totaled $16.2 million in fiscal 2018, an increase of $1.3 million, or 9%, compared to $14.9 million in fiscal 2017. This increase was attributable primarily to (i) a $1.8 million increase of professional services related primarily to our YUTIQ three-year uveitis Phase 3 clinical development program and regulatory filings, (ii) a $774,000 increase in U.S. personnel and related costs, including incentive compensation and (iii) a $404,000 increase in pre-clinical studies, related primarily to our short-acting YUTIQ product candidate, and other third-party research costs; (iv) a $257,000 increase in amortization of intangible assets, attributable primarily to $615,000 of amortization of the DEXYCU / Icon intangible asset offset by the completed amortization of our previous patent technology intangible assets as of December 2017; and (v) a $116,000 increase in U.S. stock-based compensation, partially offset by decreases of (i) $1.6 million of CRO costs for our YUTIQ three-year uveitis clinical development, (ii) $472,000 of direct U.K. restructuring costs in fiscal 2017.

Sales and Marketing

In anticipation of the commercial launch of DEXYCU and, if approved by the FDA, YUTIQ, we commenced the build-out of our commercial infrastructure and marketing activities in the fourth quarter of fiscal 2018. Sales and marketing expense totaled $1.5 million in fiscal 2018 and consisted primarily of $1.0 million of marketing program and agency costs and approximately $450,000 of personnel and related costs, including travel and stock-based compensation.

General and Administrative

General and administrative expenses totaled $11.5 million in fiscal 2018, an increase of $310,000, or 3%, compared to $11.2 million in fiscal 2017. The increase was attributable primarily to (i) approximately $900,000 of consulting services, which included interim CFO services, business development and the effect of a $218,000 fiscal 2017 credit for audit costs in connection with the May 2017 Alimera arbitration settlement; (ii) approximately $204,000 of facility and office expense, which included our New Jersey office that opened in July 2017; and (iii) approximately $116,000 of stockholder meeting and stock exchange costs, including our delisting from the Australian Securities Exchange, partially offset by net decreases of (i) approximately $813,000 for personnel and related costs largely due to the absence of $1.2 million of fiscal 2017 severance compensation to our former CEO and former Vice President, Corporate Affairs and General Counsel, and (ii) approximately $230,000 of legal, audit and other professional fees that resulted from a combination of lower patent legal fees and the absence of approximately $605,000 of legal fees associated with our CEO transition and the arbitration proceedings and the restructuring of our Alimera collaboration agreement, which were partially offset by fiscal 2018 legal fees associated with potential financing and business development transactions and our ASX delisting.

Interest (Expense) Income and Other

On March 28, 2018, we borrowed $15.0 million under a term loan facility in connection with the Icon Acquisition. Following consummation of the Second Tranche Transaction on June 25, 2018, we borrowed an additional $5.0 million under that term loan facility. For fiscal 2018 we incurred $511,000 of interest expense on the term loan and amortized $209,000 of deferred debt issue costs and debt discount.

Interest income and other increased to $101,000 in fiscal 2018 compared to $91,000 in fiscal 2017, due primarily to higher interest rates on amounts invested in an institutional money market fund.

Change in Fair Value of Derivative Liability

Change in fair value of derivative liability totaled $26.3 million in fiscal 2018, attributable to the classification of the Second Tranche transaction as a liability (see Notes 10 and 12 to the accompanying consolidated financial statements). The Units associated with the Second Tranche Transaction were settled to equity upon the Second Tranche Transaction closing on June 25, 2018. The Second Tranche Warrants were also liability classified and were revalued at June 30, 2018.

Acquisition of Icon Bioscience, Inc.

We acquired the rights to DEXYCU on March 28, 2018 through the acquisition of Icon Bioscience, Inc., or Icon. We paid Icon's security holders approximately $15 million at the closing of the transaction, and are obligated to pay certain post-closing contingent cash payments upon the achievement of specified milestones based upon certain net sales and partnering revenue standards, in each case subject to the terms and conditions set forth in that certain Agreement and Plan of Merger, dated March 28, 2018, by and among us, Oculus Merger Sub, Inc., or Merger Sub, Icon and Shareholder Representative Services LLC, solely in its capacity as the representative of Icon's securityholders, which we refer to as 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, or 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 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 sales 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 acquired in connection with the acquisition of Icon.

Years Ended June 30, 2017 and 2016

	Year Ended June 30,		Change	
	2017	2016	Amounts	%
	(In thousands except percentages)			
Revenues:				
Collaborative research and development	$ 6,569	$ 398	$ 6,171	1,551%
Royalty income	970	1,222	(252)	(21)%
Total revenues	7,539	1,620	5,919	365%
Operating expenses:				
Research and development	14,880	14,381	499	3%
General and administrative	11,235	9,013	2,222	25%
Total operating expenses	26,115	23,394	2,721	12%
Operating loss	(18,576)	(21,774)	3,198	15%
Interest and other income, net	91	72	19	26%
Loss before income taxes	(18,485)	(21,702)	3,217	15%
Income tax benefit	—	155	(155)	(100)%
Net loss	$(18,485)	$(21,547)	$ 3,062	14%

Revenues

Collaborative research and development revenue totaled $6.6 million in fiscal 2017, an increase of $6.2 million, or 1,551%, compared to $398,000 in fiscal 2016. This increase was attributable primarily to $5.6 million of revenue recognized upon the termination of the Restated Pfizer Agreement in December 2016. In addition, revenues derived from our collaboration agreement with Alimera increased by $426,000, which included $136,000 of revenue recognized from a May 2017 arbitration settlement of Alimera's calendar year 2014 reporting of ILUVIEN net profits.

In July 2017, we restructured the Alimera collaboration agreement to (a) license Durasert three-year uveitis in the EMEA to Alimera and (b) to convert the net profit share arrangement to a sales-based royalty for all ILUVIEN licensed indications. See Notes 4 in the accompanying Notes to Consolidated Financial Statements contained in this Transition Report on Form 10-K for more information related to the Alimera collaboration agreement and to the settlement of a dispute relating to the computation of ILUVIEN net profits for calendar year 2014.

Retisert royalty income decreased by $252,000, or 21%, to $970,000 in fiscal 2017 compared to $1.22 million in fiscal 2016.

Research and Development

Research and development expenses totaled $14.9 million in fiscal 2017, an increase of $499,000, or 3%, compared to $14.4 million in fiscal 2016. This increase was attributable primarily to (i) a $1.4 million increase of professional services related primarily to our Durasert three-year uveitis Phase 3 clinical development program and completed MAA filing and planned NDA filing, (ii) an $879,000 increase in U.S. personnel and related costs, including incentive compensation and the August 2016 hire of our Chief Medical Officer and (iii) a $596,000 increase in U.S. stock-based compensation, partially offset by decreases of (i) $1.1 million of CRO costs for our Durasert three-year uveitis clinical development, (ii) $1.0 million of U.K. costs primarily related to the effect of the U.K. restructuring, which included a $147,000 foreign exchange impact of a stronger US$ currency, and (iii) $268,000 of U.S. pre-clinical studies and other third-party research costs related primarily to prior year studies of potential TKI compounds and purchases of lab and clinical supplies for our Durasert three-year uveitis clinical development program.

General and Administrative

General and administrative expenses totaled $11.2 million in fiscal 2017, an increase of $2.2 million, or 24%, compared to $9.0 million in fiscal 2016. This increase was attributable primarily to (i) approximately $1.5 million of personnel and related costs, including annual incentive compensation, of which $1.2 million represented severance compensation to our former CEO and former Vice President, Corporate Affairs and General Counsel, (ii) approximately $1.3 million of legal fees, which included approximately $175,000 of legal fees associated with the CEO transition and severance arrangements, $430,000 of legal fees related to the Alimera arbitration proceedings and agreement restructuring and $253,000 of patent legal fees, partially offset by a $619,000 decrease in consulting services costs, which consisted primarily of prior year uveitis market assessment analyses and the $218,000 fiscal 2017 cancellation of previously accrued audit costs in connection with the Alimera arbitration settlement.

Interest and Other Income

Interest and other income increased to $91,000 in fiscal 2017, an increase of $19,000, or 23%, compared to $72,000 in fiscal 2016, due primarily to higher money market interest rates.

Income Tax Benefit

Income tax benefit was $0 in fiscal 2017 compared to an income tax benefit of $155,000 in fiscal 2016. We incurred $4,000 in fiscal 2016 of federal alternative minimum tax expense based on U.S. taxable income for calendar year 2014 attributable primarily to the $25.0 million ILUVIEN FDA-approval milestone. Refundable foreign research and development tax credits were not available for fiscal 2017 as a result of the consolidation of our research and development activities in the U.S. during the quarter ended September 30, 2016.

Inflation and Seasonality

Our management believes inflation has not had a material impact on our operations or financial condition and that our operations are not currently subject to seasonal influences.

Recently Adopted and Recently Issued Accounting Pronouncements

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board, or 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 February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use, or ROU, model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. As a result, ASU 2016-02 became effective on January 1, 2019. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. We are currently evaluating the impact of the pending adoption of the new standard on our consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, which we refer to as 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 Transition Report on Form 10-K).

Liquidity and Capital Resources

Our operations for the six months ended December 31, 2018 were financed primarily from $38.8 million of cash and cash equivalents at June 30, 2018 and approximately $28.9 million of gross proceeds from the September 2018 exercise of the 20,184,224 Second Tranche Warrants. At December 31, 2018, our cash and cash equivalents totaled $45.3 million.

As of December 31, 2018, our long-term debt consisted of $20.0 million, which represented the amount outstanding under the SWK Loan pursuant to the Credit Agreement. On February 13, 2019, we refinanced the SWK Loan in connection with entering into a new term loan facility (Loan Agreement) of up to $60 million with CRG. 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. Under the terms of the Loan Agreement, we have the option to borrow up to an additional $15.0 million on or before June 30, 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 the election of the Company, so long as no default or event of default under the Loan Agreement has occurred and is continuing. The Company is required to make quarterly, interest only payments until the Maturity Date. In addition, the Company is 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. The Company 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 on or prior to December 31, 2019, an amount equal to 10% of the aggregate outstanding principal amount of the 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 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, including the Guarantors, are guaranteeing the obligations of us 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 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.

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, 2018 we had a total accumulated deficit of $408.4 million. Other than the right to borrow up to an additional $15 million on or before June 30, 2019 under the terms of the CRG Loan Agreement, we do not currently have any significant assured sources of additional financing. We have no 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. As a result, the inherent uncertainty associated with achieving sufficient operating and financing cash flows raises substantial doubt about our ability to continue as a going concern for one year from the issuance of our financial statements included in this Transition Report on Form 10-K. We believe that our cash and cash equivalents of $45.3 million at December 31, 2018, incremental financing cash flows of approximately $26.4 million from the first, and potential second, borrowing under our CRG Loan Agreement and expected cash inflows under our existing collaboration agreements will enable us to fund our current and planned operations (including the U.S. commercial launches of YUTIQ and DEXYCU and payment of a $15.0 million milestone due to the Icon security holders following the commercial launch of DEXYCU) through calendar year 2019. In order to extend our ability to fund our operations beyond then, management's plans include obtaining additional financing from the sale of equity securities through an underwritten public offering and/or the sale of Common Stock through our existing at-the-market (ATM) program or from other sources and/or, as applicable, reducing or deferring operating expenses.

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 NIPU 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;
- 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; and
- our views on the availability, timing and desirability of raising capital.

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):

	Six Months Ended December 31,		Year Ended June 30,		
	2018	2017 (unaudited)	2018	2017	2016
Net loss:	$(44,720)	$(11,765)	$(53,171)	$(18,485)	$(21,547)
Changes in operating assets and liabilities	(940)	(977)	924	318	2,073
Other adjustments to reconcile net loss to cash flows from operating activities	23,074	1,736	30,340	(2,323)	3,158
Cash flows used in operating activities	$(22,586)	$(11,006)	$(21,907)	$(20,490)	$(16,316)
Cash flows (used in) provided by investing activities	$ (132)	$ (64)	$(16,888)	$ 13,577	$ (4,462)
Cash flows provided by financing activities	$ 29,204	$ 7,044	$ 60,671	$ 8,503	$ 16,990

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.

Operating cash inflows increased by $807,000, or 38%, from fiscal 2017 to fiscal 2018, primarily due to an $800,000 increase in amounts received from feasibility study agreements. Operating cash inflows increased by $94,000, or 5%, from fiscal 2016 to fiscal 2017, as a result primarily of $250,000 received from a feasibility study agreement and a $156,000 increase in amounts received in connection with the Prior Alimera Agreement, partially offset by a $290,000 decrease in Retisert royalties.

Operating cash outflows increased by approximately $2.2 million, or 9.8%, from fiscal 2017 to fiscal 2018, as a result primarily of (a) a $1.9 million increase in professional fees, which consisted primarily of YUTIQ regulatory and clinical consulting fees and DEXYCU and YUTIQ marketing and managed markets consulting services, partially offset by lower patent legal fees; (b) $258,000 of term loan interest payments; (c) a $352,000 increase in third-party research and development costs; (d) a $135,000 increase in travel and facility costs; and (e) a $98,000 increase in stockholder meeting and statutory filing costs, partially offset by a $679,000 decrease in CRO costs for the YUTIQ Phase 3 development program. Personnel and related costs were flat on a year-over-year basis, reflecting a significant net increase in employee headcount and higher incentive compensation offset by $1.2 million of severance compensation in fiscal 2017. Operating cash outflows increased by $4.2 million, or 22.7%, from fiscal 2016 to fiscal 2017, as a result primarily of (a) $2.5 million of professional fees, which consisted primarily of YUTIQ three-year uveitis clinical and regulatory consulting fees and general legal fees associated with the CEO transition and costs of the Alimera arbitration and (b) $2.1 million of personnel and benefit costs, which included $1.2 million of severance compensation and in fiscal 2017, the additions of a Chief Medical Officer and EVP of Corporate and Commercial Development and an approximate $390,000 increase in fiscal 2016 incentive compensation awards (paid in fiscal 2017) compared to the prior year, partially offset by a $208,000 decrease in CRO costs for YUTIQ clinical development.

Cash flows from investing activities in fiscal 2018 consisted principally of $16.8 million of cash used, net of cash acquired plus transaction costs, for the Icon acquisition. Cash flows from investing activities in fiscal 2017 and 2016 were attributable primarily to maturities of marketable securities, net of purchases, of $13.7 million for fiscal 2017 and purchases of marketable securities, net of maturities, of $4.3 million for fiscal 2016. Purchases of property and equipment totaled $132,000 in the six months ended December 31, 2018, $108,000 in fiscal 2018, $147,000 in fiscal 2017 and $113,000 in fiscal 2016.

Cash flows from financing activities for the six months ended December 31, 2018 consisted primarily of (i) approximately $28.9 million of gross proceeds from the exercise of the Second Tranche Warrants, partially offset by (ii) cash outflows of $195,000 from the net settlement of vested stock units to satisfy statutory tax withholdings. 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. Cash flows from financing activities in fiscal 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 (see Note 11 of the accompanying Notes to Consolidated Financial Statements contained in this Transition Report on Form 10-KT) and (ii) $20.0 million of gross proceeds from a term loan agreement (see Note 10 of the accompanying Notes to Consolidated Financial Statements contained in this Transition Report on Form 10-KT). Share issue and debt issue costs totaled approximately $1.9 million in connection with these financing transactions. Cash flows from financing activities in fiscal 2018 also included the sale of 5,900,000 shares of common stock under our ATM program for gross proceeds of $7.3 million, net of $239,000 of share issue costs. Cash flows from financing activities in fiscal 2017 were related predominately to the sale of shares of our common stock under our ATM program for gross proceeds of $8.9 million, less $233,000 of program adoption costs and $244,000 of share issue costs. Cash flows from financing activities in fiscal 2016 were attributable primarily to an underwritten public offering in January 2016 for gross proceeds of $17.8 million, net of $1.3 million of share issue costs. In addition, cash flows from financing activities included proceeds from the exercise of stock options totaling $535,000 in the six months ended December 31, 2018, $503,000 in fiscal 2018, $99,000 in fiscal 2017 and $490,000 in fiscal 2016.

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-[43] of this Transition 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, 2018. 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, 2018, 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, 2018. 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, 2018, which is included on page F-3 of our Transition 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 Transition Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting**.**

ITEM 9B.OTHER INFORMATION

None.

PART III

Certain information required by Part III is omitted from this Transition Report on Form 10-K and is incorporated herein by reference from our definitive proxy statement relating to our 2019 annual meeting of stockholders, pursuant to Regulation 14A of the Exchange Act of 1934, also referred to in this Transition Report on Form 10-K as our 2019 Proxy Statement, which we expect to file with the SEC no later than April 30, 2019.

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 2019 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required to be disclosed in Item 11 is hereby incorporated by reference to our 2019 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 2019 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 2019 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 2019 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.

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		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
	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
10.4	Employment Agreement, between pSivida Corp. and Leonard S. Ross, dated December 17, 2010	8-K	12/21/10	10.1
10.5	Option Amendment Agreement, between pSivida Corp. and Leonard S. Ross, dated December 17, 2010	8-K	12/21/10	10.2
10.6	Retention Bonus Letter, dated January 5, 2017, by and between pSivida Corp. and Leonard Ross	8-K	01/10/17	10.1
10.7	Employment Agreement, between EyePoint Pharmaceuticals, Inc. and Dario Paggiarino, dated March 27, 2018	10-Q	05/10/18	10.7

Exhibit No.		Exhibit Description	Incorporated by Reference to SEC Filing		
			Form	SEC Filing Date	Exhibit No.
10.8		Employment Agreement, dated August 1, 2018, by and between EyePoint Pharmaceuticals, Inc. and David Price	8-K	08/03/18	10.1
10.9		Employment Agreement, dated May 11, 2018, by and between EyePoint Pharmaceuticals, Inc. and Leonard Blum	10-K	09/18/18	10.12
10.10	+	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
10.11	+	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
10.12	+	Form of Stock Option Award Agreement for Inducement grants to executive officers	10-K	09/18/18	10.15
		Material Contracts - Management Contracts and Compensatory Plans (continued)			
10.13		2008 Equity Incentive Plan, as amended on November 19, 2009	10-K	09/10/15	10.6
10.14	+	Form of Stock Option Certificate for grants to executive officers under the pSivida Corp. 2008 Incentive Plan	8-K	09/10/08	10.1
10.15		pSivida Corp. 2016 Long Term Incentive Plan, as amended	10-Q	02/09/17	4.1
10.16	+ (a)	Form of Indemnification Agreement between EyePoint Pharmaceuticals, Inc. and its officers and directors			
10.17		EyePoint Pharmaceutical Short Term Incentive Plan	10-K	09/18/18	10.20
10.18	+	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
10.19	+	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
10.20		Stock Option Award Agreement, dated May 14, 2018, by and between EyePoint Pharmaceuticals, Inc. and Leonard M. Blum	10-Q	11/09/18	10.1
10.21		Stock Option Award Agreement, dated May 14, 2018, by and between EyePoint Pharmaceuticals, Inc. and Leonard M. Blum	10-Q	11/09/18	10.2
10.22		Stock Option Award Agreement, dated August 1, 2018, by and between EyePoint Pharmaceuticals, Inc. and David Price	10-Q	11/09/18	10.3
10.23		Performance Stock Unit Award Agreement, dated August 1, 2018, by and between EyePoint Pharmaceuticals, Inc. and David Price	10-Q	11/09/18	10.4
10.24		Stock Option Award Agreement, dated August 14, 2018, by and between EyePoint Pharmaceuticals, Inc. and John Weet	10-Q	11/09/18	10.5
10.25	(a)	Stock Option Award Agreement, dated November 26, 2018, by and between EyePoint Pharmaceuticals, Inc. and Ron Honig			

Exhibit No.		Exhibit Description	Incorporated by Reference to SEC Filing		
			Form	SEC Filing Date	Exhibit No.
		Material Contracts - Leases			
10.26		Lease Agreement between pSivida Corp. and Farley White Aetna Mills, LLC dated November 1, 2013	10-Q	11/13/13	10.1
10.27		First Amendment of Lease, dated February 6, 2014, between Farley White Aetna Mills and pSivida Corp.	10-K	09/18/18	10.24
10.28		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			
10.29	#	Amended and Restated License Agreement between Control Delivery Systems, Inc. and Bausch & Lomb Incorporated dated December 9, 2003, as amended on June 28, 2005	20-F	01/18/06	4.12
10.30	#	Second Amendment to Amended and Restated License Agreement between pSivda US, Inc. and Bausch & Lomb dated August 1, 2009	10-K	09/25/09	10.13
10.31	#	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
10.32	#	Amended and Restated Collaborative Research and License Agreement, dated as of June 14, 2011, by and among pSivida Corp, pSivida US, Inc., pSiMedica Limited and Pfizer, Inc.	10-K/A	12/27/11	10.13
10.33		Agreement, dated April 11, 2017, by and between pSivida Corp., pSiMedica Limited and Pfizer, Inc.	10-K	09/13/17	10.25
		Material Contracts - Other Agreements			
10.34		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
10.35		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
10.36		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
10.37		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
10.38		Credit Agreement, dated as of March 28, 2018, among pSivida Corp., SWK Funding LLC and the financial institutions party thereto from time to time as lenders	8-K	03/29/18	10.4
10.39		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
10.40		Fee Letter, dated February 13, 2019, by and between EyePoint Pharmaceuticals, Inc. and CRG Servicing LLC	8-K	02/19/19	10.2

Exhibit No.		Exhibit Description	Incorporated by Reference to SEC Filing		
			Form	SEC Filing Date	Exhibit No.
		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			
101		The following materials from EyePoint Pharmaceuticals' Transition Report on Form 10-K for the six months ended December 31, 2018, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets at December 31, 2018, June 30, 2018 and 2017; (ii) Consolidated Statements of Comprehensive Loss for the six months ended December 31, 2018 and the years ended June 30, 2018, 2017 and 2016; (iii) Consolidated Statements of Stockholders' Equity for the six months ended December 31, 2018 and the years ended June 30, 2018, 2017 and 2016; (iv) Consolidated Statements of Cash Flows for the six months ended December 31, 2018 and the years ended June 30, 2018, 2017 and 2016; and (v) Notes to Consolidated Financial Statements.			

Confidential treatment has been granted for portions of this exhibit

\+ 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 18, 2019

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 18, 2019
/s/ NANCY LURKER **Nancy Lurker**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 18, 2019
/s/ DAVID PRICE **David Price**	Chief Financial Officer (Principal Financial Officer)	March 18, 2019
/s/ LEONARD S. ROSS **Leonard S. Ross**	VP, Finance and Chief Accounting Officer (Principal Accounting Officer)	March 18, 2019
/s/ DAVID J. MAZZO **David J. Mazzo**	Director	March 18, 2019
/s/ MICHAEL ROGERS **Michael Rogers**	Director	March 18, 2019
/s/ DOUGLAS GODSHALL **Douglas Godshall**	Director	March 18, 2019
/s/ JAY DUKER **Jay Duker**	Director	March 18, 2019
/s/ KRISTINE PETERSON **Kristine Peterson**	Director	March 18, 2019
/s/ RONALD W. EASTMAN **Ronald W. Eastman**	Director	March 18, 2019
/s/ JOHN LANDIS **John Landis**	Director	March 18, 2019
/s/ DAVID R. GUYER **David R. Guyer**	Director	March 18, 2019

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, 2018 and June 30, 2018 and 2017, the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows for the six month period ended December 31, 2018, and each of the three years in the period ended June 30, 2018, 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, 2018 and June 30, 2018 and 2017, and the results of its operations and its cash flows for the six month period ended December 31, 2018, and each of the three years in the period ended June 30, 2018, 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, 2018, 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 18, 2019, expressed an unqualified opinion on the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has 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.

Going Concern

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

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 18, 2019

We have served as the Company's auditor since 2008.

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, 2018, 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, 2018, 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 six month period ended December 31, 2018, of the Company and our report dated March 18, 2019, expressed an unqualified opinion on those financial statements, and included explanatory paragraphs regarding the Company's adoption of a new accounting standard 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 18, 2019

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

	December 31, 2018	June 30, 2018	June 30, 2017
Assets			
Current assets:			
Cash and cash equivalents	$ 45,261	$ 38,776	$ 16,898
Accounts and other receivables	627	353	251
Prepaid expenses and other current assets	1,434	780	591
Inventory	279	—	—
Total current assets	47,601	39,909	17,740
Property and equipment, net	288	253	313
Intangible assets, net	30,129	31,358	364
Other assets	—	—	110
Restricted cash	150	150	150
Total assets	$ 78,168	$ 71,670	$ 18,677
Liabilities and stockholders' equity			
Current liabilities:			
Accounts payable	$ 2,640	$ 2,940	$ 1,016
Accrued expenses	3,789	3,723	4,224
Accrued development milestone	15,000	15,000	—
Deferred revenue	30	—	50
Total current liabilities	21,459	21,663	5,290
Long-term debt	17,621	17,309	—
Derivative liability	—	19,780	—
Other long-term liabilities	1,455	1,231	51
Total liabilities	40,535	59,983	5,341
Commitments and 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 at December 31, 2018 and June 30, 2018 and 120,000,000 shares authorized at June 30, 2017; 95,372,236, 74,512,048 and 39,356,999 shares issued and outstanding at December 31, 2018, June 30, 2018 and June 30, 2017, respectively	95	74	39
Additional paid-in capital	445,192	374,766	323,284
Accumulated deficit	(408,493)	(363,991)	(310,820)
Accumulated other comprehensive income	839	838	833
Total stockholders' equity	37,633	11,687	13,336
Total liabilities and stockholders' equity	$ 78,168	$ 71,670	$ 18,677

See notes to consolidated financial statements

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

	Six Months Ended December 31, 2018	Year Ended June 30, 2018	2017	2016
Revenues:				
Collaborative research and development	$ 1,883	$ 1,343	$ 6,569	$ 398
Royalty income	1,045	1,618	970	1,222
Total revenues	2,928	2,961	7,539	1,620
Operating expenses:				
Research and development	10,412	16,178	14,880	14,381
Sales and marketing	8,174	1,512	—	—
General and administrative	8,901	11,545	11,235	9,013
Total operating expenses	27,487	29,235	26,115	23,394
Operating loss	(24,559)	(26,274)	(18,576)	(21,774)
Interest and other income, net	367	101	91	72
Interest expense	(1,642)	(720)	—	—
Change in fair value of derivative liability	(18,886)	(26,278)	—	—
Loss before income taxes	(44,720)	(53,171)	(18,485)	(21,702)
Income tax benefit	—	—	—	155
Net loss	$ (44,720)	$(53,171)	$(18,485)	$(21,547)
Net loss per share:				
Basic and diluted	$ (0.53)	$ (1.15)	$ (0.52)	$ (0.68)
Weighted average common shares outstanding:				
Basic and diluted	85,057	46,226	35,344	31,623
Net loss	$ (44,720)	$(53,171)	$(18,485)	$(21,547)
Other comprehensive income (loss):				
Foreign currency translation adjustments	1	5	(21)	(96)
Net unrealized gain on marketable securities	—	—	2	3
Other comprehensive income (loss)	1	5	(19)	(93)
Comprehensive loss	$ (44,719)	$(53,166)	$(18,504)	$(21,640)

See notes to consolidated financial statements

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number of Shares	Par Value Amount				
Balance at July 1, 2015	29,412,365	$ 29	$293,060	$ (270,666)	$ 945	$ 23,368
Net loss	—	—	—	(21,547)	—	(21,547)
Other comprehensive loss	—	—	—	—	(93)	(93)
Issuance of stock, net of issue costs	4,440,000	5	16,495	—	—	16,500
Exercise of stock options	320,554	—	490	—	—	490
Stock-based compensation	—	—	2,163	—	—	2,163
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

See notes to consolidated financial statements

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

	Six Months Ended December 31, 2018	Year Ended June 30, 2018	2017	2016
Cash flows from operating activities:				
Net loss	$ (44,720)	$(53,171)	$(18,485)	$(21,547)
Adjustments to reconcile net loss to cash flows used in operating activities:				
Amortization of intangible assets	1,229	981	724	756
Depreciation of property and equipment	97	167	91	152
Amortization of debt discount	312	209	—	—
Amortization of bond (discount) premium on marketable securities	—	—	(9)	87
Amortization of noncurrent portion of deferred revenue	—	—	(5,585)	—
Stock-based compensation	2,550	2,704	2,456	2,163
Change in fair value of derivative liability	18,886	26,278	—	—
Changes in operating assets and liabilities:				
Accounts and other receivables	(59)	7	219	116
Prepaid expenses and other current assets	(652)	(174)	(99)	187
Inventory	(279)	—	—	—
Accounts payable	(298)	1,747	(346)	626
Accrued expenses	94	(585)	650	1,036
Deferred revenue	30	(50)	(97)	103
Deferred rent	224	(20)	(9)	5
Net cash used in operating activities	(22,586)	(21,907)	(20,490)	(16,316)
Cash flows from investing activities:				
Purchases of marketable securities	—	—	(5,052)	(17,517)
Maturities of marketable securities	—	—	18,743	13,168
Acquisition of Icon Bioscience Inc., net of cash acquired	—	(16,780)	—	—
Purchases of property and equipment	(132)	(108)	(147)	(113)
Proceeds from sale of property and equipment	—	—	33	—
Net cash (used in) provided by investing activities	(132)	(16,888)	13,577	(4,462)
Cash flows from financing activities:				
Proceeds from exercise of warrants	28,863	—	—	—
Proceeds from issuance of stock, net of issuance costs	—	41,515	8,404	16,500
Proceeds from issuance of long-term debt	—	20,000	—	—
Payment of debt issue costs	—	(1,347)	—	—
Net settlement of stock units to satisfy statutory tax withholding	(195)	—	—	—
Proceeds from exercise of stock options	536	503	99	490
Net cash provided by financing activities	29,204	60,671	8,503	16,990
Effect of foreign exchange rate changes on cash and cash equivalents	(1)	2	(5)	(20)
Net increase (decrease) in cash, cash equivalents and restricted cash	6,485	21,878	1,585	(3,808)
Cash, cash equivalents and restricted cash at beginning of year	38,926	17,048	15,463	19,271
Cash, cash equivalents and restricted cash at end of year	$ 45,411	$ 38,926	$ 17,048	$ 15,463
Supplemental cash flow information:				
Cash interest paid	$ 1,241	$ 258	$ —	$ —
Supplemental disclosure of non-cash investing and financing activities:				
Accrued development milestone	—	15,000	—	—
Accrued term loan exit fee	—	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

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

1. Operations

EyePoint Pharmaceuticals, Inc. (together with its subsidiaries, the "Company"), incorporated in Delaware, is a specialty biopharmaceutical 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, a three-year non-erodible fluocinolone acetonide insert for the treatment of non-infectious posterior uveitis ("NIPU"), was approved by the FDA in October 2018 and launched directly in the U.S. in February 2019. 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 approximately three years. 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. NIPU is the third leading cause of blindness in the U.S. and affects between 55,000 to 120,000 people.

DEXYCU™ (dexamethasone intraocular suspension) 9%, approved by the FDA in February 2018 for the treatment of post-operative ocular inflammation, 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 are approximately 4.8 million cataract surgeries performed annually in the U.S. and the Company launched DEXYCU directly in the U.S. in March 2019 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"). Retisert®, one of the Company's earlier generation products, was approved in 2005 by the FDA for the treatment of NIPU and is sold in the U.S. by Bausch & Lomb Incorporated ("Bausch & Lomb").

The Company's 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. The Company's strategy includes developing products independently while continuing to leverage its technology platforms through collaborations and license agreements.

The Company has financed its operations primarily from sales of equity securities, long-term debt and the receipt of license fees, milestone payments, research and development funding and royalty income from its collaboration partners. The Company has a history of operating losses and, to date, has not had significant recurring cash inflows from revenue. The Company had cash and cash equivalents of $45.3 million at December 31, 2018.

In February 2019, the Company refinanced its existing $20.0 million term loan (see Note 10) and made an initial draw of $35.0 million from a new term loan agreement (the "CRG Loan Agreement") with CRG Servicing LLC ("CRG") (see Note 18), resulting in incremental net proceeds of approximately $11.4 million. Subsequent to the refinancing, the Company had cash and cash equivalents of $48.5 million at February 28, 2019.

Pursuant to the CRG Loan Agreement, the Company has an option to draw up to an additional $15.0 million on or before June 30, 2019. An additional $10.0 million is available subject to the achievement of $25.0 million of 3-month trailing product net sales on or before March 31, 2020.

During the first quarter of calendar 2019, the Company began selling its two products, YUTIQ and DEXYCU. The cash flows related to these two commercialized products are dependent on the amount and timing of cash receipts from the sales of YUTIQ and DEXYCU. The Company has limited history of direct commercialization of its products and there is inherent uncertainty associated with the cash flows related to these two newly commercialized products.

A combination of the Company's limited currently available cash, cash equivalents and available borrowings, together with its history of losses, absence of recurring inflows of cash from operations 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 for one year from the issuance of these financial statements.

In addition to the cash flows related to the launch of the Company's products, management's plans to extend the Company's ability to fund its operations include obtaining additional financing from the sale of equity securities through an underwritten public offering and/or the sale of shares of the Company's common stock (the "Common Stock") through its existing at-the-market ("ATM") program or from other sources or, as applicable, reducing or deferring operating expenses.

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.

In November 2018, the Company amended its by-laws to change its fiscal year from June 30 to December 31 of each year. Accordingly, these financial statements contain six-month transitional financial statements as of and for the period ended December 31, 2018 and will become calendar year financial statements thereafter. Any amounts shown as of and for the six months ended December 31, 2017 are unaudited. The years ended June 30, 2018, 2017 and 2016 may be referred to herein as fiscal 2018, fiscal 2017 and fiscal 2016, 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 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 $839,000 at December 31, 2018, $838,000 at June 30, 2018 and $833,000 at June 30, 2017. 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 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, 2018, a total of $43.2 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, 2018 or at each of June 30, 2018 and 2017. 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.

Total collaborative research and development revenue and royalty income from customers that accounted for greater than 10% of total revenues for the six months ended December 31, 2018 and for the years ended June 30, 2018, 2017 and 2016 are summarized in the following table:

Customer / Category	Six Months Ended December 31, 2018	Year Ended June 30, 2018	2017	2016
Ocumension Therapeutics	59%	*	*	*
Alimera Sciences	21%	24%	*	14%
Bausch & Lomb	16%	35%	13%	77%
Feasibility studies	*	36%	*	*
Pfizer	*	*	74%	*

* Less than 10%

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

Receivables consist primarily of quarterly royalties earned under license agreements with Alimera and Bausch & Lomb.

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.

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 recognizes the rent holiday and scheduled rent increases on a straight-line basis over the lease term, with the excess of cumulative rent expense over cash payments recorded as a deferred rent liability.

Impairment of Intangible Assets

The Company's finite life intangible assets, which historically included its Durasert and Tethadur™ patented technologies, also includes the DEXYCU product (utilizing the Verisome technology) following the March 2018 acquisition of Icon. The previous intangible assets were amortized on a straight-line basis over twelve years and were fully amortized as of December 31, 2017. 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 are within the scope of 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.

Prior to the adoption of ASC 606, revenue was recognized under ASC 605, Revenue Recognition. Under the prior standard, revenue was recognized when there was persuasive evidence that an arrangement existed, delivery had occurred, the price was fixed and determinable, and collection was reasonably assured. Multiple-deliverable arrangements, such as license and development agreements, were analyzed to determine whether the deliverables could be separated or whether they must be accounted for as a single unit of accounting. When deliverables were separable, consideration received was allocated to the separate units of accounting based on the relative selling price method using management's best estimate of the standalone selling price of deliverables when vendor-specific objective evidence or third-party evidence of selling price was not available. Allocated consideration was recognized as revenue upon application of the appropriate revenue recognition principles to each unit. When the Company determined that an arrangement should be accounted for as a single unit of accounting, it determined the period over which the performance obligations would be performed and revenue would be recognized.

Collaborative research and development revenue — The Company analyzes each element of its collaborative 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, 2018.

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 during the six months 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. Prior to the adoption of ASU 2016-09, the Company recognized compensation expense for only the portion of share-based payment awards that were expected to vest. Based on historical trends, the Company applied estimated forfeiture rates to determine the number of awards that were expected to vest. Additional expense was recorded if the actual forfeiture rate for each tranche of option grants was lower than estimated, and a recovery of prior expense was recorded if the actual forfeiture rate was higher than estimated.

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:

	Six Months Ended December 31,	Year Ended June 30,		
	2018	2018	2017	2016
Stock options	8,139,377	7,750,244	6,895,685	4,981,421
Warrants	486,812	20,671,036	623,605	623,605
Restricted stock units	1,090,213	1,398,129	948,500	—
Performance stock units	370,000	466,668	210,000	—
Deferred stock units	35,418	35,001	—	—
	10,121,820	30,321,078	8,677,790	5,605,026

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 February 2016, the FASB issued ASU No. 2016-02, *Leases*. 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 leases with terms longer than 12 months. Leases will be classified as either finance or operating, with such classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Based on the change in the Company’s fiscal year, ASU 2016-02 became effective on January 1, 2019. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is evaluating the impact the adoption of this standard will have on its consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): 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).

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”) among the Company, Icon, and Shareholder Representative Services LLC (“SRS”), solely in its capacity as representative of Icon’s securityholders. The Icon Acquisition has been 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 an equity financing and a debt financing, both of which closed concurrently with the Icon Acquisition (see Notes 11 and 10, respectively).

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 the Company's 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 consideration of DEXYCU 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.

The purchase price on the date of the Icon Acquisition was $32.0 million, 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 has determined these payments do 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 $32.0 million purchase price was allocated to a single finite-lived intangible asset with an expected amortization life of approximately 13 years (see Note 6). 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.

4. License and Collaboration Agreements

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 licensed products. In addition, the Company was entitled to receive 20% 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. Alimera was entitled to recover 20% of previously incurred and unapplied net losses (as defined) for commercialization of each product in a country, but only by an offset of up to 4% of the net profits earned in that country each quarter, reducing the Company's net profit share to 16% in each country until those net losses were recouped. In the event that Alimera sublicensed commercialization in any country, the Company was entitled to 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions. The Company was also entitled to reimbursement of certain patent maintenance costs with respect to the patents licensed to Alimera.

Revenue under the Prior Alimera Agreement, as well as all patent fee reimbursements, totaled $39,000 for the six months ended December 31, 2018, $148,000 for fiscal 2018, $659,000 for fiscal 2017 and $233,000 for fiscal 2016, which are included in collaborative research and development revenues in the accompanying consolidated statements of comprehensive loss. These revenues included (i) $50,000 and

$585,000 of net profit share earned in fiscal 2018 and 2017, respectively, of which the fiscal 2017 total included $136,000 recognized in connection with an arbitration settlement related to calendar year 2014 reporting by Alimera; and (ii) $157,000 of non-royalty sublicense consideration earned in fiscal 2016. The remainder of Alimera revenues included in collaborative research and development for each year consisted principally of patent fee reimbursements.

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 Durasert for NIPU product to Alimera for Europe, the Middle East and Africa (the "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.

Sales-based royalties started at the rate of 2%. Commencing December 12, 2018, the sales-based royalty increased to 6% on aggregate calendar year net sales up to $75 million and to 8% on any calendar year sales in excess of $75 million. Alimera's share of contingently recoverable accumulated ILUVIEN commercialization losses under the original net profit share arrangement, capped at $25 million, are to be reduced as follows: (i) $10 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) on January 1, 2020, another $5 million will be cancelled, provided, however, that such date of cancellation may be extended under certain circumstances related to Alimera's regulatory approval process for ILUVIEN for NIPU, with such extension, if any, subject to mutual agreement by the parties; 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.

Royalty income under the Amended Alimera Agreement totaled $588,000 in the six months ended December 31, 2018 and $575,000 in fiscal 2018.

Following consummation of the Amended Alimera Agreement, the Company withdrew its previously filed EU marketing approval application ("MAA") and its orphan drug designation for posterior uveitis, and Alimera became responsible for filing a Type II variation for ILUVIEN for the treatment of NIPU in the 17 EU countries where ILUVIEN is currently approved for the treatment of DME. 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. Alimera has reported that it expects to receive regulatory approval for the Type II variation in the first half of calendar year 2019. If the variation is approved, Alimera plans to commercialize the three-year NIPU indication under its ILUVIEN trademark.

Prior to the July 1, 2018 adoption of ASC 606, the Company had recorded royalties earned from Alimera one quarter in arrears upon receipt of payment. Under ASC 606, the Company is required to recognize royalty income based on an estimate of royalties earned in each fiscal quarter. As a result, $218,000 of royalties earned for the quarter ended June 30, 2018 that would have been recorded as royalty income in the three months ended September 30, 2018 have been accounted for as a cumulative effect adjustment to beginning accumulated deficit at July 1, 2018.

Pfizer

In June 2011, the Company and Pfizer entered into an Amended and Restated Collaborative Research and License agreement (the "Restated Pfizer Agreement") to focus solely on the development of a sustained-release bioerodible micro-insert injected into the subconjunctiva designed to deliver latanoprost for human ophthalmic disease or conditions other than uveitis (the "Latanoprost Product"). Pfizer made an upfront payment of $2.3 million and the Company agreed to provide Pfizer options under various circumstances for an exclusive, worldwide license to develop and commercialize the Latanoprost Product.

The estimated selling price of the combined deliverables under the Restated Pfizer Agreement of $6.7 million was partially recognized as collaborative research and development revenue over the expected performance period using the proportional performance method with costs associated with developing the Latanoprost Product reflected in operating expenses in the period in which they were incurred. No collaborative research and development revenue was recorded during fiscal 2016 and through the first quarter of fiscal 2017.

On October 25, 2016, the Company notified Pfizer that it had discontinued development of the Latanoprost Product, which provided Pfizer a 60-day option to acquire a worldwide license in return for a $10.0 million payment and potential sales-based royalties and development, regulatory and sales performance milestone payments. Pfizer did not exercise its option and the Restated Pfizer Agreement automatically terminated on December 26, 2016. The remaining deferred revenue balance of $5.6 million was recognized as revenue in the three-month period ended December 31, 2016. Per the terms of the Restated Pfizer Agreement, the Company has retained the right to develop and commercialize the Latanoprost Product on its own or with a partner.

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 totaled $456,000 in the six months ended December 31, 2018, approximately $1.0 million in fiscal 2018, $970,000 in fiscal 2017 and approximately $1.2 million in fiscal 2016. Accounts receivable from Bausch & Lomb totaled $253,000 at December 31, 2018, $306,000 at June 30, 2018 and $246,000 at June 30, 2017.

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 2018. 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, 2018, OncoSil has not received regulatory approval in any jurisdiction, although an application for CE Mark approval in Europe continues to be pending. The Company has no consequential performance obligations under the OncoSil license agreement, and, accordingly, any amounts to which the Company is entitled under the agreement are recognized as revenue on the earlier of receipt or when collectability is reasonably assured. Revenue related to the OncoSil agreement totaled $100,000 in the six months ended December 31, 2018, and in each of fiscal 2018, fiscal 2017 and fiscal 2016. At December 31, 2018, 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 chronic NIPU in the greater China territory, which is comprised of 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 approximately $10 million upon the achievement by Ocumension of certain prescribed development, regulatory and commercial sales-based milestones. In addition, the Company is entitled to receive mid-single digit sales-based royalties.

Other than a fixed number of hours of technical assistance support to be provided at no cost by the Company, 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 short-acting line extension candidate for the treatment of NIPU.

Applying the revenue guidance under ASC 606, the Company recognized approximately $1.7 million of collaborative research and development revenue in the three months ended December 31, 2018. The remaining balance of $30,000 attributable to the Company's technical assistance obligation has been recorded as current deferred revenue in the accompanying consolidated balance sheet.

Feasibility Study 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 $15,000 in the six months ended December 31, 2018, $1.1 million in fiscal 2018, $211,000 in fiscal 2017 and $33,000 in fiscal 2016. At December 31, 2018, no deferred revenue was recorded for any such agreements.

5. Inventory

Inventory consisted of the following (in thousands):

	December 31, 2018	June 30, 2018
Raw materials	$ 198	$ —
Work in process	41	—
Finished goods	40	—
Total inventory	$ 279	$ —

6. Intangible Assets

The reconciliation of intangible assets for the six months ended December 31, 2018 and for the years ended June 30, 2018 and 2017 was as follows (in thousands):

	Six Months Ended December 31, 2018	Year Ended June 30, 2018	2017
Patented technologies			
Gross carrying amount at beginning of period	$ 68,322	$ 35,610	$ 36,196
Acquisition of Icon Bioscience Inc.	—	31,973	—
Foreign currency translation adjustments	—	739	(586)
Gross carrying amount at end of period	68,322	68,322	35,610
Accumulated amortization at beginning of period	(36,964)	(35,246)	(35,094)
Amortization expense	(1,229)	(981)	(724)
Foreign currency translation adjustments	—	(737)	572
Accumulated amortization at end of period	(38,193)	(36,964)	(35,246)
Net book value at end of period	$ 30,129	$ 31,358	$ 364

The net book value of the Company's intangible assets at December 31, 2018, June 30, 2018 and June 30, 2017 is summarized as follows (in thousands):

	December 31, 2018	June 30, 2018	2017	Estimated Remaining Useful Life at December 31, 2018 (Years)
Patented technologies				
DEXYCU / Verisome	$ 30,129	$31,358	$ —	12.25
Durasert	—	—	265	—
Tethadur	—	—	99	—
	$ 30,129	$31,358	$364	

The Company amortizes its intangible assets with finite lives on a straight-line basis over their respective estimated useful lives. Amortization expense totaled $1.2 million in the six months ended December 31, 2018, $981,000 in fiscal 2018, $724,000 in fiscal 2017 and $756,000 in fiscal 2016, all of which amounts were included in research and development expense in the accompanying consolidated financial statements. Following the launch of DEXYCU, amortization expense will be included as a component of cost of sales.

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 useful life estimated to be 13 years at the rate of approximately $2.5 million per year.

7. Property and Equipment, Net

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

	December 31, 2018	June 30, 2018	June 30, 2017
Property and equipment	$ 882	$ 805	$ 698
Leasehold improvements	101	101	101
Gross property and equipment	983	906	799
Accumulated depreciation and amortization	(695)	(653)	(486)
	$ 288	$ 253	$ 313

Depreciation expense totaled $97,000 in the six months ended December 31, 2018, $167,000 in fiscal 2018, $91,000 in fiscal 2017 and $152,000 in fiscal 2016.

8. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2018	June 30, 2018	June 30, 2017
Personnel costs	$ 1,998	$1,763	$1,632
Clinical trial costs	798	742	1,984
Professional fees	571	926	590
Interest	343	254	—
Other	79	38	18
	$ 3,789	$3,723	$4,224

9. Restructuring

In July 2016, the Company announced its plan to consolidate all research and development activities in its U.S. facility. Following employee consultations under local U.K. law, the Company determined to close its U.K. research facility and terminated the employment of its U.K. employees. The U.K. facility lease, set to expire on August 31, 2016, was extended through November 30, 2016 to facilitate an orderly transition and the required restoration of the premises. A summary reconciliation of the restructuring costs is as follows (in thousands):

	Balance at June 30, 2016	Charged to Expense	Payments	Balance at June 30, 2017
Termination benefits	$ 118	$ 273	$ (391)	$ —
Facility closure	40	73	(113)	—
Other	29	126	(155)	—
	$ 187	$ 472	$ (659)	$ —

The Company recorded approximately $472,000 of restructuring costs during fiscal 2017 to research and development expense. These costs consisted of (i) $273,000 of additional employee severance for discretionary termination benefits upon notification of the affected employees in accordance with ASC 420, *Exit or Disposal Cost Obligations*; and (ii) $199,000 of professional fees, travel and lease extension costs.

In addition, for the first quarter of fiscal 2017, the Company recorded $99,000 of non-cash stock-based compensation expense in connection with the extension, through June 30, 2017, of the exercise period for all vested stock options held by the U.K. employees at July 31, 2016 and a $133,000 credit to stock-based compensation expense to account for forfeitures of all non-vested stock options at that date.

The Company paid all of the restructuring costs associated with the plan of consolidation as of March 31, 2017.

10. Term Loan Agreement

On March 28, 2018 (the "Closing Date"), the Company entered into a Credit Agreement (the "SWK Credit Agreement") among the Company, as borrower, SWK Funding LLC, as agent (the "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 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").

The SWK Loan was originally scheduled to mature on March 27, 2023 (the "Maturity Date") 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 (see Note 18). In addition to repayment of the $20 million principal balance, the Company paid (i) a $1.2 million prepayment penalty, (ii) a $1.2 million exit fee (the "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 the first anniversary of the Loan.

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. The SWK Warrant is exercisable (i) with respect to the Initial Advance Warrant Shares, any time on or after the 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, 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 the 1.5% upfront 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 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. 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 method.

11. Stockholders' Equity

2018 Equity Financing

On the 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 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").

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.

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 (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 exercise price of each Second Tranche Warrant issued in the Second Tranche Transaction 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 Common Stock on the Nasdaq Stock Market 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 Second Tranche Warrants were exercisable at any time 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. CMS approved transitional pass-through status and reimbursement through a C-code with an effective date of October 1, 2018. Following written notice of such approval to the holders of the Second Tranche Warrants on September 7, 2018, the Second Tranche Warrants were exercised in September 2018 at a purchase price of $1.43 per share for proceeds of $28.9 million.

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 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 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 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 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 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 re-measured at June 30, 2018, resulting in a change in fair value of derivative of approximately $1.6 million and a derivative liability balance of $19.8 million at June 30, 2018. The Second Tranche Warrants were revalued immediately prior to exercise and resulted in a change in fair value of $18.9 million. The change in fair value 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.

ATM Facility

In February 2017, the Company entered into an ATM program (the "Prior ATM Program") pursuant to which, under a previous Form S-3 shelf registration statement, the Company could, 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 paid the sales agent a commission of up to 3.0% of the gross proceeds from the sale of such shares. The Company incurred approximately $223,000 of legal, accounting and other costs to establish and activate the Prior ATM Program. Prior to the Company's delisting from the Australian Securities Exchange ("ASX") in May 2018, the Company's ability to sell shares under the Prior ATM Program was subject to ASX listing rules, as defined, limiting the number of shares the Company could issue in any 12-month period without stockholder approval, as well as other applicable rules and regulations of the ASX and Nasdaq Stock Market.

During fiscal 2017 (from March 2017 through May 9, 2017), the Company sold 5,100,000 shares of Common Stock under the Prior ATM Program ("ATM Shares Sold") at a weighted average price of $1.74 per share for gross proceeds of approximately $8.9 million. Share issue costs, including sales agent commissions, totaled $244,000 during fiscal 2017. At a special meeting of stockholders held on June 27, 2017, the Company's stockholders ratified the ATM Shares Sold, thereby refreshing the Company's capacity to issue shares of Common Stock without prior stockholder approval under the ASX listing rules. 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 60,000,000 shares to 120,000,000 shares.

During fiscal 2018 (from July 2017 through November 7, 2017), the Company sold 5,900,000 shares of Common Stock under the Prior ATM Program at a weighted average price of $1.23 per share for gross proceeds of approximately $7.3 million. Share issue costs, including sales agent commissions, totaled $239,000 during fiscal 2018.

In January 2019, the Company entered into a new ATM program (the "New ATM Program"), which replaced the Prior ATM Program in its entirety. Pursuant to the New 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. To date, the Company has not sold any shares under the New ATM Program.

Share Offering

In January 2016, the Company sold 4,440,000 shares of Common Stock in an underwritten public offering at a price of $4.00 per share for gross proceeds of $17.8 million. Underwriter discounts and commissions and other share issue costs totaled approximately $1.3 million.

Warrants to Purchase Common Shares

The following table provides a reconciliation of fixed price warrants to purchase Common Stock for the six months ended December 31, 2018 and for the years ended June 30, 2018 and 2017, which table excludes the Second Tranche Warrants that were subject to a variable exercise price:

	Six Months Ended December 31, 2018		Year Ended June 30, 2018		2017	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of period	486,812	$ 1.23	623,605	$ 2.50	623,605	$ 2.50
Issued	—	—	486,812	1.23	—	—
Expired	—	—	(623,605)	2.50	—	—
Balance and exercisable at end of period	486,812	$ 1.23	486,812	$ 1.23	623,605	$ 2.50

In connection with the SWK Loan (see Note 10), the Company issued warrants (i) to purchase 409,091 shares of Common Stock on March 28, 2018 at an exercise price of $1.10 per share with a seven-year term and (ii) to purchase 77,721 shares of Common Stock on June 26, 2018 at an exercise price of $1.93 per share with a seven-year term.

On August 7, 2017, previously issued 5-year investor warrants expired unexercised.

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"), provided for the issuance of up to 3,000,000 shares of Common Stock reserved for issuance under the 2016 Plan plus any additional shares of 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 December 31, 2018, a total of 1,302,978 shares were available for new awards.

Stock Options

The following table provides a reconciliation of stock option activity under the Company's equity incentive plans for the six months ended December 31, 2018:

	Number of options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at July 1, 2018	6,460,244	$ 2.79		
Granted	361,483	2.40		
Exercised	(200,000)	1.10		
Forefeited	(10,600)	2.76		
Expired	(156,750)	2.85		
Outstanding at December 31, 2018	6,454,377	$ 2.82	7.18	$ 189
Exercisable at December 31, 2018	2,959,475	$ 3.47	5.00	$ 53

During the six months ended December 31, 2018, the Company granted 165,000 options to employees with ratable annual vesting over 3 years, 1,667 options to a non-executive director with 1-year cliff vesting, 95,000 options to two newly appointed non-executive directors with ratable annual vesting over 3 years and 99,816 options to external consultants with 1-year cliff vesting. During the six months ended December 31, 2018, a total of 409,891 options vested. All option grants have a 10-year term.

In determining the grant date fair value of option awards under the equity incentive plans, the Company applied the Black-Scholes option pricing model. Based upon limited option exercise history, the Company has generally used the "simplified" method outlined in SEC Staff Accounting Bulletin No. 110 to estimate the expected life of stock option grants. Management believes that the historical volatility of the Company's stock price on the Nasdaq Stock Market best represents the expected volatility over the estimated life of the option. The risk-free interest rate is based upon published U.S. Treasury yield curve rates at the date of grant corresponding to the expected life of the stock option. An assumed dividend yield of zero reflects the fact that the Company has never paid cash dividends and has no intentions to pay dividends in the foreseeable future.

The key assumptions used to apply the option pricing model for options granted under the 2016 Plan during the six months ended December 31, 2018 and the years ended June 30, 2018, 2017 and 2016 were as follows:

	Six Months Ended December 31, 2018	Year Ended June 30, 2018	2017	2016
Option life (in years)	5.50 - 6.00	5.50 - 6.00	5.50 - 6.25	5.50 - 6.25
Stock volatility	59% - 61%	59% - 64%	70% - 72%	76% - 80%
Risk-free interest rate	2.78% - 3.09%	2.18% - 2.89%	1.23% - 2.08%	1.47% - 1.97%
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 six months ended December 31, 2018 and the years ended June 30, 2018, 2017 and 2016 (in thousands except per share amounts):

	Six Months Ended December 31, 2018	Year Ended June 30, 2018	2017	2016
Weighted-average grant date fair value per share	$ 1.37	$1.06	$1.95	$2.74
Total cash received from exercise of stock options	219	503	99	490
Total intrinsic value of stock options exercised	284	152	53	967

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.

In connection with retention bonus agreements entered into in January 2017, a total of 305,616 RSUs were issued on December 22, 2017 and were fully vested on December 22, 2018.

The following table provides a reconciliation of RSU activity under the 2016 Plan for the six months ended December 31, 2018:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Nonvested at July 1, 2018	898,129	$ 1.58
Vested	(305,616)	1.05
Forfeited	(2,300)	1.81
Nonvested at December 31, 2018	590,213	$ 1.86

The weighted-average remaining vesting term of the RSUs at December 31, 2018 was 1.29 years.

Performance-Based Stock Units

Performance Stock Units ("PSUs") were awarded to certain employees in June 2017. 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 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 to a service-based condition with a vesting date of October 12, 2019.

The following table provides a reconciliation of PSU activity under the 2016 Plan for the six months ended December 31, 2018:

	Number of Performance Stock Units	Weighted Average Grant Date Fair Value
Nonvested at July 1, 2018	241,668	$ 1.52
Vested	(96,668)	1.52
Nonvested at December 31, 2018	145,000	$ 1.52

The weighted-average remaining vesting term of the outstanding PSUs at December 31, 2018 was approximately 7 months.

Deferred Stock Units

A total of 35,001 deferred stock units ("DSUs") were issued to incumbent non-executive directors on June 21, 2018 with one-year cliff vesting and a grant date fair value of $1.95 per share. An additional 417 DSUs were awarded in September 2018 to one non-executive director with one-year cliff vesting and a grant date fair value of $2.32 per share. Subsequent to vesting, the DSUs will be settled in shares of 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.

The following table provides a reconciliation of DSU activity under the 2016 Plan for the six months ended December 31, 2018:

	Number of Deferred Stock Units	Weighted Average Grant Date Fair Value
Nonvested at July 1, 2018	35,001	$ 1.95
Granted	417	2.32
Nonvested at December 31, 2018	35,418	$ 1.95

At December 31, 2018, the weighted-average remaining vesting term of the DSUs was approximately 5.6 months.

Inducement Award Grants

In connection with the September 15, 2016 hire of the Company's President and CEO, the Company granted 850,000 options to purchase Common Stock with ratable annual vesting over 4 years, an exercise price of $3.63 per share and a 10-year term. Although the stock options were not awarded under the 2008

Plan, the stock options are subject to and governed by the terms and conditions of the 2008 Plan. On the same date, the Company also granted an additional inducement award of 500,000 market-based Restricted Stock Units ("market-based RSUs"). Subject to a service condition, the number of shares underlying the market-based RSU that will vest is based upon a 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 through September 15, 2019. 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.

In connection with the May 14, 2018 hire of the Company's Executive Vice President and General Manager, US ("EVP & GM"), the Company granted 375,000 options to purchase Common Stock with ratable annual vesting over 3 years, 65,000 options with 1-year cliff vesting and 225,000 PSUs. The options had an exercise price of $1.95 per share and a 10-year term and, although not awarded under the 2016 Plan, are subject to and governed by the terms and conditions of the 2016 Plan. The PSUs were subject to proportional vesting based on cumulative measurement for the 3-year period ending June 30, 2021, with two-thirds of the award based upon defined amounts of the Company's product revenues and one-third upon measurement of the net present value of certain business development transactions consummated by the Company. As of September 26, 2018, the EVP & GM's service with the Company ended and vesting of certain options was accelerated in accordance with the terms of the option awards, with an option exercise period through December 26, 2018.

In connection with the August 1, 2018 hire of the Company's Chief Financial Officer, the Company granted as inducement awards (i) 385,000 options to purchase Common Stock with ratable annual vesting over 3 years and an exercise price of $2.22 per share; and (ii) 225,000 PSUs. The PSUs are subject to proportional vesting based on cumulative measurement for the 3-year period ending June 30, 2021, with two-thirds of the award based upon defined amounts of the Company's product revenues and one-third based upon the net present value of each applicable business development transaction measured as of the date that each such transaction is consummated by the Company. The performance conditions of the PSUs were not deemed to be probable of occurrence at December 31, 2018 and, accordingly, no stock-based compensation has been recorded for the six months ended December 31, 2018.

In connection with the August 14, 2018 hire of the Company's Senior Vice President of Regulatory and Quality, the Company granted as an inducement award 100,000 options to purchase Common Stock with ratable annual vesting over 3 years and an exercise price of $2.10 per share.

In connection with the November 26, 2018 hire of the Company's Senior Vice President, General Counsel and Company Secretary, the Company granted as an inducement award 350,000 options to purchase Common Stock with ratable annual vesting over 3 years and an exercise price of $2.07 per share.

Each of the inducement equity awards issued during the six months ended December 31, 2018 are subject to and governed by the terms and conditions of the 2016 Plan and the stock options have a 10-year term. During the six months ended December 31, 2018, a total of 402,500 options vested.

The following table provides a reconciliation of the Company's inducement stock option awards for the six months ended December 31, 2018:

	Number of options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at July 1, 2018	1,290,000	$ 3.06		
Granted	835,000	2.14		
Exercised	(162,291)	1.95		
Forfeited	(250,000)	1.95		
Expired	(27,709)	1.95		
Outstanding at December 31, 2018	1,685,000	$ 2.89	8.71	$ —
Exercisable at December 31, 2018	425,000	$ 3.63	7.71	$ —

The key assumptions used to apply the option pricing model for inducement options granted during the six months ended December 31, 2018 and the years ended June 30, 2018 and 2017 were as follows:

	Six Months Ended December 31, 2018	Year Ended June 30, 2018	Year Ended June 30, 2017
Option life (in years)	6.00	5.50 – 6.00	5.50 – 6.25
Stock volatility	59% – 61%	60% – 62%	70%
Risk-free interest rate	2.81% – 2.94%	2.88% – 2.91%	2.13%
Expected dividends	0.0%	0.0%	0.0%

The following table summarizes information about employee inducement option awards for the six months ended December 31, 2018 and the years ended June 30, 2018 and 2017 (in thousands except per share amounts):

	Six Months Ended December 31, 2018	Year Ended June 30, 2018	Year Ended June 30, 2017
Weighted-average grant date fair value per share	$ 1.24	$ 1.14	$ 0.84
Total cash received from exercise of stock options	317	—	—
Total intrinsic value of stock options exercised	44	—	—

Stock-Based Compensation Expense

The Company’s statements of comprehensive loss included total compensation expense from stock-based payment awards as follows (in thousands):

	Six Months Ended December 31, 2018	Year Ended June 30, 2018	2017	2016
Compensation expense included in:				
Research and development	$ 913	$1,252	$1,109	$ 702
Sales and marketing	325	50	—	—
General and administrative	1,312	1,402	1,347	1,461
	$ 2,550	$2,704	$2,456	$2,163

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, 2018, there was approximately $4.4 million of unrecognized compensation expense related to outstanding equity awards under the 2016 Plan, the 2008 Plan and inducement awards that is expected to be recognized as expense over a weighted-average period of approximately 1.5 years.

13. Fair Value Measurements

The following tables summarize the Company's assets and liabilities carried at fair value measured on a recurring basis at December 31, 2018, June 30, 2018 and 2017 by valuation hierarchy (in thousands):

Description	December 31, 2018 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	$ —	$ —

Description	June 30, 2018 Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	$ 28,826	$ 28,826	$ —	$ —
	$ 28,826	$ 28,826	$ —	$ —
Liabilities:				
Derivative liabilities	$ 19,780	$ —	$ —	$ 19,780
	$ 19,780	$ —	$ —	$ 19,780

Description	June 30, 2017 Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	$ 13,521	$ 13,521	$ —	$ —
	$ 13,521	$ 13,521	$ —	$ —

Financial instruments that potentially subject the Company to concentrations of credit risk have historically consisted principally of cash and cash equivalents. At December 31, 2018, June 30, 2018 and June 30, 2017, 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.

The Second Tranche Transaction was determined to be liability classified (see Note 11), which required that the liability be measured at fair value each period with changes in fair value 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 includes unobservable inputs. 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 Transaction 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

The Additional Advance Warrants were initially determined to be liability classified (see Note 10), 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 includes unobservable inputs. The Additional Advance Warrant 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 the Common Stock, the risk-free interest rate and management's assessments of the probability of the Additional Advance being drawn upon. Upon the closing of the Second Tranche Transaction in June 2018, the Additional Advance Warrants no longer met the criteria to be classified as a liability. The Company remeasured the Additional Advance Warrants immediately prior to the close of the Second Tranche Transaction and reclassified the liability balance to equity. Significant assumptions used to value this liability were as follows:

	March 28, 2018 (Date of Issuance)	June 25, 2018 (Date of Reclassification to Equity)
Volatility	55.20%	55.10%
Risk free interest rate	1.70%	2.80%
Term (in years)	7	7
Dividend rate	0%	0%
Valuation date stock price	$ 1.07	$ 1.93
Probability of issuance	80%	100%

Upon the closing of the Second Tranche Transaction, the Company issued the Second Tranche Warrants, which were determined to be liability classified, which requires 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. Significant assumptions used to value this liability were as follows:

	June 25, 2018 (Date of issuance)	June 30, 2018
Volatility	81.00%	85.40%
Risk free interest rate	2.10%	2.10%
Term (in years)	0.5	0.5
Dividend rate	0%	0%
Valuation date stock price	$ 2.00	$ 2.08
Probability of issuance	100%	100%

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 exercise by the Second Tranche Investors, measured as the excess of the closing share price on the exercise 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 liabilities for which fair value is determined by Level 3 inputs for the year ended June 30, 2018 and for the six months ended December 31, 2018 (in thousands):

	Second Tranche Transaction Liability	Additional Advance Warrant Liability	Second Tranche Warrants Liability	Total
Balance at July 1, 2017	$ —	$ —	$ —	$ —
Initial fair value of derivative liability	4,734	69	18,165	22,968
Change in fair value	24,319	18	1,615	25,952
Reclassification to equity	—	(87)	—	(87)
Settlement	(29,053)	—	—	(29,053)
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	$ —	$ —	$ —	$ —

Also included in the change in fair value for the year ended June 30, 2018 was $326,000 of transaction costs that were expensed in connection with the issuance of the derivative liabilities.

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 $216,000 for the six months ended December 31, 2018, $220,000 for fiscal 2018, $193,000 for fiscal 2017 and $209,000 for fiscal 2016 in connection with these retirement plans.

15. Income Taxes

The components of income tax benefit are as follows (in thousands):

	Six Months Ended December 31, 2018	Year Ended June 30, 2018	2017	2016
U.S. operations:				
Current income tax expense	$ —	$ —	$ —	$ 4
Deferred income tax benefit	—	—	—	—
	—	—	—	4
Non-U.S. operations:				
Current income tax benefit	—	—	—	(159)
Deferred income tax benefit	—	—	—	—
	—	—	—	(159)
Income tax benefit	$ —	$ —	$ —	$ (155)

During the fiscal year ended June 30, 2016, the Company recognized a current income tax benefit of $159,000 related to foreign research and development tax credits earned by its U.K. subsidiary.

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

	Six Months Ended December 31, 2018	Year Ended June 30, 2018	2017	2016
U.S. operations	$ (44,804)	$ (53,000)	$ (17,566)	$ (19,780)
Non-U.S. operations	84	(171)	(919)	(1,922)
Loss before income taxes	$ (44,720)	$ (53,171)	$ (18,485)	$ (21,702)

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 six months ended December 31, 2018, 27.5% for fiscal 2018 and 34% for each of fiscal 2017 and fiscal 2016 to loss before income taxes, and actual income tax benefit is reconciled in the following table (in thousands):

	Six Months Ended December 31, 2018	Year Ended June 30, 2018	2017	2016
Income tax benefit at statutory rate	$ (9,391)	$ (14,622)	$ (6,284)	$ (7,379)
State income taxes, net of federal benefit	(1,657)	(1,552)	(928)	(1,044)
Non-U.S. income tax rate differential	186	(66)	(121)	778
Change in fair value of derivative	3,900	7,227	—	—
Change in federal tax rate	—	14,673	—	—
Research and development tax credits	(231)	(284)	(242)	(397)
Permanent items	—	(15)	(9)	216
Changes in valuation allowance	7,166	(5,385)	7,489	6,789
Other, net	27	24	95	882
Income tax benefit	$ —	$ —	$ —	$ (155)

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, 2018	June 30, 2018	2017
Deferred tax assets:			
Net operating loss carryforwards	$ 53,259	$ 47,774	$ 39,439
Deferred revenue	70	—	20
Stock-based compensation	4,788	4,241	5,107
Tax credits	3,696	3,463	1,727
Other	682	185	186
Total deferred tax assets	62,495	55,663	46,479
Deferred tax liabilities:			
Intangible assets	8,207	8,542	123
Deferred tax assets, net	54,288	47,121	46,356
Valuation allowance	54,288	47,121	46,356
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 $7.1 million for the six months ended December 31, 2018 and $765,000, $7.5 million and $6.8 million during the fiscal years ended June 30, 2018, 2017 and 2016, 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, 2018 the Company had U.S. federal net operating loss carry forwards of approximately $185.9 million, 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, 2018, the Company had state net operating loss carry forwards of approximately $144.3 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, 2018 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, 2018, 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, 2018, June 30, 2018 or 2017.

As of December 31, 2018, June 30, 2018 and 2017, the Company had no accrued penalties or interest related to uncertain tax positions.

16. Commitments and Contingencies

Operating Leases

On May 17, 2018, the Company amended its lease in Watertown, Massachusetts (the "Second Amendment"). The original 5-year lease for approximately 13,650 square feet of combined office and laboratory space (the "Existing Space") of the building located at 480 Pleasant Street, Watertown, MA 02472 (the "Premises") was set to expire in April 2019. Under the Second Amendment, the Company leased an additional 6,590 square feet of rentable area (the "Additional Space", and together with the Existing Space, the "Total Space") on the Premises, with a commencement date of September 10, 2018 (the "Additional Space Effective Time"). 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 Second Amendment extends the term of the lease through May 31, 2025; provided, however, that the base rent for the Total Space was abated during the first four months ending January 10, 2019. The Company has an option to further extend the term of the lease for one additional five-year period. 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 for a period of 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.

Commencing July 1, 2017, the Company leases approximately 3,000 square feet of office space in Liberty Corner, 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.

At December 31, 2018, the Company's total future minimum lease payments under non-cancellable operating leases were as follows (in thousands):

Fiscal Year Ending December 31:	
2019	$ 826
2020	879
2021	895
2022	849
2023 and beyond	1,990
	$ 5,439

Rent expense related to the Company's real estate and other operating leases charged to operations was approximately $374,000 for the six months ended December 31, 2018, $508,000 for fiscal 2018, $442,000 for fiscal 2017 and $485,000 for fiscal 2016.

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 only one business segment, being the biotechnology sector. 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		
	Six Months Ended December 31,	Year Ended June 30,			At December 31,	At June 30,	
	2018	2018	2017	2016	2018	2018	2017
U.S.	$ 2,828	$ 2,861	$ 7,439	$ 1,520	$ 288	$ 253	$ 313
U.K.	100	100	100	100	—	—	—
Consolidated	$ 2,928	$ 2,961	$ 7,539	$ 1,620	$ 288	$ 253	$ 313

18. Subsequent Event

On February 13, 2019, the Company refinanced its existing SWK Loan (see Note 10) with the CRG Loan Agreement. Pursuant to the CRG Loan Agreement, the Company (i) made an initial draw of $35 million; (ii) has the right to draw up to an additional $15 million on or before June 30, 2019; and (iii) subject to achievement of prescribed three-month trailing product revenues of YUTIQ and DEXYCU on or before March 31, 2020, may draw up to an additional $10 million. The CRG Loan Agreement bears interest at a fixed rate of 12.5% per annum payable in arrears on the last business day of each calendar quarter, with principal due at maturity on December 31, 2023. 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. Certain prepayment premiums apply to any loan repayments made through December 31, 2021. The Company will also be required to pay an exit fee of 6% of the aggregate principal amount advanced under the CRG Loan Agreement.

In connection with the first draw under the Loan Agreement, a 1.5% financing fee of $525,000 and an expense reimbursement of $350,000 were deducted from the net borrowing proceeds.

As a result of the early repayment of the SWK Loan, the Company expects to record a loss on extinguishment of debt of approximately $3.8 million for the quarter ending March 31, 2019. This amount will consist of (i) the $1.2 million prepayment penalty; (ii) the make whole interest payment of $306,000 and (iii) the write-off of the remaining balance of unamortized debt discount of approximately $2.3 million.

19. Quarterly Financial Data (unaudited)

The following tables summarize the quarterly results of operations for the six months ended December 31, 2018 and the years ended June 30, 2018 and 2017 (in thousands except per share amounts):

	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

	Fiscal Year 2017				
	First Quarter Ended September 30, 2016	Second Quarter Ended December 31, 2016 (2)	Third Quarter Ended March 31, 2017	Fourth Quarter Ended June 30, 2017	Year Ended June 30, 2017
Total revenues	$ 277	$ 5,971	$ 590	$ 701	$ 7,539
Operating loss	(7,186)	(94)	(5,160)	(6,136)	(18,576)
Net loss	(7,162)	(67)	(5,140)	(6,116)	(18,485)
Net loss per share - basic and diluted	$ (0.21)	$ —	$ (0.15)	$ (0.16)	$ (0.52)
Weighted average common shares - basic and diluted	34,175	34,177	34,366	38,673	35,344

(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.

(2) Results for the second quarter of fiscal 2017 included $5.6 million of revenue recognized as a result of the December 2016 termination of the Company's Restated Pfizer Agreement (see Note 4).

20. Stub Period Comparative Data (Unaudited)

The condensed consolidated statement of operations for the six months ended December 31, 2017 is as follows (in thousands except per share amounts):

	Six Months Ended December 31, 2017
Revenues:	
Collaborative research and development	$ 601
Royalty income	717
Total revenues	1,318
Operating expenses:	
Research and development	8,088
General and administrative	5,044
Total operating expenses	13,132
Loss from operations	(11,814)
Interest and other income	49
Net loss	$ (11,765)
Net loss per common share - basic and diluted	$ (0.28)
Weighted average common shares - basic and diluted	41,980

Exhibit 10.16

INDEMNIFICATION AGREEMENT

This Indemnification Agreement ("Agreement") is made as of , 20 by and between EyePoint Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and ("Indemnitee"). This Agreement supersedes and replaces any and all previous agreements between the Company and Indemnitee covering the subject matter of this Agreement.

RECITALS

WHEREAS, the Board of Directors of the Company (the "Board") believes that highly competent persons have become more reluctant to serve publicly-held corporations as directors, officers or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the Board has determined that, in order to attract and retain qualified individuals, the Company will attempt to maintain on an ongoing basis, at its sole expense, liability insurance to protect persons serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among United States-based corporations and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors, officers, and other persons in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Certificate of Incorporation of the Company (as amended, the "Certificate of Incorporation") requires indemnification of the officers and directors of the Company. Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware (the "DGCL"). The Certificate of Incorporation and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the board of directors, officers and other persons with respect to indemnification;

WHEREAS, the uncertainties relating to such insurance and to indemnification may increase the difficulty of attracting and retaining such persons;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company and its stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Certificate of Incorporation and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder; and

WHEREAS, Indemnitee does not regard the protection available under the Certificate of Incorporation and insurance as adequate in the present circumstances, and may not be willing to serve or continue to serve as an officer or director without adequate protection, and the Company desires Indemnitee to serve or continue to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that Indemnitee be so indemnified.

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1. Services to the Company. Indemnitee agrees to serve as a director or officer, as applicable, of the Company. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law), in which event the Company shall have no obligation under this Agreement to continue Indemnitee in such position. This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries or any Enterprise) and Indemnitee. Indemnitee specifically acknowledges that Indemnitee's employment with the Company (or any of its subsidiaries or any Enterprise), if any, is at will, and the Indemnitee may be discharged at any time for any reason, with or without cause, except as may be otherwise provided in any written employment contract between Indemnitee and the Company (or any of its subsidiaries or any Enterprise), other applicable formal severance policies duly adopted by the Board, or, with respect to service as a director or officer of the Company, by the Certificate of Incorporation, the Company's By-laws (the "By-laws"), and the DGCL. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve as an officer or director of the Company, as provided in Section 16 hereof.

Section 2. Definitions. As used in this Agreement:

(a) References to "agent" shall mean any person who is or was a director, officer, or employee of the Company or a subsidiary of the Company or other person authorized by the Company to act for the Company, to include such person serving in such capacity as a director, officer, employee, fiduciary or other official of another corporation, partnership, limited liability company, joint venture, trust or other enterprise at the request of, for the convenience of, or to represent the interests of the Company or a subsidiary of the Company.

(b) A "Change in Control" shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

i. Acquisition of Stock by Third Party. Any Person (as defined below) is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing fifteen percent (15%) or more of the combined voting power of the Company's then outstanding securities unless the change in relative Beneficial Ownership of the Company's securities by any Person results solely from a reduction in the aggregate number of outstanding shares of securities entitled to vote generally in the election of directors;

ii. Change in Board of Directors. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 2(b)(i), 2(b)(iii) or 2(b)(iv)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;

iii. Corporate Transactions. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the Surviving Entity) more than 50% of the combined voting power of the voting securities of the Surviving Entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such Surviving Entity;

iv. Liquidation. The approval by the stockholders of the Company of a complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets, including by license; and

v. Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 2(b), the following terms shall have the following meanings:

(A) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.

(B) "Person" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; provided, however, that Person shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

(C) "Beneficial Owner" shall have the meaning given to such term in Rule 13d-3 under the Exchange Act; provided, however, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Company approving a merger of the Company with another entity.

(d) “Surviving Entity” shall mean the surviving entity in a merger or consolidation or any entity that controls, directly or indirectly, such surviving entity.

(c) “Corporate Status” describes the status of a person who is or was a director, officer, employee or agent of the Company or of any other corporation, limited liability company, partnership or joint venture, trust or other enterprise which such person is or was serving at the request of the Company.

(d) “Disinterested Director” shall mean a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(e) “Enterprise” shall mean the Company and any other corporation, limited liability company, partnership, joint venture, trust or other enterprise of which Indemnitee is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, employee, agent or fiduciary.

(f) “Expenses” shall include all reasonable attorneys’ fees, retainers, court costs, transcript costs, fees of experts and other professionals, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, any federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses shall also include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent, and (ii) for purposes of Section 14(d) only, Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee’s rights under this Agreement, by litigation or otherwise. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee’s counsel as being reasonable in the good faith judgment of such counsel shall be presumed conclusively to be reasonable. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(g) “Independent Counsel” shall mean a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning the Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the

Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees and expenses of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(h) The term "Proceeding" shall include any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative, legislative, or investigative (formal or informal) nature, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party, potential party, non-party witness or otherwise by reason of Indemnitee's Corporate Status, by reason of any action taken by Indemnitee (or a failure to take action by Indemnitee) or of any action (or failure to act) on Indemnitee's part while acting pursuant to Indemnitee's Corporate Status, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can be provided under this Agreement. If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph.

(i) Reference to "other enterprise" shall include employee benefit plans; references to "fines" shall include any excise tax assessed with respect to any employee benefit plan; references to "serving at the request of the Company" shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner Indemnitee reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the Company" as referred to in this Agreement.

Section 3. Indemnity in Third-Party Proceedings. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company and, in the case of a criminal Proceeding had no reasonable cause to believe that Indemnitee's conduct was unlawful. The parties hereto intend that this Agreement shall provide to the fullest extent permitted by law for indemnification in excess of that expressly permitted by statute, including, without limitation, any indemnification provided by the Certificate of Incorporation, the By-laws, vote of its stockholders or disinterested directors or applicable law.

Section 4. Indemnity in Proceedings by or in the Right of the Company. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 4 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 4, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company. No indemnification for Expenses shall be made under this Section 4 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the Company, unless and only to the extent that the Delaware Court (as hereinafter defined) or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification.

Section 5. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is a party to (or a participant in) and is successful, on the merits or otherwise, in any Proceeding or in defense of any claim, issue or matter therein, in whole or in part, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with or related to each successfully resolved claim, issue or matter to the fullest extent permitted by law. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

Section 6. Indemnification For Expenses of a Witness. Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a witness or otherwise asked to participate in any Proceeding to which Indemnitee is not a party, Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith.

Section 7. Partial Indemnification. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of Expenses, but not, however, for the total amount thereof, the Company shall nevertheless indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

Section 8. Additional Indemnification.

(a) Notwithstanding any limitation in Sections 3, 4, or 5, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is a party to or threatened to be made a party to any Proceeding (including a Proceeding by or in the right of the Company to procure a judgment in its favor) by reason of Indemnitee's Corporate Status.

(b) For purposes of Section 8(a), the meaning of the phrase "to the fullest extent permitted by applicable law" shall include, but not be limited to:

i. to the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL, and

ii. to the fullest extent authorized or permitted by any amendments to or replacements of the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.

Section 9. Exclusions. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnification payment in connection with any claim involving Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; or

(b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Exchange Act (as defined in Section 2(b) hereof) or similar provisions of state statutory law or common law, (ii) any reimbursement of the Company by the Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by the Indemnitee from the sale of securities of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act) or (iii) any reimbursement of the Company by Indemnitee of any compensation pursuant to any compensation recoupment or clawback policy adopted by the Board or the compensation committee of the Board, including but not limited to any such policy adopted to comply with stock exchange listing requirements implementing Section 10D of the Exchange Act; or

(c) except as provided in Section 14(d) of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation or (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

Section 10. Advances of Expenses. Notwithstanding any provision of this Agreement to the contrary (other than Section 14(d)), the Company shall advance, to the extent not prohibited by law, the Expenses incurred by Indemnitee in connection with any Proceeding (or any part of any Proceeding) not initiated by Indemnitee or any Proceeding initiated by Indemnitee with the prior approval of the Board as provided in Section 9(c), and such advancement shall be made within thirty (30) days after the receipt by the Company of a statement or statements requesting such advances from time to time, whether prior to or after final disposition of any Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee's ability to repay the Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. In accordance with Section 14(d), advances shall include any and all Expenses incurred pursuing an action to enforce this right of advancement, including Expenses incurred preparing and forwarding statements to the Company to support the advances claimed. The Indemnitee shall qualify for advances upon the execution and delivery to the Company of this Agreement, which shall constitute an undertaking providing that the Indemnitee undertakes to repay the amounts advanced (without interest) to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company. No other form of undertaking shall be required other than the execution of this Agreement. This Section 10 shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 9.

Section 11. Procedure for Notification and Defense of Claim.

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof. The written notification to the Company shall include a description of the nature of the Proceeding and the facts underlying the Proceeding. To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of such Proceeding. The omission by Indemnitee to notify the Company hereunder will not relieve the Company from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights under this Agreement. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification.

(b) The Company will be entitled to participate in the Proceeding at its own expense.

Section 12. Procedure Upon Application for Indemnification.

(a) Upon written request by Indemnitee for indemnification pursuant to Section 11(a), a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case: (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to

Indemnitee; or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Board, by the stockholders of the Company; and, if it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten (10) days after such determination. Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or Expenses (including attorneys' fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Company promptly will advise Indemnitee in writing with respect to any determination that Indemnitee is or is not entitled to indemnification, including a description of any reason or basis for which indemnification has been denied.

(b) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) hereof, the Independent Counsel shall be selected as provided in this Section 12(b). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Board, and the Company shall give written notice to Indemnitee advising Indemnitee of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten (10) days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 2 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or the Delaware Court has determined that such objection is without merit. If, within twenty (20) days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 11(a) hereof and the final disposition of the Proceeding, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Delaware Court for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by such court or by such other person as such court shall designate, and the person with respect to whom all objections are so resolved

or the person so appointed shall act as Independent Counsel under Section 12(a) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 14(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

Section 13. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall, to the fullest extent not prohibited by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 11(a) of this Agreement, and the Company shall, to the fullest extent not prohibited by law, have the burden of proof to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 14(e), if the person, persons or entity empowered or selected under Section 12 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall, to the fullest extent not prohibited by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 60-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 13(b) shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 12(a) of this Agreement and if **(**A) within fifteen (15) days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat, or (ii) if the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that Indemnitee's conduct was unlawful.

(d) For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise, including financial statements, or on information supplied to Indemnitee by the directors or officers of the Enterprise (as defined below) in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser, financial advisor or other expert selected with reasonable care by or on behalf of the Enterprise. The provisions of this Section 13(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which the Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) The knowledge and/or actions, or failure to act, of any director, officer, trustee, partner, managing member, fiduciary, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

Section 14. Remedies of Indemnitee.

(a) Subject to Section 14(e), in the event that (i) a determination is made pursuant to Section 12 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 10 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 12(a) of this Agreement within ninety (90) days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 5, 6 or 7 or the second to last sentence of Section 12(a) of this Agreement within ten (10) days after receipt by the Company of a written request therefor, (v) payment of indemnification pursuant to Section 3, 4 or 8 of this Agreement is not made within ten (10) days after a determination has been made that Indemnitee is entitled to indemnification, or (vi) in the event that the Company or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or Proceeding designed to deny, or to recover from, the Indemnitee the benefits provided or intended to be provided to the Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of Indemnitee's entitlement to such indemnification or advancement of Expenses. Alternatively, Indemnitee, at Indemnitee's option, may seek an award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding seeking an adjudication or an award in arbitration within 180 days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 14(a). The Company shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this Section 14 shall be conducted in all respects as a de novo trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 14 the Company shall have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 14, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) The Company shall, to the fullest extent not prohibited by law, be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 14 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement. It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder. The Company shall, to the fullest extent permitted by law, indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefor) advance, to the extent not prohibited by law, such Expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advancement of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only to the extent Indemnitee is successful on such underlying claims or otherwise as permitted by law, whichever is greater.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement of Indemnitee to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

Section 15. Non-exclusivity; Survival of Rights; Insurance; Subrogation.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the By-laws, any agreement, a vote of stockholders or a resolution of directors, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by Indemnitee in Indemnitee's Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in Delaware law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Certificate of Incorporation and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents of the Enterprise, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such director, officer, employee or agent under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company shall give prompt notice of such claim or of the commencement of a Proceeding, as the case may be, to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.

(c) In the event of any payment made by the Company under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

(d) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable (or for which advancement is provided hereunder) hereunder if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

(e) The Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, fiduciary, employee or agent of any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of Expenses from such other corporation, limited liability company, partnership, joint venture, trust or other enterprise.

Section 16. Duration of Agreement. This Agreement shall continue until and terminate upon the later of: (a) ten (10) years after the date that Indemnitee shall have ceased to serve as a director or officer of the Company and (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding commenced by Indemnitee pursuant to Section 14 of this Agreement relating thereto. The indemnification and advancement of expenses rights provided by or granted pursuant to this Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Company or of any other Enterprise, and shall inure to the benefit of Indemnitee and Indemnitee's spouse, assigns, heirs, devisees, executors and administrators and other legal representatives.

Section 17. Severability. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

Section 18. Enforcement.

(a) The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director or officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving or continuing to serve as a director or officer of the Company.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; provided, however, that this Agreement is a supplement to and in furtherance of the Certificate of Incorporation, the By-laws and applicable law, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder.

Section 19. Modification and Waiver. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement nor shall any waiver constitute a continuing waiver.

Section 20. Notice by Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification or advancement of Expenses covered hereunder. The failure of Indemnitee to so notify the Company shall not relieve the Company of any obligation which it may have to the Indemnitee under this Agreement or otherwise.

Section 21. Notices. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed, (c) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (d) sent by facsimile transmission or email, with receipt of oral confirmation that such transmission has been received:

(a) If to Indemnitee, at the address indicated on the signature page of this Agreement, or such other address as Indemnitee shall provide to the Company.

(b) If to the Company to

EyePoint Pharmaceuticals, Inc.
480 Pleasant Street
Watertown, MA 02472
Attention: Corporate Counsel
Facsimile: (617) 926-5050
Email: jmercer@eyepointpharma.com

or to any other address as may have been furnished to Indemnitee by the Company.

Section 22. Contribution. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

Section 23. Applicable Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 14(a) of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Court of Chancery of the State of Delaware (the "Delaware Court"), and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) appoint, to the extent such party is not otherwise subject to service of process in the State of Delaware, irrevocably RL&F Service Corp., 920 North King Street, 2nd Floor, Wilmington, New Castle County, Delaware 19801 as its agent in the State of Delaware as such party's agent for acceptance of legal process in connection with any such action or proceeding against such party with the same legal force and validity as if served upon such party personally within the State of Delaware, (iv) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (v) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

Section 24. Identical Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

Section 25. Miscellaneous. Use of the masculine pronoun shall be deemed to include usage of the feminine pronoun where appropriate. The headings of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed as of the day and year first above written.

EYEPOINT PHARMACEUTICALS, INC.	INDEMNITEE
By: _____	_____
Name:	Name:
Office:	Address: _____
	_____
	_____

Schedule of Material Differences to Exhibit 10.16

The following directors and executive officers are parties to an Indemnification Agreement with the Company, each of which are substantially identical in all material respects to the representative Indemnification Agreement filed herewith as Exhibit 10.16 except as to the name of the signatory and the date of each signatory's Indemnification Agreement, which are listed below. The actual Indemnification Agreements are omitted pursuant to Instruction 2 to Item 601 of Regulation S-K.

Indemnitee	Effective Date
Nancy S. Lurker	September 15, 2016
David Price	August 1, 2018
Leonard S. Ross	September 26, 2016
Dario Paggiarino	September 26, 2016
David J. Mazzo	July 7, 2008
Douglas Godshall	March 5, 2012
Michael W. Rogers	July 7, 2008
Ronald W. Eastman	March 28, 2018
Jay S. Duker, M.D.	September 27, 2016
Kristine Peterson	June 27, 2017
Göran Ando, M.D.	June 14, 2018
John Landis	October 30, 2018
David R. Guyer M.D.	January 25, 2019

Nonstatutory Stock Option
Inducement Award

1. Grant of Option.

This certificate evidences a nonstatutory stock option (this "Stock Option") granted by **EyePoint Pharmaceuticals, Inc.**, a Delaware corporation (the "Company"), on **November 26, 2018** (the "Date of Grant") to **Ron Honig** (the "Participant"). This Stock Option is granted to the Participant in connection with his entering into employment with the Company and is regarded by the parties as an inducement material to the Participant's entering into employment within the meaning of Nasdaq Listing Rule 5635(c). Under this Stock Option, the Participant may purchase, in whole or in part, on the terms herein provided, a total of **350,000** shares of common stock of the Company (the "Shares") at **$2.07** per Share, which is not less than the fair market value of a Share on the Date of Grant. The latest date on which this Stock Option, or any part thereof, may be exercised is 5:00 P.M. Eastern Time on **November 26, 2028** (the "Final Exercise Date"). The Stock Option evidenced by this certificate is intended to be, and is hereby designated, a nonstatutory option, meaning an option that does *not* qualify as an incentive stock option as defined in section 422 of the Internal Revenue Code of 1986, as amended from time to time (the "Code"). This Stock Option shall be subject to and governed by, and shall be construed and administered in accordance with, the terms and conditions of the Company's 2016 Long-Term Incentive Plan (as from time to time in effect, the "Plan"), which terms and conditions are incorporated herein by reference. A copy of the Plan has been made available to the Participant. Notwithstanding the foregoing, this Stock Option is not awarded under the Plan and the grant of this Stock Option shall not reduce the number of shares of Stock available for issuance under awards issued pursuant to the Plan.

2. Vesting.

(a)During Employment. This Stock Option will vest and become exercisable with respect to **one third (1/3)** of the Shares on each of the **first, second and third** anniversaries of the Grant Date.

(b)Termination of Employment. Notwithstanding the foregoing, upon termination of the Participant's Employment, any portion of this Stock Option that is not then exercisable will immediately expire and the remainder of this Stock Option will remain exercisable for three months; provided, that any portion of this Stock Option held by the Participant immediately prior to the Participant's death, to the extent then exercisable, will remain exercisable for one year following the Participant's death; further provided, that if termination of the Participant's Employment resulted from reasons that in the determination of the Administrator cast such discredit on the Participant as to justify immediate forfeiture of this Stock Option, this Stock Option shall expire in its entirety immediately upon termination of the Participant's Employment and no portion of this Stock Option shall thereafter remain exercisable; and further provided, that in no event shall any portion of this Stock Option be exercisable after the Final Exercise Date.

(c)Notwithstanding the foregoing provisions of this Section 2, this Stock Option shall not vest or become eligible to vest on any date specified above unless the Participant has continuously been, since the Grant Date until the date immediately prior to such termination of Employment, Employed by the Company, its Affiliates or its subsidiaries.

3. Exercise of Stock Option.

Each election to exercise this Stock Option shall be in writing, signed by the Participant or the Participant's executor, administrator, or legally appointed representative (in the event of the Participant's incapacity) or the person or persons to whom this Stock Option is transferred by will or the applicable laws of descent and distribution (collectively, the "Option Holder"), and received by the Company at its principal office, accompanied by this certificate and payment in full as provided in the Plan. Subject to the further terms and conditions provided in the Plan, the purchase price may be paid as follows: (i) by delivery of cash or check acceptable to the Administrator; or (ii) through a broker-assisted exercise program acceptable to the Administrator; or (iii) by any other means acceptable to the Administrator, or (iv) by any combination of the foregoing means of exercise. In the event that this Stock Option is exercised by an Option Holder other than the Participant, the Company will be under no obligation to deliver Shares hereunder unless and until it is satisfied as to the authority of the Option Holder to exercise this Stock Option.

4. Withholding.

Except as otherwise determined by the Administrator, this Stock Option may not be exercised unless the person exercising this Stock Option timely remits to the Company, in cash, all amounts required to be withheld upon exercise (all as determined by the Administrator) or makes other arrangements satisfactory to the Administrator for the payment of such taxes.

5. Nontransferability of Stock Option.

This Stock Option is not transferable by the Participant otherwise than by will or the laws of descent and distribution, and is exercisable during the Participant's lifetime only by the Participant (or in the event of the Participant's incapacity, the person or persons legally appointed to act on the Participant's behalf).

6. Provisions of the Plan.

This Stock Option is subject to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the date of the grant of this Stock Option has been furnished to the Participant. By accepting this Stock Option, the Participant agrees to be bound by the terms of the Plan and this certificate. All initially capitalized terms used herein will have the meaning specified in the Plan, unless another meaning is specified herein.

IN WITNESS WHEREOF, the Company has caused this instrument to be executed by its duly authorized officer.

EyePoint Pharmaceuticals, Inc.

By /s/ Nancy Lurker
Nancy Lurker

Dated: **November 26, 2018**

Acknowledged and agreed:

By: /s/ Ron Honig
Ron Honig

Dated: **November 26, 2018**

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 and 333-227525 on Form S-8 and Registration Nos. 333-226341 and 333-228581 on Form S-3 of our reports dated March 18, 2019, relating to the financial statements of EyePoint Pharmaceuticals, Inc. (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.'s internal control over financial reporting, appearing in this Transition Report on Form 10-K of EyePoint Pharmaceuticals, Inc. for the six months ended December 31, 2018.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 18, 2019

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 Transition 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 18, 2019

/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, **David Price**, certify that:

1. I have reviewed this Transition 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 18, 2019

/s/ David Price

Name: David Price
Title: Chief Financial Officer
(Principal Financial 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 Transition Report of EyePoint Pharmaceuticals, Inc. (the "Company") on Form 10-K for the six months ended December 31, 2018, 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 18, 2019

/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 Transition Report of EyePoint Pharmaceuticals, Inc. (the "Company") on Form 10-K for the six months ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Price, 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 18, 2019

/s/ David Price

Name: David Price
Title: Chief Financial Officer
(Principal Financial Officer)