As filed with the Securities and Exchange Commission on June 2, 2015.

Registration No. 333-204344

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

AMENDMENT NO. 1
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

OCULAR THERAPEUTIX, INC.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**20-5560161**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

34 Crosby Drive, Suite 105
Bedford, MA 01730
(781) 357-4000
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Amarpreet Sawhney, Ph.D.
President and Chief Executive Officer
Ocular Therapeutix, Inc.
34 Crosby Drive, Suite 105
Bedford, MA 01730
(781) 357-4000
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Brian A. Johnson, Esq. **Wilmer Cutler Pickering Hale and Dorr LLP** **7 World Trade Center** **250 Greenwich Street** **New York, New York 10007** **(212) 230-8800**	**Patrick O'Brien, Esq.** **Ropes & Gray LLP** **Prudential Tower** **800 Boylston Street** **Boston, Massachusetts 02199** **(617) 951-7527**

Approximate date of commencement of proposed sale to public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

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

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(3)
Common Stock, $0.0001 par value per share	4,600,000	$24.03	$110,538,000	$12,845

(1) Includes 600,000 shares of common stock the underwriters have the option to purchase.
(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended and based on the average of the high and low sales price of the registrant's common stock as reported on the NASDAQ Global Market on June 1, 2015.
(3) Previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. Neither we nor the selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we and the selling stockholders are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS (Subject to Completion)
Dated June 2, 2015

4,000,000 SHARES

Ocular Therapeutix

COMMON STOCK

Ocular Therapeutix, Inc. is offering 3,200,000 shares of common stock, and the selling stockholders identified in this prospectus are offering 800,000 shares of our common stock. We will not receive any proceeds from the sale of any shares by the selling stockholders.

Our common stock is listed on The NASDAQ Global Market under the symbol "OCUL". On June 1, 2015, the last sale price of our common stock as reported on The NASDAQ Global Market was $24.03 per share.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to rely on certain reduced public company disclosure requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Investing in the common stock involves risks. See "Risk Factors" beginning on page 15.

PRICE $ A SHARE

	Price to Public	***Underwriting Discounts and Commissions(1)***	***Proceeds to Company***	***Proceeds to Selling Stockholders***
Per share	*$*	*$*	*$*	*$*
Total	*$*	*$*	*$*	*$*

(1) We have agreed to reimburse the underwriters for certain FINRA-related expenses. See "Underwriting."

The selling stockholders identified in this prospectus have granted the underwriters the right to purchase up to an additional 600,000 shares of common stock at the public offering price less the underwriting discount. We will not receive any proceeds from the sale of any shares by the selling stockholders.

The Securities and Exchange Commission and state securities regulators have not approved or disapproved these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on or about June , 2015.

MORGAN STANLEY *COWEN AND COMPANY* *RBC CAPITAL MARKETS*

NOMURA *BTIG*

June , 2015

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We are responsible for the information contained in this prospectus. We, the selling stockholders, and the underwriters have not authorized anyone to provide you with different information, and we, the selling stockholders, and the underwriters take no responsibility for any other information others may give you. If anyone provides you with different or inconsistent information, you should not rely on it. We, the selling stockholders, and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements and Industry Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes appearing elsewhere in this prospectus, before making an investment decision.

Overview of Ocular Therapeutix

We are a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using our proprietary hydrogel platform technology. Our bioresorbable hydrogel based product candidates are designed to provide sustained delivery of therapeutic agents to the eye. Our hydrogel is a bioresorbable proprietary formulation of polyethylene glycol, or PEG, which when constituted with water takes on a gelatinous consistency. The product candidates in our development pipeline have the potential to overcome many of the significant limitations of existing eye drop based therapies for ophthalmic diseases and conditions affecting the front of the eye by replacing the current standard of care regimen of weeks or months of eye drop dosing with as little as a single product application. Our lead sustained release drug delivery product candidates are OTX-DP and OTX-TP, which are inserted into the canaliculus through a natural opening called the punctum located in the inner portion of the eyelid near the nose. Our OTX-DP and OTX-TP product candidates combine our hydrogel technology with U.S. Food and Drug Administration, or FDA, approved therapeutic agents with the goal of providing sustained delivery of drug to the eye. We also have a hydrogel based drug delivery depot, which is in preclinical development for the treatment of diseases and conditions of the back of the eye, including wet age related macular degeneration, or wet AMD. Our hydrogel depot is designed to be delivered via intravitreal injection to release therapeutic agents, such as antibodies to vascular endothelial growth factor, or VEGF, over a sustained period. In addition to our ongoing product development, we have launched our first commercial product, ReSure Sealant, a hydrogel based ophthalmic wound sealant approved by the FDA in January 2014 to seal corneal incisions following cataract surgery. ReSure Sealant is the first and only surgical sealant to be approved by the FDA for ophthalmic use. Our product candidates target large and growing markets. Transparency Market Research, a provider of business information reports and services, estimates that the annual worldwide market for ophthalmic medications was nearly $16 billion in 2012 and is expected to increase to $21.6 billion by 2018.

Poor patient compliance with eye drop regimens and the need for frequent administration of eye drops at high drug concentrations due to rapid washout by the tears can create challenges in the successful management of ocular diseases and conditions. For example, poor patient compliance can lead to diminished efficacy and disease progression and high drug concentrations can create side effects. We are developing therapies to replace standard of care eye drop regimens with our innovative drug eluting punctum plugs. Our plugs are sustained release drug delivery depots that are inserted into a natural opening called the punctum located in the inner portion of the eyelid near the nose. The plugs are designed to release a therapeutic agent to the surface of the eye over an extended period. The goal for our punctum plug product candidates is to change the management of many front-of-the-eye diseases and conditions from frequent, pulsed eye drop therapy, characterized by significant variations in drug concentration over time, to longer term, sustained delivery of therapeutic agents to improve patient outcomes.

Our most advanced product candidate, OTX-DP, incorporates the FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient in our hydrogel and is in Phase 3 clinical development for the treatment of ocular inflammation and pain following cataract surgery. We recently reported topline results from two Phase 3 clinical trials for this indication. In the first Phase 3 clinical trial, OTX-DP met both primary efficacy endpoints, absence of pain at day 8 and absence of inflammatory cells at day 14, with statistical significance. In the second Phase 3 clinical trial, OTX-DP met the primary efficacy endpoint for absence of pain at day 8 with statistical significance but did not meet the primary efficacy endpoint for absence of inflammatory cells at day 14. Although we have been conducting our Phase 3 clinical trials of OTX-DP in patients who have undergone cataract surgery, these trials are intended to support a label for all post-surgical ocular inflammation and pain. We met with the FDA in April 2015 to discuss the path forward for seeking marketing approval of OTX-DP for the treatment of ocular inflammation and pain following ophthalmic surgery. In this pre-NDA clinical meeting, the FDA indicated that the existing data from our Phase 2 and Phase 3 clinical trials are appropriate to support an NDA submission for OTX-DP solely for an ocular pain indication. The FDA further indicated that we would need additional data from a third Phase 3 clinical trial for the inflammation endpoint to support the potential labeling expansion of OTX-DP's indications for use. We plan to initiate this third Phase 3 clinical trial for OTX-DP for the treatment of post-surgical ocular inflammation and pain in the second half of 2015. We expect to submit an NDA for OTX-DP solely for the treatment of ocular pain following ophthalmic surgery in the second half of 2015. Based on our expectations regarding initiation of our third Phase 3 clinical trial of OTX-DP and design of the trial and our estimates regarding patient enrollment, we expect to have topline efficacy data available from this trial in the second half of 2016. If the results of our third Phase 3 clinical trial of OTX-DP are favorable and subject to receiving approval for the pain indication pursuant to the initial NDA, we plan to submit an NDA supplement for OTX-DP for the treatment of ocular inflammation following ophthalmic surgery in the second half of 2016. If we receive approval of our initial NDA and our NDA supplement, we expect to commercially launch OTX-DP for post-surgical ocular inflammation and pain in the United States in the first half of 2017.

In addition, we completed a Phase 2 clinical trial of OTX-DP for the treatment of allergic conjunctivitis in November 2014. Based on encouraging results from this trial, we expect to initiate two Phase 3 clinical trials of OTX-DP for this indication in the middle of 2015, with topline efficacy data from the first Phase 3 clinical trial expected to be available in the fourth quarter of 2015. We also initiated an exploratory Phase 2 clinical trial of OTX-DP for the treatment of inflammatory dry eye disease in January 2015.

We have also received conditional acceptance of the name DEXTENZA™ from the FDA for our OTX-DP product candidate. We plan to include a request for a proprietary name review for DEXTENZA as part of our NDA submission of OTX-DP for the treatment of ocular pain following ophthalmic surgery.

Our second product candidate, OTX-TP, incorporates travoprost, an FDA-approved prostaglandin analog that reduces elevated intraocular pressure, as an active pharmaceutical ingredient in our hydrogel. We completed a Phase 2a clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension in May 2014 and initiated a Phase 2b clinical trial of OTX-TP for this indication in November 2014.

In addition to OTX-DP and OTX-TP, we are engaged in the preclinical development of a sustained release hydrogel depot administered via intravitreal injection to address the large and growing markets for diseases and conditions of the back of the eye. Our initial development efforts are focused on the use of our sustained release hydrogel depot in combination with anti-VEGF compounds for the treatment of wet AMD. Our initial goal for this program is to provide sustained release of an anti-VEGF compound over a four to six month period, thereby reducing the frequency of the current monthly or bi-monthly intravitreal injection regimen for wet AMD. We also have a pipeline of earlier stage punctum plug product candidates, including OTX-MP, which has completed a Phase 1 clinical trial evaluating safety and pharmacokinetics in patients following cataract surgery.

Following our receipt of FDA approval for ReSure Sealant, we commercially launched this product in the United States in February 2014 through a network of ophthalmology focused distributors. ReSure Sealant is approved to seal corneal incisions following cataract surgery and is the first and only surgical sealant to be approved by the FDA for ophthalmic use. In the pivotal clinical trials that formed the basis for FDA approval, ReSure Sealant provided superior wound closure and a better safety profile than sutured closure. We plan to use the limited revenues we expect from sales of ReSure Sealant to contribute to the funding of our product development pipeline and commercialization efforts.

Our clinical stage product candidates and our marketed product are based on a proprietary bioresorbable hydrogel technology platform that uses PEG as a key component. Bioresorbable materials gradually break down in the body into non-toxic, water soluble compounds that are cleared by normal biological processes. PEG is used in many pharmaceutical products and is widely considered to be safe and biocompatible. Our technology platform allows us to tailor the physical properties, drug release profiles and bioresorption rates of our hydrogels to meet specific applications. We have used this platform to engineer each of our punctum plug product candidates, ReSure Sealant and our intravitreal hydrogel depot. Our technical capabilities include a deep understanding of the polymer chemistry of PEG based hydrogels and the design of the specialized manufacturing processes required to achieve a reliable, preservative free and pure product.

We have in-licensed all of the patent rights and a significant portion of the technology for ReSure Sealant and our hydrogel platform technology product candidates from Incept, LLC, or Incept, an intellectual property holding company. Amarpreet Sawhney, our President and Chief Executive Officer, is a general partner of Incept and has a 50% ownership stake in Incept.

Our founders and management team have significant experience in developing and commercializing medical products for other companies using bioresorbable hydrogel technology, including FDA-approved and currently marketed medical products such as DuraSeal Dural Sealant® (marketed by Integra Lifesciences, Inc.), a sealant for cranial and spine surgery, and Mynx® (marketed by Cardinal Health, Inc.), a sealant for femoral artery punctures after angiography and angioplasty. Dr. Sawhney was the founder, President and Chief Executive Officer of Confluent Surgical, Inc., the company that developed and commercialized the DuraSeal Dural Sealant and was the technology founder of AccessClosure, Inc., the company that developed and commercialized Mynx. The annual sales of Mynx were in excess of $80 million in 2013 prior to the acquisition of Mynx by Cardinal Health, Inc. in April 2014.

The following table summarizes the status of our key product development programs and our marketed product. We hold worldwide exclusive commercial rights to the core technology underlying all of our products in development.

Product / Program	Indication	Description (Active Pharmaceutical Ingredient)	Pre-clinical	Phase 1	Phase 2	Phase 3	Regulatory Approval
Approved Product							
ReSure Sealant	Cataract incision closure	Ocular sealant					FDA Approved / Launched in U.S.
Late Stage Product Candidates							
OTX – DP	Post-surgical ocular inflammation and pain	Punctum Plug (Dexamethasone)					
OTX – DP	Allergic conjunctivitis	Punctum Plug (Dexamethasone)					
OTX – TP	Glaucoma	Punctum Plug (Travoprost)					
Earlier Stage Product Candidates							
OTX – DP	Inflammatory dry eye disease	Punctum Plug (Dexamethasone)					
OTX – MP	Bacterial conjunctivitis	Punctum Plug (Moxifloxacin)					
Intravitreal Hydrogel Depot	Wet AMD	Anti-VEGF hydrogel depot (Anti-VEGF compounds)					

Anticipated Benefits of Our Punctum Plug Technology

Our punctum plug product candidates are intended to replace existing eye drop based therapies for management of front-of-the-eye diseases and conditions. Eye drops are widely used to deliver medications directly to the ocular surface and to intraocular tissue in the front of the eye. Eye drops are administrable by the patient or care provider, inexpensive to produce and treat the local tissue. However, eye drops have significant limitations, especially when used for chronic diseases or when requiring frequent administration, including:

- lack of patient compliance leading to diminished efficacy and disease progression;
- difficulty in administration leading to poor compliance and bacterial contamination;
- need for frequent administration at high drug concentrations due to the rapid wash out of eye drops by tears which can result in side effects such as spikes in intraocular pressure;
- side effects caused by antimicrobial preservatives included in eye drops.

As a result of these limitations, eye drops are often suboptimal as a therapeutic option for the treatment of many diseases and conditions of the front of the eye. We believe our punctum plugs may offer a range of favorable attributes as compared to eye drops, including:

- *Improved patient compliance*. Our punctum plugs are inserted by a healthcare professional and are designed to provide sustained release of drug to the ocular surface. Because patients are not responsible for self-administration of the drug and the punctum plugs dissipate over time and do not require removal, we believe our punctum plugs address the problem of patient compliance.

- *Ease of administration*. We have designed our punctum plugs to provide the entire course of medication with a single administration by a healthcare professional for acute conditions or for several months for chronic conditions. We believe this avoids the need for frequent administration and the potential complications that could result if doses are missed.
- *Sustained delivery of drug*. We have designed our punctum plugs to deliver drug in a sustained fashion to the surface of the eye in order to avoid the peak and valley dosing and related side effects and spikes in intraocular pressure associated with eye drops. We also believe sustained dosing may improve the therapeutic profile of the active pharmaceutical ingredient because it eliminates periods of little or no drug presence between eye drop administrations. Further, we are designing our product candidates so that their drug release profiles can be tailored to match the treatment needs of the disease. For example, steroids for ophthalmic purposes generally require administration over four weeks, with tapered dosing over this period. In contrast, prostaglandin analogs require administration in a steady fashion over the duration of treatment. Our punctum plugs are designed to fully dissipate over a period of two to three times the length of the expected period of release of the therapeutic agent and can be removed if necessary by a healthcare professional.
- *Avoidance of preservative side effects.* Our punctum plugs do not involve the use of preservatives, such as benzalkonium chloride, or BAK, which has been linked to side effects including burning, stinging, hyperemia, irritation, eye dryness and, less frequently, conjunctivitis or corneal damage.

Overview of Our Key Product Candidates and Marketed Product

OTX-DP for the Treatment of Post-Surgical Ocular Inflammation and Pain, Allergic Conjunctivitis and Inflammatory Dry Eye Disease

Our OTX-DP product candidate incorporates the FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient in our proprietary punctum plug. Dexamethasone is known for its anti-inflammatory properties and is used to treat, among other conditions, inflammation and pain following ocular surgery. We are developing OTX-DP for the treatment of post-surgical ocular inflammation and pain, allergic conjunctivitis and inflammatory dry eye disease. We have designed OTX-DP to provide a sustained release of dexamethasone over a period of approximately 30 days.

We recently reported topline results from two Phase 3 clinical trials for this indication. In the first Phase 3 clinical trial, OTX-DP met both primary efficacy endpoints, absence of pain at day 8 and absence of inflammatory cells at day 14, with statistical significance. In this first Phase 3 clinical trial, 33.7% of OTX-DP treated patients showed an absence of inflammatory cells in the anterior chamber of the study eye on day 14 following drug product insertion, compared to 14.6% of those receiving placebo vehicle control punctum plug ($p=0.0015$). In addition, 76.1% of patients receiving OTX-DP reported absence of pain in the study eye on day 8 following insertion of the drug product, compared to 36.1% of those receiving placebo vehicle control punctum plug ($p< 0.0001$). In the second Phase 3 clinical trial, OTX-DP met the primary efficacy endpoint for absence of pain at day 8 with statistical significance but did not meet the primary efficacy endpoint for absence of inflammatory cells at day 14. In this second Phase 3 clinical trial, 77.5% of patients receiving OTX-DP reported an absence of pain in the study eye on day 8 following insertion of the drug product, compared to 58.8% of those receiving placebo vehicle control punctum plug, a difference which was statistically significant ($p=0.0025$). However, 39.4% of OTX-DP treated patients showed an absence of inflammatory cells in the anterior chamber of the study eye on day 14 following drug product insertion, compared to 31.3% of those receiving placebo vehicle control punctum plug, a difference which was not statistically significant ($p=0.2182$). Although we have been conducting our Phase 3 clinical trials of OTX-DP in patients who have undergone cataract surgery, these trials are intended to support a label for all post-surgical ocular inflammation and pain.

We met with the FDA in April 2015 to discuss the path forward for seeking marketing approval of OTX-DP for the treatment of ocular inflammation and pain following ophthalmic surgery. In this pre-NDA clinical meeting, the FDA indicated that the existing data from our Phase 2 and Phase 3 clinical trials are appropriate to support an NDA submission solely for an ocular pain indication. The FDA further indicated that we would need additional data from a third Phase 3 clinical trial for the inflammation endpoint to support the potential labeling expansion of OTX-DP's indications for use. We plan to initiate this third Phase 3 clinical trial for OTX-DP for the treatment of post-surgical ocular inflammation and pain in the second half of 2015. We expect to enroll approximately 330 patients in this trial, with patients randomized in a 1:1 ratio to receive either OTX-DP or placebo. We plan to make modifications to the design of this third Phase 3 clinical trial compared to our two completed Phase 3 clinical trials of OTX-DP based on our learnings from these prior trials. These modifications relate to factors we believe impacted the results of the second Phase 3 clinical trial, including the use of rescue medications in patients with mild inflammation at the day 8 visit and the use of high dose oral non-steroidal anti-inflammatory drugs, or NSAIDs. Based on feedback from our meeting with the FDA, in the third Phase 3 clinical trial we plan to exclude patients receiving high doses of NSAIDs, such as Naproxen. In addition, we intend to provide additional guidance to study investigators regarding the use of rescue medications per the study protocol. We expect to submit an NDA for OTX-DP solely for the treatment of ocular pain following ophthalmic surgery in the second half of 2015. Based on our expectations regarding initiation of our third Phase 3 clinical trial of OTX-DP and design of the trial and our estimates regarding patient enrollment, we expect to have topline efficacy data available from this trial in the second half of 2016. If the results of our third Phase 3 clinical trial of OTX-DP are favorable and subject to receiving approval for the pain indication pursuant to the initial NDA, we plan to submit an NDA supplement for OTX-DP for the treatment of ocular inflammation following ophthalmic surgery in the second half of 2016. If we receive approval of our initial NDA and our NDA supplement, we expect to commercially launch OTX-DP for post-surgical ocular inflammation and pain in the United States in the first half of 2017.

In addition, in November 2014 we completed a Phase 2 clinical trial evaluating the safety and efficacy of OTX-DP for the treatment of allergic conjunctivitis. Based upon the encouraging results of this Phase 2 clinical trial and a subsequent meeting with the FDA, we expect to initiate two Phase 3 clinical trials of OTX-DP for this indication in the middle of 2015, with topline efficacy data from the first Phase 3 clinical trial expected to be available in the fourth quarter of 2015. In January 2015, we initiated a Phase 2 exploratory clinical trial of OTX-DP for the treatment of inflammatory dry eye disease. We expect to complete this trial in the fourth quarter of 2015 and then assess the future direction of the clinical development of this product candidate based on these results.

Ocular inflammation and pain are common side effects following ophthalmic surgery. Physicians prescribe anti-inflammatory drugs, such as corticosteroids, which are typically administered through eye drops multiple times per day, following ocular surgery as the standard of care. Physicians also frequently prescribe non-steroidal anti-inflammatory drugs, or NSAIDs, as adjunctive or combination therapy to supplement the use of corticosteroids. If left untreated, inflammation of the eye may result in further ocular complications, including scarring and vision loss. Market Scope estimates that approximately 5.3 million ocular surgeries will be performed in the United States in 2015.

According to IMS Health data, approximately 20 million prescriptions were filled in the United States in 2014 for anti-inflammatory drugs administered by eye drops for ocular diseases and conditions, resulting in sales of approximately $2.7 billion. According to IMS Health data, approximately 6.9 million anti-allergy eye drop prescriptions were filled in the United States in 2014, resulting in sales of approximately $868 million.

OTX-TP for the Treatment of Glaucoma

Our OTX-TP product candidate incorporates the prostaglandin analog travoprost as an active pharmaceutical ingredient in our proprietary punctum plug. Travoprost reduces elevated intraocular pressure by enhancing the drainage of fluid from the eye. We are developing OTX-TP for the treatment of glaucoma and ocular hypertension. We have completed a Phase 2a clinical trial of OTX-TP and initiated a Phase 2b clinical trial of OTX-TP in the United Sates in November 2014. We expect to complete enrollment of this trial in the third quarter of 2015, with topline efficacy data expected to be available in the fourth quarter of 2015. Our Phase 2a and Phase 2b clinical trials are designed to assess clinically meaningful response to treatment, and are not powered to measure any efficacy endpoints with statistical significance.

Glaucoma is a progressive and highly individualized disease in which elevated levels of intraocular pressure are associated with damage to the optic nerve, which results in irreversible vision loss. In order to lower intraocular pressure, physicians typically prescribe drugs administered as eye drops. The classes of topical drugs used to treat glaucoma include prostaglandin analogues, or PGAs, beta-blockers, alpha-adrenergic agonists and carbonic anhydrase inhibitors. PGAs are the most widely prescribed class of drugs for glaucoma and are considered first-line glaucoma treatment. According to the Glaucoma Research Foundation, approximately 3 million people in the United States suffer from glaucoma.

According to IMS Health data, approximately 33 million prescriptions were filled in the United States in 2014 for drugs administered by eye drops for the treatment of glaucoma, resulting in sales of approximately $2.4 billion. According to IMS Health, PGAs account for approximately half of the prescription volume in the glaucoma market.

Intravitreal Hydrogel Depot for the Treatment of Back-of-the-Eye Diseases and Conditions

We are engaged in the preclinical development of a sustained release hydrogel depot administered via intravitreal injection to address the large and growing markets for diseases and conditions of the back of the eye. Our initial development efforts are focused on the use of our sustained release hydrogel depot in combination with anti-VEGF compounds for the treatment of wet AMD. Our initial goal for this program is to provide sustained release of an anti-VEGF compound over a four to six month period, thereby reducing the frequency of the current monthly or bi-monthly intravitreal injection regimen for wet AMD.

We are pursuing a multi-pronged strategy to seek to maximize the potential of this technology. We are collaborating with several different pharmaceutical companies using protein-based anti-VEGF agents on this program and are also conducting our own internal development using the anti-VEGF agent bevacizumab. We are exploring the delivery of small molecule drugs, such as tyrosine-kinase inhibitors, or TKIs, in our hydrogel depot and have been researching the optimal candidates for this program. We have narrowed our search down to several lead candidates. We believe this class of drugs is well suited for use with our platform given its high potency, multi-target capability, and low water solubility. In the absence of a sophisticated drug delivery system, these drugs have been difficult to deliver to the eye at therapeutic levels without causing local and systemic toxicity. We feel our local drug delivery technology gives us advantages in this regard. By selecting compounds that are compatible with our hydrogel platform technology and that will have expiration of relevant patents within the timeline of our development program, we would also avoid the need to license these molecules, thus retaining full worldwide rights to our products. We may seek to move forward on delivery of a small molecule on our own in parallel with a protein based anti-VEGF delivery program, which would require the involvement of a partner. We plan to continue working with our pharmaceutical company partners on development efforts and exploring potential business development deal structures as well as advancing our internal development efforts on our sustained release hydrogel depot for the treatment of back-of-the-eye diseases.

There are a range of back-of-the-eye diseases and conditions that can significantly affect vision. One of the principal back-of-the-eye conditions is wet AMD, a serious disease of the central portion of the retina. Wet AMD is the leading cause of blindness in people over the age of 55 in the United States and the European Union. According to a study on the burden of AMD published in 2006 in the peer-reviewed journal *Current Opinion in Ophthalmology*, approximately 1.2 million people in the United States suffer from wet AMD. In addition, AMD Alliance International reports that approximately 200,000 new cases of wet AMD arise each year in the United States.

The current standard of care for wet AMD are drugs that target VEGF. The anti-VEGF market for the treatment of wet AMD consists predominantly of two drugs that are approved for marketing and primarily prescribed for the treatment of wet AMD, Lucentis marketed in the United States by Genentech and Eylea marketed in the United States by Regeneron, and off-label use of the cancer therapy Avastin. In 2014, sales of Lucentis and Eylea totaled approximately $3.5 billion in the United States.

ReSure Sealant for the Prevention of Wound Leakage Following Cataract Surgery

ReSure Sealant is a topical liquid hydrogel that creates a temporary, adherent, soft and lubricious sealant to prevent post-surgical leakage from clear corneal incisions that are made during cataract surgery. The FDA granted marketing approval for ReSure Sealant in January 2014. We commercially launched ReSure Sealant in the United States in February 2014 through a network of ophthalmology focused distributors. We plan to use the limited revenues we expect from sales of ReSure Sealant to contribute to the funding of our product development pipeline and commercialization efforts.

A cataract is a clouding of the lens inside the front of the eye. During cataract surgery, a patient's cloudy natural lens is removed and replaced with a prosthetic intraocular lens. According to the World Health Organization, cataracts are the leading cause of visual impairment eventually progressing to blindness. According to the American Academy of Ophthalmology Cataract and Anterior Segment Panel's 2011 Preferred Practice Pattern Guidelines, cataract extraction is the most commonly performed eye surgery in the United States. Market Scope estimates that in 2015 there will be approximately 3.8 million cataract extractions performed in the United States.

Clear corneal incisions that allow entry to the eye are the preferred method for performing cataract surgery. The most common post-surgical approach is to allow the incisions to self-seal, or close, through normal biological processes. However, self-sealing incisions can open spontaneously. Sutures are the most widely used alternative method of wound closure. However, sutures have a number of shortcomings that limit their use in ophthalmic surgery. In a 2012 survey of ophthalmologists in the United States conducted by Lachman Consulting LLC, a healthcare consulting firm, respondents indicated that they use sutures in approximately 14% of cataract surgeries.

We previously commercialized in Europe an earlier version of ReSure Sealant that was approved and marketed as an ocular bandage. However, we ceased our commercialization of the product in 2012 to focus on the ongoing clinical development of ReSure Sealant pursuant to FDA requirements after the FDA requested that we withdraw an application for the earlier version of ReSure Sealant that we had submitted under Section 510(k) of the Food, Drug and Cosmetic Act because the FDA believed that the technical characteristics of the earlier version of ReSure Sealant were not substantially equivalent to a predicate device. After withdrawing our 510(k) application, we filed an investigational device exemption application to conduct a pivotal clinical trial to support approval of ReSure Sealant as an ocular sealant and subsequently received premarket approval, or PMA, from the FDA.

Our Strategy

Our goal is to change the management of many ophthalmic diseases and conditions from frequent, pulsed therapy, characterized by significant variations in drug concentration over time, to longer term, sustained delivery of therapeutic agents to improve patient outcomes. The key elements of our strategy to achieve this goal are to:

- Create proprietary solutions for ophthalmic diseases and conditions based on our bioresorbable hydrogel technology platform combined with FDA-approved therapeutic agents to improve the delivery of these agents.
- Improve patient compliance and management of front-of-the-eye diseases and conditions by replacing standard of care eye drop therapies with our sustained release product candidates.
- Rapidly complete clinical development of and seek marketing approval for our most advanced punctum plug product candidates for diseases and conditions of the front of the eye.
- Apply our sustained release punctum plug technology for treatment of additional diseases and conditions of the front of the eye.
- Maximize commercial potential of ReSure Sealant and any other products for which we receive marketing approval.
- Pursue development of our intravitreal hydrogel depot and other technologies for back-of-the-eye diseases and conditions.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus. These risks include the following:

- We depend heavily on the success of our punctum plug product candidates, in particular OTX-DP and OTX-TP. To generate product revenues sufficient to achieve profitability, we will need to obtain marketing approval for and successfully commercialize one or both of OTX-DP and OTX-TP. The FDA may not accept for review or approve the NDA we plan to submit for OTX-DP for the treatment of pain following ocular surgery.
- Clinical trials of our product candidates may not be successful. If clinical trials of our punctum plug product candidates or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.
- We only recently commercially launched ReSure Sealant in the United States and have no other marketed products. If we are unable to develop and expand our sales, marketing and distribution capabilities, scale up our manufacturing processes and capabilities, obtain and maintain patent protection for or gain market acceptance by physicians, patients and third-party payors of ReSure Sealant or any of our product candidates for which we obtain marketing approval, or experience significant delays in doing so, our business will be materially harmed.
- Our product candidates, if approved, will face competition from generic and branded versions of existing drugs, many of which have achieved widespread acceptance among physicians, payors and patients for the treatment of ophthalmic diseases and conditions. In addition, because the active pharmaceutical ingredients in our product candidates are available on a generic basis, or are soon to be available on a generic basis, competitors will be able to offer and sell products with the same active pharmaceutical ingredient as our products so long as these competitors do not infringe any patents that we license.

- Even if we successfully obtain marketing approval for one or more of our product candidates, the approved product will be subject to ongoing review and extensive regulation. For example, the FDA required two post-approval studies as a condition for approval of our PMA application for ReSure Sealant. Failure to comply with any post-approval requirements may result in restrictions or limitations on our ability to commercialize such product, including required modifications in product labeling or the approved indication for use or negative publicity.
- We have incurred significant losses since our inception and may need substantial additional funding. As of March 31, 2015, we had an accumulated deficit of $97.0 million. We expect to continue to incur significant expenses and operating losses over the next several years.

Our Corporate Information

We were incorporated under the laws of the state of Delaware on September 12, 2006 under the name I-Therapeutics, Inc. We subsequently changed our name to I-Therapeutix, Inc. in October 2006 and to Ocular Therapeutix, Inc. in September 2009. Our principal executive offices are located at 34 Crosby Drive, Suite 105, Bedford, MA 01730, and our telephone number is (781) 357-4000. Our website address is www.ocutx.com. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

In this prospectus, unless otherwise stated or the context otherwise requires, references to “Ocular,” “we,” “us,” “our” and similar references refer to Ocular Therapeutix, Inc. Ocular Therapeutix and ReSure are our trademarks. The other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. We have omitted the ® and ™ designations, as applicable, for the trademarks named in this prospectus.

Implications of Being an Emerging Growth Company

As a company with less than $1 billion of revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may remain an emerging growth company until December 31, 2019, subject to the satisfaction of certain conditions. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure and other requirements that are applicable to other public companies that are not emerging growth companies. In particular, in this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

THE OFFERING

Common stock offered by us	3,200,000 shares
Common stock offered by the selling stockholders	800,000 shares
Common stock to be outstanding immediately following this offering	24,702,479 shares
Underwriters' option to purchase additional shares	The selling stockholders identified in this prospectus have granted the underwriters an option for a period of 30 days to purchase up to 600,000 additional shares of our common stock.
Use of proceeds	We currently estimate that we will use the net proceeds to us from this offering, together with our existing cash, cash equivalents and marketable securities, to fund the clinical development of our most advanced product candidates, OTX-DP and OTX-TP, additional preclinical and regulatory activities for our other product candidates, including for back-of-the-eye diseases, and for working capital and other general corporate purposes, including expansion of our manufacturing capacity, sales and marketing activities and pursuit of our other research and development efforts. We will not receive any proceeds from the sale of any shares by the selling stockholders. See the "Use of Proceeds" section in this prospectus for more information.
Risk Factors	You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
NASDAQ Global Market symbol	"OCUL"

The number of shares of our common stock to be outstanding after this offering is based on 21,502,479 shares of our common stock outstanding as of May 31, 2015.

The number of shares of our common stock to be outstanding after this offering excludes:

- 2,076,952 shares of our common stock issuable upon the exercise of stock options outstanding as of May 31, 2015, at a weighted average exercise price of $12.54 per share;
- 18,939 shares of our common stock issuable upon the exercise of warrants outstanding as of May 31, 2015 held by lenders under our current and prior credit facilities, at a weighted average exercise price of $7.92 per share;
- 1,502,599 shares of our common stock available for future issuance as of May 31, 2015 under our 2014 Stock Incentive Plan; and
- 227,007 shares of our common stock available for future issuance as of May 31, 2015 under our 2014 Employee Stock Purchase Plan.

Unless otherwise indicated, all information in this prospectus assumes:

- no exercise of the outstanding options described above;
- no exercise of the warrants held by lenders under our current and prior credit facilities; and
- no exercise by the underwriters of their option to purchase up to 600,000 additional shares of our common stock from the selling stockholders.

SUMMARY FINANCIAL DATA

You should read the following summary financial data together with our financial statements and the related notes appearing elsewhere in this prospectus and the “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus. We have derived the statement of operations data for the years ended December 31, 2012, 2013 and 2014 from our audited financial statements appearing elsewhere in this prospectus. The statement of operations data for the three months ended March 31, 2014 and 2015 and the balance sheet data as of March 31, 2015 have been derived from our unaudited financial statements appearing elsewhere in this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information in those statements. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results that should be expected for any full year.

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue:					
Product revenue	$ 10	$ —	$ 460	$ 27	$ 238
Collaboration revenue	—	—	312	—	188
Total revenue	10	—	772	27	426
Operating expenses:					
Cost of product revenue	7	—	91	9	56
Research and development	11,540	10,517	18,880	4,958	4,719
Selling and marketing	657	625	1,982	310	870
General and administrative	1,477	1,761	6,913	1,575	1,894
Total operating expenses	13,681	12,903	27,866	6,852	7,539
Loss from operations	(13,671)	(12,903)	(27,094)	(6,825)	(7,113)
Other income (expense):					
Interest income	4	13	7	1	40
Interest expense	(377)	(441)	(1,119)	(43)	(505)
Other income (expense), net	(49)	14	(442)	(141)	—
Total other expense, net	(422)	(414)	(1,554)	(183)	(465)
Net loss	(14,093)	(13,317)	(28,648)	(7,008)	(7,578)
Accretion of redeemable convertible preferred stock to redemption value	(35)	(27)	(11)	(6)	—
Net loss attributable to common stockholders	$(14,128)	$(13,344)	$(28,659)	$(7,014)	$ (7,578)
Net loss per share attributable to common stockholders, basic and diluted[(1)]	$ (5.60)	$ (5.11)	$ (2.69)	$ (2.45)	$ (0.35)
Weighted average common shares outstanding, basic and diluted[(1)]	2,523	2,609	10,653	2,860	21,363

	As of March 31, 2015	
	Actual	As Adjusted(2)
	(in thousands)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$67,423	$ 139,005
Working capital(3)	62,243	133,825
Total assets	71,497	143,079
Long-term debt, net of discount, including current portion	14,954	14,954
Total stockholders' equity	52,073	123,655

(1) See Note 12 to our audited financial statements appearing elsewhere in this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

(2) The as adjusted balance sheet data gives effect to our issuance and sale of 3,200,000 shares of common stock in this offering at an assumed public offering price of $24.03 per share, which was the last reported sale price of our common stock on The NASDAQ Global Market on June 1, 2015, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any proceeds from any sale of shares of our common stock in this offering by the selling stockholders.

(3) We define working capital as current assets less current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this prospectus, including our financial statements and the related notes appearing elsewhere in this prospectus, before deciding to invest in our common stock. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

Risks Related to Our Financial Position and Need For Additional Capital

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $14.1 million for the year ended December 31, 2012, $13.3 million for the year ended December 31, 2013, $28.7 million for the year ended December 31, 2014 and $7.6 million for the three months ended March 31, 2015. As of March 31, 2015, we had an accumulated deficit of $97.0 million. Through March 31, 2015, we have financed our operations primarily through private placements of our preferred stock and borrowings under credit facilities. In July 2014, we completed an initial public offering, or IPO, of our common stock, and in August 2014 the underwriters in our IPO exercised their over-allotment option in full. Related to our IPO, we received total net proceeds of approximately $66.4 million from the issuance and sale of 5,750,000 shares of common stock, including in connection with the exercise by the underwriters of their over-allotment option, after deducting underwriting discounts and offering costs. In the first quarter of 2014, we began recognizing revenue from sales of ReSure Sealant, which was approved in January 2014 by the U.S. Food and Drug Administration, or FDA, to close clear corneal incisions following cataract surgery. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials and, beginning in the first quarter of 2014, commercialization of ReSure Sealant. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year.

We anticipate that our expenses will increase substantially if and as we:

- pursue the clinical development of our most advanced product candidates, the punctum plug candidates OTX-DP and OTX-TP;
- continue the research and development of our other product candidates;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical development;
- develop and expand our sales, marketing and distribution capabilities for ReSure Sealant and any of our product candidates for which we obtain marketing approval;
- scale up our manufacturing processes and capabilities to support sales of ReSure Sealant, our ongoing clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts; and
- operate as a public company.

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

- we are required by the FDA or the European Medicines Agency, or EMA, to perform trials or studies in addition to those currently expected;
- there are any delays in receipt of regulatory clearance to begin our planned clinical programs; or
- there are any delays in enrollment of patients in or completing our clinical trials or the development of our product candidates.

ReSure Sealant is currently our only source of revenue from product sales. We do not expect sales of ReSure Sealant to generate revenue that is sufficient for us to achieve profitability. Instead, for us to become and remain profitable, we will need to succeed in developing and commercializing products with greater market potential. This will require us to be successful in a range of challenging activities, including:

- successfully completing clinical development of our product candidates;
- obtaining marketing approval for these product candidates;
- manufacturing at commercial scale, marketing, selling and distributing those products for which we obtain marketing approval;
- achieving an adequate level of market acceptance of and obtaining and maintaining coverage and adequate reimbursement from third-party payors for our products; and
- protecting our rights to our intellectual property portfolio.

We may never succeed in these activities and may never generate revenue that is sufficient or great enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

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

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct late stage clinical trials for our punctum plug product candidates, in particular OTX-DP and OTX-TP, and seek marketing approval for any such product candidate for which we obtain favorable pivotal clinical results. We also expect to devote significant financial resources to conducting research and development and potentially seeking regulatory approval for our other product candidates. In addition, we plan to devote substantial financial resources to our commercialization efforts, including product manufacturing, sales, marketing and distribution for ReSure Sealant and any of our product candidates for which we obtain marketing approval. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

As of March 31, 2015, we had cash, cash equivalents and marketable securities of $67.4 million. We believe that the net proceeds to us from this offering, together with our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements at least through the third quarter of 2017. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the level of product sales from ReSure Sealant and any additional products for which we obtain marketing approval in the future;

- ReSure Sealant and any additional products for which we obtain marketing approval in the future;
- the progress, costs and outcome of the clinical trials of our punctum plug product candidates, in particular OTX-DP and OTX-TP;
- the scope, progress, costs and outcome of preclinical development and clinical trials of our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates by the FDA, the EMA or other regulatory authorities;
- the extent to which we choose to establish collaboration, distribution or other marketing arrangements for our products and product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or invest in other businesses, products and technologies.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. We may never generate the necessary data or results required to obtain regulatory approval of products with the market potential sufficient to enable us to achieve profitability. We do not expect to generate meaningful revenue from sales of any product for several years, if at all. Accordingly, we may need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through a combination of revenue from sales of ReSure Sealant, equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights as holders of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our pledge of our assets as collateral to secure our obligations under our credit facility may limit our ability to obtain additional debt financing.

If we raise additional funds through collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Our substantial indebtedness may limit cash flow available to invest in the ongoing needs of our business.

We have a significant amount of indebtedness. In April 2014, we entered into a credit facility with Silicon Valley Bank and MidCap Financial SBIC, LP, pursuant to which we were able to borrow an aggregate principal amount of up to $20.0 million, of which we borrowed $15.0 million. We did not borrow the remaining $5.0 million, and this amount is no longer available to us. Our obligations under this agreement are secured by all of our assets other than our intellectual property. Our intellectual property rights are subject to a negative pledge arrangement under the agreement. We could in the future incur additional indebtedness beyond such amounts.

Our substantial debt combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of cash, cash equivalents and marketable securities to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- obligating us to negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions, encumbering our intellectual property, incurring indebtedness or liens, paying dividends, making investments and engaging in certain other business transactions;
- limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our existing cash, cash equivalents and marketable securities, revenue from sales of ReSure Sealant and funds from external sources. However, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the conditions of our credit facility could result in an event of default under those instruments. In the event of an acceleration of amounts due under our credit facility as a result of an event of default, including upon the occurrence of an event that would reasonably be expected to have a material adverse effect on our business, operations, properties, assets or condition or a failure to pay any amount due, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness. In addition, the covenants under our existing credit facility, the pledge of our assets as collateral and the negative pledge of our intellectual property limit our ability to obtain additional debt financing.

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

We are an early-stage company. Our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies and clinical trials, manufacturing initial quantities of our products and product candidates and, beginning in the first quarter of 2014, commercializing ReSure Sealant. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

Risks Related to Product Development

We depend heavily on the success of our punctum plug product candidates, in particular OTX-DP and OTX-TP. Clinical trials of our product candidates may not be successful. If we are unable to successfully complete clinical development of and obtain marketing approvals for our product candidates, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize these product candidates, our business will be materially harmed.

We have devoted a significant portion of our financial resources and business efforts to the development of our punctum plug product candidates for diseases and conditions of the front of the eye. In particular, we are investing substantial resources to complete the development of OTX-DP for post-surgical ocular inflammation and pain, allergic conjunctivitis and inflammatory dry eye disease and OTX-TP for glaucoma. We cannot accurately predict when or if any of our punctum plug product candidates will prove effective or safe in humans or whether these product candidates will receive marketing approval. Our ability to generate product revenues sufficient to achieve profitability will depend heavily on our obtaining marketing approval for and commercializing one or both of OTX-DP and OTX-TP.

The commercial success of our punctum plug product candidates and other product candidates will depend on many factors, including the following:

- successful completion of preclinical studies and clinical trials;
- applying for and receiving marketing approvals from applicable regulatory authorities for our product candidates;
- scaling up our manufacturing processes and capabilities to support additional or larger clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- developing, validating and maintaining a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP;
- developing and expanding our sales, marketing and distribution capabilities for ReSure Sealant and successfully launching commercial sales of any of our product candidates for which we obtain marketing approval;
- developing and expanding our sales, marketing and distribution capabilities and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- maintaining a continued acceptable safety profile of our products following approval;
- obtaining and maintaining coverage and adequate reimbursement from third-party payors;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- protecting our rights in our intellectual property portfolio.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

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

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, including our punctum plug product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later stage clinical trials, interim results of a clinical trial do not necessarily predict final results and results from one completed clinical trial may not be replicated in a subsequent clinical trial with a similar study design. Some of our completed studies, including our pilot studies for OTX-TP and our Phase 1 clinical trial of OTX-MP, were conducted with small patient populations, making it difficult to predict whether the favorable results that we observed in such studies will be repeated in larger and more advanced clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In general, the FDA requires two adequate and well controlled clinical trials to support the effectiveness of a new drug for marketing approval. In a Phase 2 clinical trial of OTX-DP that we completed in 2013 in which we were evaluating OTX-DP for ocular inflammation and pain following cataract surgery, OTX-DP did not meet the primary efficacy endpoint for inflammation with statistical significance at the pre-specified time point at day 8. However, we did achieve statistical significance for this inflammation endpoint at days 14 and 30. Accordingly, we measured the primary efficacy endpoint for inflammation in our two completed Phase 3 clinical trials of OTX-DP at day 14. In the first of these two Phase 3 clinical trials, OTX-DP met both primary endpoints for ocular inflammation and pain following cataract surgery with statistical significance. However, in the second Phase 3 clinical trial, OTX-DP met only one of the two primary efficacy endpoints with statistical significance. In this second trial, OTX-DP did not meet the primary endpoint relating to absence of inflammatory cells in the study eye at day 14.

According to the trial protocols, the two primary efficacy endpoints in our completed Phase 2 and Phase 3 clinical trials are fixed sequence endpoints. As such, a statistical analysis of the trial results required that we first assess the primary endpoint regarding absence of inflammatory cells in the study eye. The protocol and statistical analysis plan for the trial did not contemplate assessing the primary endpoint regarding absence of pain in the study eye in the event the clinical trial of OTX-DP did not meet the first primary endpoint with statistical significance. The FDA has informed us that the hierarchy of the two primary endpoints for inflammation and pain is applicable in connection with their review of an NDA seeking approval for OTX-DP solely for an ocular pain indication. However, the FDA has also informed us that pain endpoints from the Phase 2 and two Phase 3 trials, with respect to which we received favorable data, would support the NDA submission. We therefore plan to proceed with an NDA submission for OTX-DP solely for an ocular pain indication using the existing data from our completed Phase 2 and Phase 3 clinical trials notwithstanding the FDA's comment regarding the applicability of the hierarchy of the two primary endpoints in our completed Phase 2 and Phase 3 clinical trials. Prior to submitting this NDA, we will need to complete process validation for the manufacture of OTX-DP, obtain stability data for 12 months and finalize the clinical study report containing complete efficacy and safety data, which could take longer than we currently expect and could delay the proposed submission of the NDA.

We also plan to conduct a third Phase 3 clinical trial to support the potential labeling expansion of OTX-DP's indications for use to include inflammation. We plan to make modifications to the design of this third Phase 3 clinical trial compared to our two completed Phase 3 clinical trials of OTX-DP based on our learnings from these prior trials. However, these modifications may not have the intended effect or yield favorable trial results. If the results of our third Phase 3 clinical trial of OTX-DP are favorable and subject to receiving approval for the pain indication pursuant to the initial NDA, we plan to submit an NDA supplement for OTX-DP for the treatment of ocular inflammation following ophthalmic surgery. Although we believe our planned approach for seeking marketing approval of OTX-DP is supported by our discussions with the FDA, the FDA could nonetheless fail to accept our NDA for filing or not grant marketing approval of OTX-DP for the pain indication until we obtain favorable results from the third Phase 3 clinical trial on both primary efficacy endpoints, or at all.

Retrospective post-hoc analyses that we performed on the results of our two completed Phase 3 clinical trials may not be predictive of success in our third Phase 3 clinical trial. Although we believe that the collective data from these trials, including the post-hoc analyses, provide support for our decision to conduct a third Phase 3 clinical trial and provide additional information regarding our platform technology, post-hoc analyses performed after unblinding trial results can result in the introduction of bias and are given less weight by regulatory authorities than pre-specified analyses.

In addition, in a Phase 2 clinical trial of OTX-DP that we recently completed in which we were evaluating OTX-DP for allergic conjunctivitis, OTX-DP met one of the two primary efficacy measures. The OTX-DP treatment group achieved a mean difference compared to the vehicle control group of more than 0.5 units on a five point scale on day 14 for all three time points measured in a day for both ocular itching and conjunctival redness. The OTX-DP group did not achieve a mean difference compared to the vehicle control group of 1.0 unit for the majority of the three time points measured on day 14 for either ocular itching or conjunctival redness. We met with the FDA in December 2014 to discuss the Phase 3 clinical trial design for OTX-DP for allergic conjunctivitis and the appropriate endpoints. Based on this meeting with the FDA, we plan to include the same efficacy measures, but measured at different timepoints, as those used in our Phase 2 clinical trial, including at least a 0.5 unit mean difference between the treatment group and the placebo group at day 7 at all three time points for both ocular itching and conjunctival redness and at least a 1.0 unit difference between the treatment group and the placebo group at day 7 at the majority of time points for both ocular itching and conjunctival redness. These changes may not have the intended effect or yield favorable trial results. If we do not obtain favorable clinical trial results in our Phase 3 clinical trials of OTX-DP for allergic conjunctivitis, including meeting both primary efficacy measures, we may not obtain approval for OTX-DP to treat allergic conjunctivitis.

We designed our Phase 2 clinical trials of OTX-TP for the treatment of glaucoma and ocular hypertension to assess clinically meaningful response to treatment, and did not power these trials to measure any efficacy endpoints with statistical significance. We expect that our planned Phase 3 clinical trials for OTX-TP will be the first clinical trials for OTX-TP to be powered with an appropriate number of patients to allow us to measure with statistical significance the non-inferiority of OTX-TP compared to a vehicle control punctum plug plus timolol eye drops for the treatment of glaucoma and ocular hypertension based on the primary efficacy endpoint. As a result, favorable results from our Phase 2 clinical trials may not necessarily predict a likelihood of achieving our primary endpoint in the Phase 3 clinical trials with statistical significance, which we expect will be required for us to obtain marketing approval for OTX-TP.

The success of our punctum plug product candidates is dependent upon retention of the plug following insertion and during the course of intended therapy. As such, we continue to conduct non-significant risk, or NSR, studies in the United States for our punctum plugs in an effort to increase the rate of plug retention. All NSR studies that we have performed to date have involved placebo vehicle control punctum plugs without active drug. If we determine to make any future changes to the design or composition of our plugs, such changes could affect the outcome of any subsequent clinical trials using these updated plugs. For example, in our Phase 2b clinical trial of OTX-TP, we are using a different version of a punctum plug than either of the plugs that we used in our Phase 2a clinical trial of OTX-TP. Based on the results of our completed Phase 2a clinical trial, we designed a OTX-TP plug that is being used in our Phase 2b clinical trial to deliver drug over a 90 day period at the same daily rate as the two-month version of the plug used in the Phase 2a clinical trial. To achieve this, we modified the design of the OTX-TP plug to enlarge it in order to enable the plug to carry a greater amount of drug. In addition, we incorporated minor plug structural changes to improve plug retention rates. As a result, the outcome of our Phase 2b clinical trial may differ from the outcome of our Phase 2a clinical trial. Likewise, although we do not believe that the presence of an active drug influences plug retention rates, because the plugs in our NSR studies did not contain active drug, we cannot be certain what impact, if any, the addition of an active drug may have on retention rates. If the retention rates for our plugs are inadequate to ensure that the patient is receiving appropriate therapy, we may not be able to obtain regulatory approvals or, even if approved, achieve market acceptance of our plugs.

The protocols for our clinical trials and other supporting information are subject to review by the FDA and regulatory authorities outside the United States. For our punctum plug product candidates, we have typically conducted our initial and earlier stage clinical trials outside the United States. We generally plan to conduct our later stage and pivotal clinical trials of our punctum plug product candidates in the United States. The FDA, however, could require us to conduct additional studies or require us to modify our planned pivotal clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated. For example, in connection with our initial development of ReSure Sealant, in June 2010 the FDA requested that we withdraw an application that we had submitted under Section 510(k) of the Food, Drug and Cosmetic Act, or FDCA, for the marketing of an earlier version of ReSure Sealant as an ocular bandage because the FDA believed that the technical characteristics of the earlier version of ReSure Sealant were not substantially equivalent to a predicate device. In particular, unlike predicate devices that could be removed if there is discomfort, our product candidate adhered to the corneal surface and was not easily removable by the patient. As a result of this determination by the FDA, we needed to pursue a different regulatory approval pathway and conduct additional clinical development of our product candidate to demonstrate safety and effectiveness. After withdrawing our 510(k) application, we filed an investigational device exemption application to conduct a pivotal clinical trial to support approval of ReSure Sealant as an ocular sealant. The results of this pivotal trial ultimately supported the marketing approval of ReSure Sealant in January 2014, although not in the time frame we had initially expected. The FDA is not obligated to comment on our trial protocols within any specified time period or at all or to affirmatively clear or approve our planned pivotal clinical trials. Subject to a waiting period of 30 days, we could choose to initiate our pivotal clinical trials in the United States without waiting for any additional period for comments from the FDA.

We intend to conduct, and may in the future conduct, clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We have conducted, and may in the future choose to conduct, one or more of our clinical trials outside the United States. We have typically conducted our initial and earlier stage clinical trials for our product candidates, including our punctum plug product candidates, outside the United States. We generally plan to conduct our later stage and pivotal clinical trials of our punctum plug product candidates in the United States.

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of the applicable product candidates.

Other risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials
- administrative burdens of conducting clinical trials under multiple sets of foreign regulations;
- failure of enrolled patients to adhere to clinical protocols as a result of differences in healthcare services or cultural customs;
- foreign exchange fluctuations;

- diminished protection of intellectual property in some countries; and
- political and economic risks relevant to foreign countries.

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

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

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

For example, we applied for a deferral from the FDA for the requirement to conduct pediatric studies for OTX-DP for the treatment of post-surgical ocular inflammation and pain following cataract surgery until after approval of such product in adult populations for that indication. While the FDA ultimately approved our request, if the FDA had required us to conduct pediatric studies in advance of FDA approval in adult populations, we would have experienced significant delays in our ability to obtain marketing approval for OTX-DP for this indication. We will face a similar risk if we seek a comparable deferral for other product candidates or indications.

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

- be delayed in obtaining or unable to obtain marketing approval for our product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

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

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

We may not be able to initiate or continue clinical trials for our punctum plug product candidates or our other product candidates that we may develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or similar regulatory authorities outside the United States. Although there is a significant prevalence of disease in the areas of ophthalmology in which we are focused, we may nonetheless experience unanticipated difficulty with patient enrollment.

Patient enrollment is affected by a variety of factors, including:

- the prevalence and severity of the ophthalmic disease or condition under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients;
- the conduct of clinical trials by competitors for product candidates that treat the same indications as our product candidates; and
- the lack of adequate compensation for prospective patients.

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

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

If our punctum plug product candidates or any of our other product candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In our recent Phase 3 clinical trials of OTX-DP for the treatment of ocular inflammation and pain following cataract surgery, there were two serious adverse events in the OTX-DP group in each of our two trials, none of which were ocular in nature or considered by the investigator to be related to the study treatment. There was one ocular serious adverse event in the vehicle control group in the two completed Phase 3 clinical trials, which was hypopyon, or inflammatory cells in the anterior chamber. In our earlier Phase 2 clinical trial of OTX-DP for the same indication, there were three serious adverse events, none of which was considered by the investigator to be related to the study treatment. In the OTX-DP group of this Phase 2 clinical trial of OTX-DP, the only adverse event that occurred more than once was reduced visual acuity, which occurred twice. In our two pilot studies of OTX-TP for the treatment of glaucoma and ocular hypertension and our Phase 2a clinical trial of OTX-TP for the same indication, the most common adverse event was inflammatory reaction, which was noted in three patients in our pilot studies and in five patients in our Phase 2a clinical trial.

All adverse events have been transient in nature and resolved by the end of the applicable trial. However, many compounds that initially showed promise in clinical or early stage testing for treating ophthalmic disease have later been found to cause side effects that prevented further development of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later be found to be caused by the study treatment.

We may not be successful in our efforts to develop product candidates based on our bioresorbable hydrogel technology platform other than ReSure Sealant or expand the use of our bioresorbable hydrogel technology for treating additional eye diseases and conditions.

We are currently directing all of our development efforts towards applying our proprietary bioresorbable hydrogel technology platform to product candidates that are designed to provide sustained delivery of therapeutic agents to the eye using active pharmaceutical ingredients that are currently used in FDA-approved ophthalmic drugs. We have a number of product candidates at various stages of development based on our bioresorbable hydrogel technology platform and are exploring the potential use of our hydrogel punctum plugs in other front-of-the-eye diseases and conditions. We are also developing a hydrogel based drug delivery depot designed to release therapeutic antibodies to vascular endothelial growth factor, or VEGF, over a sustained period following administration by an intravitreal injection for the treatment of diseases and conditions of the back of the eye, including wet age related macular degeneration, or wet AMD. Our existing product candidates and any other potential product candidates that we identify may not be suitable for continued preclinical or clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize our product candidates that we develop based upon our technological approach, we will not be able to obtain substantial product revenues in future periods.

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

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

Risks Related to Manufacturing

We will need to upgrade and expand our manufacturing facility and augment our manufacturing personnel and processes in order to meet our business plans. If we fail to do so, we may not have sufficient quantities of our products or product candidates to meet our commercial and clinical trial requirements.

We manufacture ReSure Sealant and our product candidates for use in clinical trials, research and development and commercial efforts at our multi-product facility located at our corporate headquarters in Bedford, Massachusetts. In order to meet our business plan, which contemplates our scaling up manufacturing processes to support ReSure Sealant sales, as well as our product candidate development programs and the potential commercialization of these product candidates, we will need to upgrade and expand our existing manufacturing facility, add manufacturing personnel and ensure that validated processes are consistently implemented in our facility. The upgrade and expansion of our facility will require additional regulatory approvals. In addition, it will be costly and time-consuming to expand our facility and recruit necessary additional personnel. If we are unable to expand our manufacturing facility in compliance with regulatory requirements or to hire additional necessary manufacturing personnel, we may encounter delays or additional costs in achieving our research, development and commercialization objectives, including in obtaining regulatory approvals of our product candidates and meeting customer demand for ReSure Sealant, which could materially damage our business and financial position.

We must comply with federal, state and foreign regulations, including quality assurance standards applicable to medical device and drug manufacturers, such as cGMP, which is enforced by the FDA through its facilities inspection program and by similar regulatory authorities in other jurisdictions where we do business. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Following a recent inspection by the FDA, for example, we received a Form FDA 483 containing an inspectional observation relating to inadequate procedures for documenting follow-up information pertinent to the investigation of complaints and for evaluation of complaints for adverse event reporting. We have submitted our response, which was accepted by the FDA, and have updated our procedures. The FDA or similar foreign regulatory authorities at any time also may implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of our products. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, product seizure or recall, imposition of a consent decree, or withdrawal of product approval, and would limit the availability of ReSure Sealant and our product candidates that we manufacture. Any manufacturing defect or error discovered after products have been produced and distributed also could result in significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

If our sole clinical manufacturing facility is damaged or destroyed or production at this facility is otherwise interrupted, our business and prospects would be negatively affected.

If the manufacturing facility at our corporate headquarters or the equipment in it is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of this 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 the necessary regulatory requirements and we would need FDA approval before selling any products manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales.

Currently, we maintain insurance coverage against damage to our property and equipment in the amount of up to $4.3 million and to cover business interruption and research and development restoration expenses in the amount of up to $2.8 million. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for ReSure Sealant or any of our product candidates if there were a catastrophic event or failure of our current manufacturing facility or processes.

We expect to continue to contract with third parties for at least some aspects of the production of our products and product candidates. This increases the risk that we will not have sufficient quantities of our products or product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently rely on third parties for some aspects of the production of ReSure Sealant and our product candidates for commercialization and preclinical testing and clinical trials, including supply of active pharmaceutical ingredient drug substance, polyethylene glycol, or PEG, the molecule that forms the basis of our hydrogels, and other raw materials and for sterilization of the finished product. In addition, while we believe that our existing manufacturing facility, or additional facilities that we will be able to build, will be sufficient to meet our requirements for manufacturing ReSure Sealant and any of our product candidates for which we obtain marketing approval, we may in the future need to rely on third-party manufacturers for some aspects of the manufacture of our products or product candidates.

We do not have any long term supply agreements in place for the clinical or commercial supply of any drug substances or raw materials for ReSure Sealant or any of our product candidates. We purchase drug substance and raw materials, including the chemical constituents for our hydrogel, from independent suppliers on a purchase order basis. Any performance failure or refusal to supply drug substance or raw materials on the part of our existing or future suppliers could delay clinical development, marketing approval or commercialization of our products. If our current suppliers do not perform as we expect, we may be required to replace one or more of these suppliers. In particular, we depend on a sole source supplier for the supply of our PEG. This sole source supplier may be unwilling or unable to supply PEG to us reliably, continuously and at the levels we anticipate or are required by the market. Although we believe that there are a number of potential long term replacements to our suppliers, including our PEG supplier, we may incur added costs and delays in identifying and qualifying any such replacements.

Reliance on third parties for aspects of the supply of our products and product candidates entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible breach of an agreement by the third party; and
- the possible termination or nonrenewal of an agreement by the third party at a time that is costly or inconvenient for us.

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

Our potential future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

Risks Related to Commercialization

Even though ReSure Sealant has received marketing approval from the FDA and even if any of our product candidates receives marketing approval, any of these products may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for these products may be smaller than we estimate.

ReSure Sealant or any of our product candidates that receives marketing approval may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. We commercially launched ReSure Sealant in the first quarter of 2014 and cannot yet accurately predict whether it will it will gain market acceptance and become commercially successful. For example, we previously commenced commercialization in Europe of an earlier version of ReSure Sealant that was approved and marketed as an ocular bandage. We recognized $0.1 million of revenue from the commercialization of this product through 2012. However, we ceased our commercialization of the product in 2012 to focus on the ongoing clinical development of ReSure Sealant pursuant to FDA requirements. If our products do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable.

The degree of market acceptance of ReSure Sealant or any product candidate for which we obtain marketing approval will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;

- our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments, including the plug retention rate for our punctum plug product candidates;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement and, for ReSure Sealant, the lack of separate reimbursement when used as part of a cataract surgery procedure;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

For example, because we do not plan to conduct any clinical trials comparing the effectiveness of OTX-DP directly to currently approved alternative treatments for either ocular inflammation and pain following cataract surgery or allergic conjunctivitis, it is possible that the market acceptance of OTX-DP, if it is approved for marketing, could be less than if we had conducted such trials.

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

If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, we may not be successful in commercializing ReSure Sealant or any product candidates if and when they are approved.

We have limited experience in the sale, marketing and distribution of drug and device products. To achieve commercial success for ReSure Sealant and any product candidate for which we obtain marketing approval, we will need to establish and maintain adequate sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties. We sell ReSure Sealant through a network of independent medical device distributors across the United States. We believe that, if approved for marketing, OTX-DP could be commercialized by the same independent network of distributors that sell ReSure Sealant. Alternatively, we may determine to build a specialty sales force to sell OTX-DP, if approved for marketing. We expect that a direct sales force will be required to effectively market and sell OTX-TP, if approved for marketing. Because we do not plan to determine whether to seek regulatory approval for any of our product candidates outside of the United States until after we receive regulatory approval for the applicable product candidate in the United States, at this time we cannot be certain when, if ever, we will recognize revenue from commercialization of our product candidates in any international markets. If we decide to commercialize our products outside of the United States, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize any product of ours that receives marketing approval. These may include independent distributors, pharmaceutical companies or our own direct sales organization.

There are risks involved with both establishing our own sales, marketing and distribution capabilities and with entering into arrangements with third parties to perform these services. We may not be successful in entering into arrangements with third parties to sell, market and distribute our products or may be unable to do so on terms that are most beneficial to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to market, sell and distribute our products effectively. Our product revenues and our profitability, if any, under third-party collaboration, distribution or other marketing arrangements may also be lower than if we were to sell, market and distribute a product ourselves. On the other hand, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of any product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Other factors that may inhibit our efforts to commercialize products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to use or prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing ReSure Sealant or any of our product candidates.

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

The development and commercialization of new drug and device products is highly competitive. We face competition with respect to our product candidates and ReSure Sealant, and will face competition with respect to any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our product candidates target markets that are already served by a variety of competing products based on a number of active pharmaceutical ingredients. Many of these existing products have achieved widespread acceptance among physicians, patients and payors for the treatment of ophthalmic diseases and conditions. In addition, many of these products are available on a generic basis, and our product candidates may not demonstrate sufficient additional clinical benefits to physicians, patients or payors to justify a higher price compared to generic products. In many cases, insurers or other third-party payors, particularly Medicare, seek to encourage the use of generic products. Given that we are developing products based on FDA-approved therapeutic agents, our product candidates, if approved, will face competition from generic and branded versions of existing drugs based on the same active pharmaceutical ingredients that are administered in a different manner, typically through eye drops.

Because the active pharmaceutical ingredients in our product candidates are available on a generic basis, or are soon to be available on a generic basis, competitors will be able to offer and sell products with the same active pharmaceutical ingredient as our products so long as these competitors do not infringe the patents that we license. For example, our licensed patents related to our punctum plug product candidates largely relate to the hydrogel composition of the punctum plugs and certain drug-release features of the punctum plugs. As such, if a third party were able to design around the formulation and process patents that we license and create a different formulation using a different production process not covered by our licensed patents or patent applications, we would likely be unable to prevent that third party from manufacturing and marketing its product.

Other companies have advanced into Phase 3 clinical development biodegradable, sustained release product candidates that could compete with our punctum plug product candidates. ReSure Sealant is the first and only surgical sealant approved for ophthalmic use in the United States, but will compete with sutures as an alternative method for closing ophthalmic wounds. Multiple companies are exploring in early stage development alternative means to deliver anti-VEGF products in a sustained release fashion to the back of the eye.

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

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

ReSure Sealant and any product candidates for which we obtain marketing approval may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

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

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

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

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

ReSure Sealant or any product candidate for which we obtain marketing approval in the United States or in other countries may not be considered medically reasonable and necessary for a specific indication, may not be considered cost-effective by third-party payors, coverage and an adequate level of reimbursement may not be available, and reimbursement policies of third-party payors may adversely affect our ability to sell our product candidates profitably. ReSure Sealant is not separately reimbursed when used as part of a cataract surgery procedure, which could limit the degree of market acceptance of this product by surgeons. In addition, while OTX-DP may be considered a post-surgical product in the same fashion as eye drops, if it receives marketing approval, it may instead be categorized as an inter-operative product. If OTX-DP is categorized as an inter-operative product, it will not be subject to separate reimbursement, which could likewise limit its market acceptance.

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

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

- decreased demand for any product candidates or products that we develop;
- injury to our reputation and significant negative media attention;

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

We currently hold $5.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $5.0 million, which may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage as we expand our clinical trials and our sales of ReSure Sealant and any other product candidates for which we obtain marketing approval. We will need to further increase our insurance coverage if we commence commercialization of any of our product candidates for which we obtain marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Dependence on Third Parties

If we are unable to train, maintain and expand our network of independent distributors, we may not be able to successfully commercialize ReSure Sealant or any other product candidates for which we obtain marketing approval.

We commercially launched ReSure Sealant in the first quarter of 2014 and plan to sell the product through a network of independent medical device distributors across the United States. As a result, our revenues are directly dependent upon the sales and marketing efforts of these independent distributors. As ReSure Sealant is a newly marketed product, we will continue to expend significant time and resources to train the independent distributors to be credible and persuasive in convincing physicians and hospitals to use ReSure Sealant. In addition, we also must train our independent distributors to ensure that a consistent and appropriate message about ReSure Sealant is delivered to our potential customers. We believe that, if approved for marketing, OTX-DP could be commercialized by the same independent network of distributors that sell ReSure Sealant.

Our relationships with our distributors are non-exclusive, and our distributors will simultaneously sell products on behalf of third parties, including products that may compete directly or indirectly with our products or product candidates. If our independent distributors fail to devote sufficient time to the sale of ReSure Sealant, or if they otherwise fail to adequately promote, market and sell ReSure Sealant, our sales could decrease. We face significant challenges and risks in managing our geographically dispersed distribution network and retaining the individuals who make up that network. If a substantial number of our independent distributors, or any significant independent distributor, were to cease to do business with us within a short period of time, our sales could be adversely affected. In such a situation, we may need to seek alternative independent distributors. Because of the competition for their services, we may be unable to recruit additional qualified independent distributors to work with us. We may also not be able to enter into agreements with them on favorable or commercially reasonable terms, if at all. Failure to retain qualified independent distributors would prevent us from successfully commercializing ReSure Sealant or any other product candidates for which we obtain marketing approval.

We may enter into collaborations with third parties for the commercialization of ReSure Sealant or the development or commercialization of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

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

Collaborations that we enter into may pose a number of risks, including the following:

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

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of our collaborators.

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

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

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

For example, we are currently conducting preclinical testing in collaboration with several pharmaceutical companies with anti-VEGF compounds to explore the feasibility of delivering their drugs using our intravitreal hydrogel depot. If we successfully complete the preclinical feasibility programs, we plan to explore broader collaborations for the development and potential commercialization of our intravitreal hydrogel depot technology for the treatment of back-of-the-eye diseases and conditions.

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

Although the majority of our clinical development is administered and managed by our own employees, we have relied, and may continue to rely, on third parties for certain aspects of our clinical development, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

Our employees have administered and managed most of our clinical development work, including our clinical trials for ReSure Sealant and our clinical trials for OTX-DP for the treatment of ocular inflammation and pain following cataract surgery. However, we have relied and may continue to rely on third parties, such as contract research organizations, or CROs, to conduct future clinical trials of OTX-MP, as well as our pilot studies of OTX-TP in Singapore and South Africa for the treatment of glaucoma. If we deem necessary, we may engage third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct or assist in our clinical trials or other clinical development work. If we are unable to enter into an agreement with a CRO or other service provider when required, our product development activities would be delayed.

Our reliance on third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we engage third parties and they do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

Risks Related to Our Intellectual Property

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

Our success depends in large part on our and our licensor's ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We and our licensor have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. Some of our licensed patents that we believe are integral to our hydrogel technology platform have terms that extend through at least 2024. However, other broader patents within our licensed patent portfolio expire between 2017 and 2019. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our licensed patent portfolio would be less effective in excluding others from commercializing products similar or identical to ours. The patent prosecution process is expensive and time-consuming, and we may not have filed or prosecuted and may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to enforce or maintain the patents, covering technology that we license from third parties. In particular, the license agreement that we have entered into with Incept, LLC, or Incept, an intellectual property holding company, which covers all of the patent rights and a significant portion of the technology for ReSure Sealant and our product candidates, provides that, with limited exceptions, Incept has sole control and responsibility for ongoing prosecution for the patents covered by the license agreement. In addition, although we have a right under the Incept license to bring suit against third parties who infringe our licensed patents in our field, other Incept licensees may also have the right to enforce our licensed patents in their own respective fields without our oversight or control. Those other licensees may choose to enforce our licensed patents in a way that harms our interest, for example, by advocating for claim interpretations or agreeing on invalidity positions that conflict with our positions or our interest. We also have no right to control the defense of any of our licensed patents if their validity or scope is challenged before the U.S. Patent and Trademark Office, or USPTO, the European Patent Office, or other patent office or tribunal. Instead, we would essentially rely on our licensor to defend such challenges, and it may not do so in a way that would best protect our interests. Therefore, our licensed patents and applications may not be prosecuted, enforced, defended or maintained in a manner consistent with the best interests of our business. If Incept fails to prosecute, enforce or maintain such patents, or loses rights to those patents, our licensed patent portfolio may be reduced or eliminated.

The patent position of pharmaceutical, biotechnology and medical device companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our licensor’s patent rights are highly uncertain. Our licensor’s pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, unlike patent law in the United States, European patent law precludes the patentability of methods of treatment of the human body and imposes substantial restrictions on the scope of claims it will grant if broader than specifically disclosed embodiments. Moreover, we have no patent protection and likely will never obtain patent protection for ReSure Sealant outside the United States and Canada. We have only two issued patents outside of the United States for two of our three punctum plug product candidates, and these expire by 2019. We have three licensed patent families in Europe and certain other parts of the world, but these families consist only of patent applications outside of the United States and have no issued or allowed patents. Patents might not be issued and we may never obtain any patent protection or may only obtain substantially limited patent protection outside of the United States with respect to our products.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensor were the first to make the inventions claimed in our licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Databases for patents and publications, and methods for searching them, are inherently limited so it is not practical to review and know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patent rights are uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, the Leahy-Smith Act provides a new administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, that provides a venue for companies to challenge the validity of competitor patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could therefore increase the likelihood that our own licensed patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them. Moreover, if such challenges occur, as indicated above, we have no right to control the defense. Instead, we would essentially rely on our licensor to consider our suggestions and to defend such challenges, with the possibility that it may not do so in a way that best protects our interests.

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

In the United States, the FDA does not prohibit physicians from prescribing an approved product for uses that are not described in the product's labeling. Although use of a product directed by off-label prescriptions may infringe our method-of-treatment patents, the practice is common across medical specialties, particularly in the United States, and such infringement is difficult to detect, prevent or prosecute. In addition, patents that cover methods of use for a medical device cannot be enforced against the party that uses the device, but rather only against the party that makes them. Such indirect enforcement is more difficult to achieve.

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

Because the active pharmaceutical ingredients in our product candidates are available on a generic basis, or are soon to be available on a generic basis, competitors will be able to offer and sell products with the same active pharmaceutical ingredient as our products so long as these competitors do not infringe any patents that we license. Our licensed patents largely relate to the hydrogel composition of our punctum plugs and the drug-release design scheme of our punctum plugs. As such, if a third party were able to design around the formulation and process patents that we license and create a different formulation using a different production process not covered by our licensed patents or patent applications, we would likely be unable to prevent that third party from manufacturing and marketing its product.

If we are not able to obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our product candidates, our business may be impaired.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA-approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

Further, our license from Incept does not provide us with the right to control decisions by Incept or its other licensees on Orange Book listings or patent term extension decisions under the Hatch-Waxman Act. Thus, if one of our important licensed patents is eligible for a patent term extension under the Hatch Waxman Act, and it covers a product of another Incept licensee in addition to our own product candidate, we may not be able to obtain that extension if the other licensee seeks and obtains that extension first.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration sooner, and our revenue could be reduced, possibly materially.

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

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

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

Our commercial success depends upon our ability to develop, manufacture, market and sell our ReSure Sealant and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology, medical device, and pharmaceutical industries. We may become party to, or threatened with, infringement litigation claims regarding our products and technology, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Moreover, we may become party to future adversarial proceedings or litigation regarding our licensed patent portfolio or the patents of third parties. Such proceedings could also include contested post-grant proceedings such as oppositions, *inter partes* review, reexamination, interference or derivation proceedings before the USPTO or foreign patent offices. The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensor can. The risks of being involved in such litigation and proceedings may increase as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses. Thus, we do not know with certainty that ReSure Sealant or any of our product candidates, or our commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property.

We are aware of a family of U.S. patent applications and issued patents that will expire in approximately December 2015 and which have claims that ReSure Sealant could be considered to be infringing. We believe that the claims of this patent family are subject to a claim of invalidity. We are also aware of a U.S. patent with an expiration in 2020 with claims directed to formulations of hydrogels and which could be alleged to cover the hydrogel formulations used in our product candidates OTX-TP and OTX-MP. Based on the specifications and file history of that patent, we believe its claims should be construed with a scope that does not cover our product candidates. We also believe that such claims, if and to the extent they were asserted against our product candidates, would be subject to a claim of invalidity.

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

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

Our license agreement with Incept, under which we license all of our patent rights and a significant portion of the technology for ReSure Sealant and our product candidates, imposes royalty and other financial obligations on us and other substantial performance obligations. We also may enter into additional licensing and funding arrangements with third parties that may impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of our product. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

Under the terms of our license agreement with Incept, we have agreed to assign to Incept our rights in any patent application filed at any time in any country for which one or more inventors are under an obligation of assignment to us. These assigned patent applications and any resulting patents are included within the specified patents owned or controlled by Incept to which we receive a license under the agreement. Incept has retained rights to practice the patents and technology licensed to us under the agreement for all purposes other than for researching, designing, developing, manufacturing and commercializing products that are delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to ophthalmic diseases or conditions. As a result, termination of our agreement with Incept, based on our failure to comply with this or any other obligation under the agreement, would cause us to lose our rights to important intellectual property or technology upon which our business depends. Additionally, the field limit of the license and the requirement that we assign to Incept our rights in any patent application restricts our ability to expand our business outside of ophthalmology.

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

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

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

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

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

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

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

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

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

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

The activities associated with the development and commercialization of our product candidates, including design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have only received approval to market ReSure Sealant in the United States, and have not received approval to market any of our product candidates or to market ReSure Sealant in any jurisdiction outside the United States. We may determine to seek a CE Certificate of Conformity, which demonstrates compliance with relevant requirements and provides approval to commercialize ReSure Sealant in the European Union. If we are unable to obtain a CE Certificate of Conformity for ReSure Sealant or any of our other product candidates for which we seek European regulatory approval, we will be prohibited from commercializing such product or products in the European Union and other places which require the CE Certificate of Conformity. In such a case, the potential market to commercialize our products may be significantly smaller than we currently estimate.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, especially if additional clinical trials are required, if approval is obtained at all. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate’s safety and purity. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, the EMA or other regulatory authorities may determine that our product candidates are not safe or effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. In addition, while we have had general discussions with the FDA concerning the design of some of our clinical trials, we have not discussed with the FDA the specifics of the regulatory pathways for our product candidates. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

The regulatory process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. If we experience delays in obtaining approval, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

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

In order to market and sell ReSure Sealant or our product candidates in the European Union and many other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be sold in that country. We or our collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

The terms of approvals, ongoing regulations and post-marketing restrictions for our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.

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

The FDA required two post-approval studies as a condition for approval of our premarket approval application, or PMA application, for ReSure Sealant. The first post-approval study, identified as the Clinical PAS, is to confirm that ReSure Sealant can be used safely by physicians in a standard cataract surgery practice and to confirm the incidence of the most prevalent adverse ocular events identified in our pivotal study of ReSure Sealant in eyes treated with ReSure Sealant. The FDA has approved the protocol for the Clinical PAS, and we initiated enrollment in December 2014. We anticipate completing the Clinical PAS in two to three years. The second post-approval study, identified as the Device Exposure Registry, is intended to link to the Medicare database to ascertain if patients are diagnosed or treated for endophthalmitis within 30 days following cataract surgery and application of the ReSure Sealant. Following review of the data from these studies, any concerns raised by the FDA could lead to modifications in product labeling, the approved indication for use or negative publicity impacting our commercialization efforts. In addition, in order to use the Medicare database in the Device Exposure Registry, we will need to obtain a Medicare tracking or research code for ReSure Sealant. In connection with ongoing discussions with the FDA and the Centers for Medicare and Medicaid Services, or CMS, we submitted an application to CMS seeking a tracking or research code for ReSure Sealant commercial use. CMS has preliminarily indicated that it is not likely to issue such a tracking or research code. If a tracking or research code is not established for ReSure Sealant, we may not be able to complete the Device Exposure Registry. We are required to provide periodic reports to the FDA on the progress of each post-approval study until it is completed. Based on results of the post-approval studies, or if we are unable to complete the Device Exposure Registry, the FDA, among other things, could modify the product labeling with respect to ReSure Sealant to the extent the FDA has any concerns with respect to endophthalmitis that we are unable to address due to the lack of completion of the study. This would negatively affect our ability to commercialize ReSure Sealant.

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

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

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

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

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which imposes obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

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

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on the research and development, clinical and business development expertise of Amar Sawhney, Ph.D., our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We maintain “key person” insurance for Dr. Sawhney, but we do not have any such insurance for any of our other executives or other employees.

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

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

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

Risks Related to Our Common Stock and This Offering

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

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

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

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation has often been instituted against that company. We also may face securities class-action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to commercialize OTX-DP, OTX-TP or our other product candidates or if our commercial launch of ReSure Sealant is unsuccessful. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources.

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

Our shares of common stock began trading on The NASDAQ Global Market on July 25, 2014. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price for our common stock and thereby affect your ability to sell your shares.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control all matters submitted to stockholders for approval.

Upon the closing of this offering, our executive officers and directors and principal stockholders will, in the aggregate, beneficially own shares representing approximately 32.3% of our capital stock (assuming no exercise of the underwriters' option to purchase additional shares). As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of voting power may:

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire.

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

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

- provide for a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- provide for advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;

- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

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

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of May 31, 2015, we had outstanding 21,502,479 shares of common stock. Of these shares, 7,294,058 shares are subject to lock-up agreements entered into in connection with this offering but will be able to be sold beginning on , 2015, which is the date that is 90 days after the date of this prospectus. Any of our remaining shares that are not restricted securities under Rule 144 under the Securities Act or subject to lock-up agreements, may be resold in the public market without restriction unless purchased by our affiliates. Moreover, assuming no exercise by the underwriters of their option to purchase additional shares, holders of an aggregate of 5,070,192 shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or, along with holders of an additional 18,939 shares of our common stock issuable upon exercise of warrants issued to our lenders, to include their shares in registration statements that we may file for ourselves or other stockholders. In connection with this offering, the holders of these securities waived these registration rights for a period that ends 90 days after the closing of this offering. In August 2014, we filed a registration statement registering all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume, notice and manner of sale limitations applicable to affiliates and the applicable lock-up agreements entered into in connection with this public offering. See "Shares Eligible for Future Sale" for more information and the "Underwriting" section of this prospectus for a description of the lock-up agreements entered into in connection with this offering.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until December 31, 2019, provided that, if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30 before that time or if we have annual gross revenues of $1 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than $1 billion of non-convertible debt over a three-year period. As an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting obligations in this prospectus. In particular, in this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly.

For as long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies as described in the preceding risk factor.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “predict,” “project,” “target,” “potential,” “would,” “could,” “should,” “continue” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this prospectus include, among other things, statements about:

- our plans to develop and commercialize our product candidates based on our proprietary bioresorbable hydrogel technology platform;
- our ongoing and planned clinical trials, including our third Phase 3 clinical trial of OTX-DP for the treatment of ocular inflammation and pain following cataract surgery, our Phase 3 clinical trials of OTX-DP for the treatment of allergic conjunctivitis, our Phase 2 clinical trial of OTX-DP for inflammatory dry eye disease and our Phase 2b clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension;
- the timing of and our ability to submit applications for, obtain and maintain regulatory approvals for OTX-DP, OTX-TP and our other product candidates;
- our commercialization of ReSure Sealant;
- the potential advantages of ReSure Sealant and our product candidates;
- the rate and degree of market acceptance and clinical utility of our products;
- the preclinical development of our anti-VEGF hydrogel depot for the treatment of wet age-related macular degeneration;
- our estimates regarding the potential market opportunity for OTX-DP, OTX-TP, ReSure Sealant and our other product candidates;
- our commercialization, marketing and manufacturing plans, capabilities and strategy;
- our intellectual property position;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our expectations related to the use of proceeds from this offering;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our plans to raise additional capital;
- the impact of government laws and regulations; and
- our competitive position.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the “Risk Factors” section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this prospectus are made as of the date of this prospectus, and we do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 3,200,000 shares of our common stock in this offering will be approximately $71.6 million, based on the assumed public offering price of $24.03 per share, which was the last reported sale price of our common stock on The NASDAQ Global Market on June 1, 2015, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any of the proceeds from any sale of shares in this offering by the selling stockholders.

As of March 31, 2015, we had cash, cash equivalents and marketable securities of $67.4 million. We currently estimate that we will use the net proceeds to us from this offering, together with our existing cash, cash equivalents and marketable securities, as follows:

- approximately $4.0 million to $4.2 million to complete Phase 3 clinical development of OTX-DP for the treatment of ocular inflammation and pain following cataract surgery, including a planned third Phase 3 clinical trial, and for the submission of an NDA to the FDA solely for ocular pain and an NDA supplement for ocular inflammation, assuming favorable clinical results;
- approximately $8.7 million to $9.1 million to initiate and complete our Phase 3 clinical trials of OTX-DP for the treatment of allergic conjunctivitis and for the submission of an NDA supplement to the FDA, assuming favorable clinical results;
- approximately $17.0 million to $17.5 million to complete our Phase 2b clinical trial and initiate Phase 3 clinical trials of OTX-TP for the treatment of glaucoma and ocular hypertension, assuming favorable clinical results in our Phase 2b clinical trial;
- approximately $41.0 million to $43.0 million for other clinical and regulatory activities and for preclinical research and development activities, including our sustained release hydrogel depot for the intravitreal injection of anti-VEGF drugs to treat wet AMD and other back-of-the-eye diseases;
- approximately $19.0 million to $21.0 million for sales and marketing activities, including the commercial launch of OTX-DP for the treatment of ocular inflammation and pain following cataract surgery and OTX-DP for the treatment of allergic conjunctivitis, assuming FDA approval of this product for these indications, personnel costs, sales commissions, travel, tradeshows and other sales and marketing expenses;
- approximately $6.5 million to expand our manufacturing capacity and for manufacturing equipment, including approximately $2.1 million in manufacturing equipment for our sustained release hydrogel depots for back-of-the-eye diseases;
- approximately $16.0 million for the payment of principal and interest under our credit facility with MidCap and SVB; and
- the remainder for working capital and other general corporate purposes, which could include the acquisition or in-license of other products, product candidates or technologies.

This expected use of net proceeds to us from this offering and our existing cash, cash equivalents and marketable securities represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials, the timing of regulatory submissions and the outcome of regulatory review, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering. We have no current agreements, commitments or understandings for any material acquisitions or licenses of any products, businesses or technologies.

Based on our planned use of the net proceeds to us from this offering and our existing cash, cash equivalents and marketable securities described above, we estimate that such funds will be sufficient to enable us to complete our Phase 3 clinical trials of OTX-DP for the treatment of ocular inflammation and pain following cataract surgery, submit an NDA to the FDA for ocular pain and an NDA supplement for ocular inflammation, assuming favorable clinical results, and commercially launch this product candidate, assuming FDA approval; initiate and complete our Phase 3 clinical trials of OTX-DP for the treatment of allergic conjunctivitis and submit an NDA supplement to the FDA, assuming favorable clinical results; and complete our Phase 2b clinical trial and, assuming favorable results, initiate and substantially complete our Phase 3 clinical trials of OTX-TP for the treatment of glaucoma and ocular hypertension. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. See the “Risk Factors” section of this prospectus for a discussion of the risks affecting our business that could have an adverse effect on our available capital resources.

Pending our use of the net proceeds to us from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

PRICE RANGE OF COMMON STOCK

Our common stock has been listed on The NASDAQ Global Market since July 25, 2014 and trades under the symbol "OCUL". Prior to that time, there was no public market for our common stock. The following table sets forth, for the periods indicated, the high and low intraday sales prices of our common stock as reported by The NASDAQ Global Market:

	High	Low
Year Ended December 31, 2014		
Third Quarter (July 25, 2014 to September 30, 2014)	$16.97	$11.90
Fourth Quarter	$24.21	$13.00
Year Ending December 31, 2015		
First Quarter	$44.19	$19.55
Second Quarter (through June 1, 2015)	$42.78	$20.63

On June 1, 2015, the last sale price of our common stock as reported on The NASDAQ Global Market was $24.03 per share. As of May 31, 2015, we had approximately 48 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends in respect of our common stock in the foreseeable future. In addition, the terms of our existing credit facility with SVB and MidCap preclude us from paying cash dividends without SVB's and MidCap's consent.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities and our capitalization as of March 31, 2015:

- on an actual basis;
- on an as adjusted basis to give effect to our issuance and sale of 3,200,000 shares of our common stock in this offering at an assumed public offering price of $24.03 per share, which was the last reported sale price of our common stock on The NASDAQ Global Market on June 1, 2015, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with our financial statements and the related notes appearing elsewhere in this prospectus and the sections of this prospectus titled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of March 31, 2015	
	Actual	As Adjusted
	(in thousands, except share and per share data)	
Cash, cash equivalents and marketable securities	$ 67,423	$ 139,005
Long-term debt, net of discount, including current portion	$ 14,954	$ 14,954
Stockholders’ equity:		
Common stock, $0.0001 par value; 100,000,000 shares authorized, actual and as adjusted; 21,428,571 shares issued and outstanding, actual; 24,628,571 shares issued and outstanding, as adjusted	2	2
Additional paid-in capital	149,077	220,659
Accumulated deficit	(97,006)	(97,006)
Total stockholders’ equity	52,073	123,655
Total capitalization	$ 67,027	$ 138,609

The table above does not include:

- 2,151,729 shares of our common stock issuable upon the exercise of stock options outstanding as of March 31, 2015, at a weighted average exercise price of $12.07 per share;
- 18,939 shares of our common stock issuable upon the exercise of warrants outstanding as of March 31, 2015 held by lenders under our current and prior credit facilities, at a weighted average exercise price of $7.92 per share;
- 1,501,730 shares of our common stock available for future issuance as of March 31, 2015 under our 2014 Stock Incentive Plan; and
- 227,007 shares of our common stock available for future issuance as of March 31, 2015 under our 2014 Employee Stock Purchase Plan.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value as of March 31, 2015 was $52.1 million, or $2.43 per share of our common stock. Our historical net tangible book value is the amount of our total tangible assets less our total liabilities. Historical net tangible book value per share represents historical net tangible book value divided by the 21,428,571 shares of our common stock outstanding as of March 31, 2015.

After giving effect to our issuance and sale of 3,200,000 shares of our common stock in this offering at an assumed public offering price of $24.03 per share, which was the last reported sale price of our common stock on The NASDAQ Global Market on June 1, 2015, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2015 would have been $123.7 million, or $5.02 per share. This represents an immediate increase in as adjusted net tangible book value per share of $2.59 to existing stockholders and immediate dilution of $19.01 in as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting as adjusted net tangible book value per share after this offering from the public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed public offering price per share		$24.03
Historical net tangible book value per share as of March 31, 2015	$2.43	
Increase in as adjusted net tangible book value per share attributable to new investors purchasing shares in this offering	2.59	
As adjusted net tangible book value per share after this offering		5.02
Dilution per share to new investors purchasing shares in this offering		$19.01

The table above is based on 21,428,571 shares of common stock outstanding as of March 31, 2015 and does not include:

- 2,151,729 shares of our common stock issuable upon the exercise of stock options outstanding as of March 31, 2015, at a weighted average exercise price of $12.07 per share;
- 18,939 shares of our common stock issuable upon the exercise of warrants outstanding as of March 31, 2015 held by lenders under our current and prior credit facilities, at a weighted average exercise price of $7.92 per share;
- 1,501,730 shares of our common stock available for future issuance as of March 31, 2015 under our 2014 Stock Incentive Plan; and
- 227,007 shares of our common stock available for future issuance as of March 31, 2015 under our 2014 Employee Stock Purchase Plan.

If any additional shares are issued in connection with the exercise of options or warrants, you will experience further dilution.

SELECTED FINANCIAL DATA

You should read the following selected financial data together with our financial statements and the related notes appearing elsewhere in this prospectus and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this prospectus. We have derived the statement of operations data for the years ended December 31, 2012, 2013 and 2014 and the balance sheet data as of December 31, 2013 and 2014 from our audited financial statements appearing elsewhere in this prospectus. We have derived the balance sheet data as of December 31, 2012 from our audited financial statements not included in this prospectus. The statement of operations data for the three months ended March 31, 2014 and 2015 and the balance sheet data as of March 31, 2015 have been derived from our unaudited financial statements appearing elsewhere in this prospectus and have been prepared on the same basis as the audited financial statements. In the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information in those statements. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results that should be expected for any full year.

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue:					
Product revenue	$ 10	$ —	$ 460	$ 27	$ 238
Collaboration revenue	—	—	312	—	188
Total revenue	10	—	772	27	426
Operating expenses:					
Cost of product revenue	7	—	91	9	56
Research and development	11,540	10,517	18,880	4,958	4,719
Selling and marketing	657	625	1,982	310	870
General and administrative	1,477	1,761	6,913	1,575	1,894
Total operating expenses	13,681	12,903	27,866	6,852	7,539
Loss from operations	(13,671)	(12,903)	(27,094)	(6,825)	(7,113)
Other income (expense):					
Interest income	4	13	7	1	40
Interest expense	(377)	(441)	(1,119)	(43)	(505)
Other income (expense), net	(49)	14	(442)	(141)	—
Total other expense, net	(422)	(414)	(1,554)	(183)	(465)
Net loss	(14,093)	(13,317)	(28,648)	(7,008)	(7,578)
Accretion of redeemable convertible preferred stock to redemption value	(35)	(27)	(11)	(6)	—
Net loss attributable to common stockholders	$(14,128)	$(13,344)	$(28,659)	$(7,014)	$ (7,578)
Net loss per share attributable to common stockholders, basic and diluted(1)	$ (5.60)	$ (5.11)	$ (2.69)	$ (2.45)	$ (0.35)
Weighted average common shares outstanding, basic and diluted(1)	2,523	2,609	10,653	2,860	21,363

	As of December 31,			As of March 31,
	2012	2013	2014	2015
	(in thousands)			
Balance Sheet Data:				
Cash, cash equivalents and marketable securities	$ 23,854	$ 17,505	$74,828	$ 67,423
Working capital(2)	20,787	14,672	70,309	62,243
Total assets	25,285	19,146	78,193	71,497
Long-term debt, net of discount, including current portion	4,065	2,457	14,865	14,954
Preferred stock warrant liability	268	254	—	—
Redeemed convertible preferred stock	65,823	74,344	—	—
Total stockholders' equity (deficit)	(46,611)	(59,472)	58,696	52,073

(1) See Note 12 to our audited financial statements appearing elsewhere in this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.
(2) We define working capital as current assets less current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Selected Financial Data" and our financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using our proprietary hydrogel platform technology. Our bioresorbable hydrogel based product candidates are designed to provide sustained delivery of therapeutic agents to the eye. Our lead sustained release drug delivery product candidates are OTX-DP and OTX-TP, which are inserted into the canaliculus through a natural opening called the punctum located in the inner portion of the eyelid near the nose. Our OTX-DP and OTX-TP product candidates combine our hydrogel technology with U.S. Food and Drug Administration, or FDA, approved therapeutic agents with the goal of providing sustained delivery of drug to the eye. We also have a hydrogel based drug delivery depot, which is in preclinical development for the treatment of diseases and conditions of the back of the eye, including wet age related macular degeneration, or wet AMD. Our hydrogel depot is designed to be delivered via intravitreal injection to release therapeutic agents, such as antibodies to vascular endothelial growth factor, or VEGF, over a sustained period. In addition to our ongoing product development, we have launched our first commercial product, ReSure Sealant, a hydrogel based ophthalmic wound sealant approved by the FDA in January 2014 to seal corneal incisions following cataract surgery. ReSure Sealant is the first and only surgical sealant to be approved by the FDA for ophthalmic use.

Our most advanced product candidate, OTX-DP, incorporates the FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient in our hydrogel and is in Phase 3 clinical development for the treatment of ocular inflammation and pain following cataract surgery. We recently reported topline results from two Phase 3 clinical trials for this indication. In the first Phase 3 clinical trial, OTX-DP met both primary efficacy endpoints, absence of pain at day 8 and absence of inflammatory cells at day 14, with statistical significance. In the second Phase 3 clinical trial, OTX-DP met the primary efficacy endpoint for absence of pain at day 8 with statistical significance but did not meet the primary efficacy endpoint for absence of inflammatory cells at day 14. Although we have been conducting our Phase 3 clinical trials of OTX-DP in patients who have undergone cataract surgery, these trials are intended to support a label for all post-surgical ocular inflammation and pain. We met with the FDA in April 2015 to discuss the path forward for seeking marketing approval of OTX-DP for the treatment of ocular inflammation and pain following ophthalmic surgery. In this pre-NDA clinical meeting, the FDA indicated that the existing data from our Phase 2 and Phase 3 clinical trials are appropriate to support an NDA submission for OTX-DP solely for an ocular pain indication. The FDA further indicated that we would need additional data from a third Phase 3 clinical trial for the inflammation endpoint to support the potential labeling expansion of OTX-DP's indications for use. We plan to initiate this third Phase 3 clinical trial for OTX-DP for the treatment of post-surgical ocular inflammation and pain in the second half of 2015. We expect to submit an NDA for OTX-DP solely for the treatment of ocular pain following ophthalmic surgery in the second half of 2015. Based on our expectations regarding initiation of our third Phase 3 clinical trial of OTX-DP and design of the trial and our estimates regarding patient enrollment, we expect to have topline efficacy data available from this trial in the second half of 2016. If the results of our third Phase 3 clinical trial of OTX-DP are favorable and subject to receiving approval for the pain indication pursuant to the initial NDA, we plan to submit an NDA supplement for OTX-DP for the treatment of ocular inflammation following ophthalmic surgery in the second half of 2016. If we receive approval of our initial NDA and our NDA supplement, we expect to commercially launch OTX-DP for post-surgical ocular inflammation and pain in the United States in the first half of 2017.

In addition, we completed a Phase 2 clinical trial of OTX-DP for the treatment of allergic conjunctivitis in November 2014. Based on encouraging results from this trial, we expect to initiate two Phase 3 clinical trials of OTX-DP for this indication in the middle of 2015. We also initiated an exploratory Phase 2 clinical trial of OTX-DP for the treatment of inflammatory dry eye disease in January 2015, with topline efficacy data from the first Phase 3 clinical trial expected to be available in the fourth quarter of 2015.

We have also received conditional acceptance of the name DEXTENZA™ from the FDA for our OTX-DP product candidate. We plan to include a request for a proprietary name review for DEXTENZA as part of our NDA submission of OTX-DP for the treatment of ocular pain following ophthalmic surgery.

Our second product candidate, OTX-TP, incorporates travoprost, an FDA-approved prostaglandin analog that reduces elevated intraocular pressure, as an active pharmaceutical ingredient in our hydrogel. We completed a Phase 2a clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension in May 2014 and initiated a Phase 2b clinical trial of OTX-TP for this indication in November 2014.

In addition to OTX-DP and OTX-TP, we are engaged in the preclinical development of a sustained release hydrogel depot administered via intravitreal injection to address the large and growing markets for diseases and conditions of the back of the eye. Our initial development efforts are focused on the use of our sustained release hydrogel depot in combination with anti-VEGF compounds for the treatment of wet AMD. Our initial goal for this program is to provide sustained release of an anti-VEGF compound over a four to six month period, thereby reducing the frequency of the current monthly or bi-monthly intravitreal injection regimen for wet AMD. We also have a pipeline of earlier stage punctum plug product candidates, including OTX-MP, which has completed a Phase 1 clinical trial evaluating safety and pharmacokinetics in patients following cataract surgery.

We have generated limited revenue to date. In the first quarter of 2014, we began recognizing revenue from sales of ReSure Sealant. We also have recognized revenues from early stage feasibility agreements with collaborative partners, which have been limited to date. All of our sustained release drug delivery products are in various phases of clinical and preclinical development. We do not expect sales of ReSure Sealant or existing collaboration agreements to generate revenue that is sufficient for us to achieve profitability. Instead, our ability to generate product revenue sufficient to achieve profitability will depend heavily on our obtaining marketing approval for and commercializing products with greater market potential, including one or both of OTX-DP and OTX-TP. Since inception, we have incurred significant operating losses. Our net loss was $7.6 million for the three months ended March 31, 2015. As of March 31, 2015, we had an accumulated deficit of $97.0 million.

Our total operating expenses were $7.5 million for the three months ended March 31, 2015, including $0.9 million in non-cash stock-based compensation expense. We anticipate that our operating expenses will increase substantially as we pursue the clinical development of our most advanced product candidates, OTX-DP and OTX-TP, continue the research and development of our other product candidates, continue the internal development of our hydrogel depot for the sustained delivery of anti-VEGF drugs for the treatment of wet AMD and other back-of-the-eye diseases and seek marketing approval for any such product candidate for which we obtain favorable pivotal clinical trial results. We expect to continue to incur additional expenses for product manufacturing, sales, marketing and distribution for ReSure Sealant and any of our product candidates for which we obtain marketing approval. In addition, we will incur additional costs associated with operating as a public company.

We do not expect to generate meaningful revenue from sales of any product for several years, if at all. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

In July 2014, we completed an initial public offering, or IPO, of our common stock, and in August 2014 the underwriters in our IPO exercised their over-allotment option in full. We received total net proceeds of approximately $66.4 million from the issuance and sale of 5,750,000 shares of common stock, including in connection with the exercise by the underwriters of their over-allotment option, after deducting underwriting discounts and offering costs. We believe that the net proceeds to us from this offering, together with our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements at least through the third quarter of 2017. See "—Liquidity and Capital Resources."

Financial Operations Overview

Revenue

From our inception through March 31, 2015, we have generated limited amounts of revenue from the sales of our products. Our ReSure Sealant product received premarket approval, or PMA, from the FDA in January 2014. We commenced sales of ReSure Sealant in the first quarter of 2014, have received only limited revenues from ReSure Sealant to date and anticipate only limited sales for the remainder of 2015. ReSure Sealant is currently our only source of revenue from product sales. We may generate revenue in the future if we successfully develop one or more of our product candidates and receive marketing approval for any such product candidate or if we enter into longer-term collaboration agreements with third parties.

In September 2013, we entered into a feasibility agreement with a biopharmaceutical company relating to our intravitreal hydrogel based drug delivery depot. Under this agreement, the biopharmaceutical company agreed to pay us up to $0.5 million under this feasibility study. In the event that the agreement is terminated in advance of the achievement of certain milestones, we would be required to refund certain portions of the funding based on the actual work completed or milestones achieved as of the date of termination. In the fourth quarter of 2014, we completed the task related to the first milestone, at which time the $0.3 million became non-refundable. The biopharmaceutical company has indicated that it will not proceed with the second phase of the agreement. We do not have any further obligations in connection with this agreement.

In October 2014, we entered into a feasibility agreement with a biotechnology company relating to our intravitreal hydrogel based drug delivery depot. Under this agreement, the biotechnology company has agreed to pay us up to $0.7 million, of which $0.3 million was a non-refundable up-front payment due upon contract execution and $0.4 million will be due upon the achievement of certain milestones. We are recognizing the non-refundable, non-contingent up-front payment of $0.3 million as revenue on a straight-line basis over the twelve-month period in which we are expected to complete our performance obligations. If and when a contingent milestone payment is earned, the additional consideration to be received will be added to the total expected payments under the contract and recognized as revenue based on the proportional performance methodology. In January 2015, we achieved the first milestone under the feasibility agreement triggering a payment due of $0.3 million. As of March 31, 2015, we had recognized revenue of $0.3 million related to this agreement.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, including salaries, related benefits, travel and stock-based compensation expense for employees engaged in research and development, clinical and regulatory and other related functions;

- expenses incurred in connection with the clinical trials of our product candidates, including with the investigative sites that conduct our clinical trials and under agreements with contract research organizations, or CROs;
- expenses relating to regulatory activities, including filing fees paid to the FDA for our submissions for product approvals;
- expenses associated with developing our pre-commercial manufacturing capabilities and manufacturing clinical study materials;
- ongoing research and development activities relating to our core bioresorbable hydrogel technology and improvements to this technology;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and supplies;
- costs relating to the supply and manufacturing of product inventory, prior to approval by the FDA or other regulatory agencies of our products;
- expenses associated with preclinical development activities; and
- payments made under our licensing agreement with Incept, LLC, or Incept.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites.

Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials and regulatory fees. We do not allocate employee and contractor-related costs, costs associated with our platform technology, costs related to manufacturing or purchasing clinical trial materials, and facility expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified. We use internal resources, including clinical monitors and clinical research associates, to manage our clinical trials, monitor patient enrollment and perform data analysis for many of our clinical trials, rather than utilizing third-party CROs. These employees work across multiple development programs and, therefore, we do not track their costs by program.

The table below summarizes our research and development expenses incurred by product development program:

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
	(in thousands)				
ReSure Sealant	$ 2,186	$ 191	$ 40	$ 18	$ 51
OTX-DP for post-surgical ocular inflammation and pain	98	552	2,151	197	661
OTX-DP for allergic conjunctivitis	30	39	1,785	559	100
OTX-TP for glaucoma	1,479	1,745	2,023	236	554
OTX-MP for ocular infection	108	—	—	—	—
Unallocated expenses	7,639	7,990	12,881	3,948	3,353
Total research and development expenses	$11,540	$10,517	$18,880	$ 4,958	$ 4,719

Our research and development expense in the first quarter of 2014 included approximately $1.7 million in a one-time, non-cash expense in connection with a license fee paid in the form of stock. We expect that our expenses will increase substantially in connection with our ongoing activities. We estimate that in 2015, we will incur approximately $28.0 million to $31.0 million of research and development expenses, including costs related to clinical trials and other research and development activities. Of this amount, we estimate we will incur approximately $10.8 million to $12.8 million of external research and development expenses related to clinical trial and regulatory costs for our OTX-DP and OTX-TP product candidates and approximately $17.2 million to $18.5 million of other research and development activities that we do not expect to track by program.

We estimate that we will incur external research and development expenses for 2015, as follows:

- approximately $2.0 million to $2.5 million for OTX-DP for post-surgical ocular inflammation and pain;
- approximately $7.5 million to $8.5 million for OTX-DP for allergic conjunctivitis;
- approximately $0.6 million to $0.7 million for OTX-DP for dry eye; and
- approximately $0.7 million to $0.8 million for OTX-TP for glaucoma and ocular hypertension.

The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our clinical trials and other research and development activities;
- the efficacy and potential advantages of our product candidates compared to alternative treatments, including any standard of care;
- the market acceptance of our product candidates;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation; and
- the timing, receipt and terms of any marketing approvals.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in clinical and preclinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include facility-related costs and professional fees for legal, patent, consulting and accounting and audit services. Additionally, in the third quarter of 2014, we began to incur increased professional fees and insurance expense associated with operating as a public company.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued development and commercialization of our product candidates. We also anticipate to incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company. In 2014, we only operated as a public company for approximately five months and, therefore, we expect to incur an increase in public company related costs in 2015 and beyond.

Selling and Marketing Expenses

Selling and marketing expenses consist primarily of salaries and related costs for personnel in selling and marketing functions as well as advertising and promotion costs. Through December 31, 2014, we incurred selling and marketing expenses in connection with our first-generation surgical sealant product. In addition, we invested in sales and marketing resources in anticipation of an earlier approval of our surgical sealant product in the United States than we ultimately received from the FDA, as a result of a change in designation from a 510(k) to a PMA regulatory path. During the three months ended March 31, 2015, we incurred selling and marketing expense in connection with ReSure Sealant, which we commercialized for the first time during 2014.

We expect selling and marketing expenses to increase in preparation for the potential commercial launch of our OTX-DP product candidate for the treatment of ocular inflammation and pain following cataract surgery, subject to approval by the FDA.

Other Income (Expense)

Interest Income. Interest income consists primarily of interest income earned on cash, cash equivalents and marketable securities. In 2014, our interest income was not significant due to nominal cash and investment balances and low interest earned on invested balances. We anticipate that our interest income will be higher in 2015 due to increased cash balances.

Interest Expense. Interest expense consists of interest expense on our debt. We borrowed $15.0 million in aggregate principal amount in April 2014 with an interest only period that has been extended through September 2015.

Other Income (Expense), Net. In 2014, other income (expense), net consisted primarily of the gain or loss associated with the change in the fair value of our preferred stock warrant liability and small amounts of miscellaneous income and expense items unrelated to our core operations. We issued warrants for the purchase of our redeemable convertible preferred stock that we believed were financial instruments that could require a transfer of assets because of the redemption feature of the underlying stock. Therefore, we classified these warrants as liabilities and they were remeasured to fair value at each reporting period, and we recorded the changes in the fair value as a component of other income (expense), net. Upon the closing of our IPO in July 2014, the underlying redeemable convertible preferred stock was converted into common stock, the preferred stock warrants became exercisable for common stock instead of preferred stock, and the fair value of the warrant liability became fixed as of that date and was reclassified to additional paid-in capital. In 2015, other income (expense), net consists of small amounts of miscellaneous income and expense items unrelated to our core operations.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued research and development expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe are 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 apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our audited financial statements appearing elsewhere in this prospectus, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We recognize revenue when the following four criteria are met in accordance with Accounting Standards Codification, or ASC, 605, *Revenue Recognition*: persuasive evidence of a sales arrangement exists; delivery of goods has occurred through transfer of title and risk and rewards of ownership; the selling price is fixed or determinable; and collectability is reasonably assured.

We record revenue from product sales net of applicable provisions for returns, chargebacks, discounts, wholesaler management fees, government and commercial rebates, and other applicable allowances in the same period in which the related sales are recorded, based on the underlying contract terms.

We analyze multiple-element arrangements based on the guidance in ASC Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements*, or ASC 605-25. Pursuant to this guidance, we evaluate multiple-element arrangements to determine (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires us to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that the delivered item has value to the customer on a standalone basis and, if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in our control. In assessing whether an item has standalone value, we consider factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, we consider whether the collaboration partner can use the other deliverables for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered item and whether there are other vendors that can provide the undelivered elements.

We allocate arrangement consideration that is fixed or determinable among the separate units of accounting using the relative selling price method. Then, we apply the applicable revenue recognition criteria in ASC 605 to each of the separate units of accounting in determining the appropriate period and pattern of recognition. We determine the selling price of a unit of accounting following the hierarchy of evidence prescribed by ASC 605-25. Accordingly, we determine the estimated selling price for units of accounting within each arrangement using vendor-specific objective evidence, or VSOE, of selling price, if available; third-party evidence, or TPE, of selling price, if VSOE is not available; or best estimate of selling price, or BESP, if neither VSOE nor TPE is available. We typically uses BESP to estimate the selling price as we generally do not have VSOE or TPE of selling price for our units of accounting. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, we consider applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with our customer and estimated costs. We validate the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting.

We recognize arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605 are satisfied for that particular unit of accounting. We will recognize as revenue arrangement consideration attributed to licenses that have standalone value relative to the other deliverables to be provided in an arrangement upon delivery. We will recognize as revenue arrangement consideration attributed to licenses that do not have standalone value relative to the other deliverables to be provided in an arrangement over our estimated performance period, as the arrangement would be accounted for as a single unit of accounting.

At the inception of an arrangement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (1) the consideration is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item as a result of a specific outcome resulting from our performance to achieve the milestone, (2) the consideration relates solely to past performance, and (3) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. Accordingly, pursuant to the guidance of ASC Topic 605-28, *Revenue Recognition—Milestone Method*, or ASC 605-28, revenue from milestone payments will be recognized in its entirety upon successful accomplishment of the milestone, assuming all other revenue recognition criteria are met.

Other contingent, event-based payments received for which payment is either contingent solely upon the passage of time or the results of a collaborative partner's performance would not be considered milestones under ASC 605-28. In accordance with ASC 605-25, such payments will be recognized as revenue when all of the four basic revenue recognition criteria are met.

Whenever we determine that an element is delivered over a period of time, revenue is recognized using either a proportional performance model or a straight-line model over the period of performance. At each reporting period, we reassess our cumulative measure of performance and makes appropriate adjustments, if necessary. We recognize revenue using the proportional performance model whenever we can make reasonably reliable estimates of the level of effort required to complete our performance obligations under an arrangement. Revenue recognized under the proportional performance model at each reporting period is determined by multiplying the total expected payments under the contract (excluding payments contingent upon achievement of milestones) by the ratio of the level of effort incurred to date to the estimated total level of effort required to complete the performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the proportional performance model as of each reporting period. Alternatively, if we cannot make reasonably reliable estimates the level of effort required to complete our performance obligations under an arrangement, then revenue under the arrangement is recognized on a straight-line basis over the period expected to complete our performance obligations. If and when a contingent milestone payment is earned, the additional consideration to be received is added to the total expected payments under the contract. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined on a straight-line basis as of the period end date. If we cannot reasonably estimate when our performance obligation period ends, then revenue is deferred until we can reasonably estimate when the performance obligation period ends.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- investigative sites or other providers in connection with clinical trials;
- vendors in connection with preclinical development activities;
- CROs in connection with clinical trials; and
- vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We measure all stock options and other stock-based awards granted to employees and directors at the fair value on the date of the grant using the Black-Scholes option-pricing model. We recognize the fair value of the awards as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. We apply the straight-line method of expense recognition to all awards with service-only conditions.

For stock-based awards granted to consultants and nonemployees, we recognize compensation expense over the period during which services are rendered by such consultants and nonemployees until completed. At the end of each financial reporting period prior to completion of the service, we remeasure the fair value of these awards using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model. Use of this model requires that we make assumptions as to the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Prior to our IPO, we had been a private company and lacked company-specific historical and implied volatility information. Therefore, we estimate our expected volatility based on the historical volatility of a publicly traded group of peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our publicly traded stock price. We use the simplified method prescribed by Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment,* to calculate the expected term of options granted to employees and directors. We base the expected term of options granted to consultants and nonemployees on the contractual term of the options. We determine the risk-free interest rate by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.

The assumptions we used to determine the fair value of stock options granted to employees and directors are as follows, presented on a weighted average basis:

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
Risk-free interest rate	1.51%	1.23%	2.24%	2.29%	1.62%
Expected term (in years)	6.25	5.38	5.96	6.00	6.00
Expected volatility	70.0%	74.6%	76.5%	77.0%	72.0%
Expected dividend yield	0%	0%	0%	0%	0%

These assumptions represented our best estimates, but the estimates involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different. We recognize compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate for pre-vesting forfeitures, we have considered our historical experience of actual forfeitures. If our future actual forfeiture rate is materially different from our estimate, our stock-based compensation expense could be significantly different from what we have recorded in the current period.

Inventory Valuation

Inventory is valued at the lower of cost or market, determined by the first-in, first-out method. Prior to initial approval by the FDA or other regulatory agencies of our products, we expense costs relating to the production of inventory in the period incurred as research and development expenses. After such time as the product receives approval, we begin to capitalize the inventory costs related to the product.

We had no inventory as of December 31, 2013. Subsequent to the approval of ReSure Sealant in January 2014, we started to capitalize inventory of this product. We review our inventories for potential obsolescence.

JOBS Act

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

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We expect to continue to take advantage of some or all of the available exemptions.

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

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Results of Operations

Comparison of the Three Months Ended March 31, 2014 and 2015

The following table summarizes our results of operations for the three months ended March 31, 2014 and 2015:

	Three Months Ended March 31, 2014	Three Months Ended March 31, 2015	Increase (Decrease)
	(in thousands)		
Revenue:			
Product revenue	$ 27	$ 238	$ 211
Collaboration revenue	—	188	188
Total revenue	27	426	399
Operating expenses:			
Cost of product revenue	9	56	47
Research and development	4,958	4,719	(239)
Selling and marketing	310	870	560
General and administrative	1,575	1,894	319
Total operating expenses	6,852	7,539	687
Loss from operations	(6,825)	(7,113)	(288)
Other income (expense):			
Interest income	1	40	39
Interest expense	(43)	(505)	(462)
Other income (expense), net	(141)	—	141
Total other expense, net	(183)	(465)	(282)
Net loss	$(7,008)	$(7,578)	$ (570)

Revenue

We generated $0.2 million of revenue from our collaboration agreements during the three months ended March 31, 2015. We generated $0.2 million of revenue during the three months ended March 31, 2015 from sales of our ReSure Sealant product compared to minimal revenue for the three months ended March 31, 2014. We received FDA approval in January 2014 for ReSure Sealant.

Research and Development Expenses

	Three Months Ended March 31, 2014	Three Months Ended March 31, 2015	Increase (Decrease)
	(in thousands)		
Direct research and development expenses by program:			
ReSure Sealant	$ 18	$ 51	$ 33
OTX-DP for post-surgical ocular inflammation and pain	197	661	464
OTX-DP for allergic conjunctivitis	559	100	(459)
OTX-TP for glaucoma	236	554	318
Unallocated expenses:			
Personnel costs	1,334	2,187	853
All other costs	2,614	1,166	(1,448)
Total research and development expenses	$ 4,958	$ 4,719	$ (239)

Research and development expenses were $4.7 million for the three months ended March 31, 2015, compared to $4.9 million for the three months ended March 31, 2014 or a decrease of $0.2 million. In the three months ended March 31, 2014, we recorded a one-time, non-cash expense of $1.7 million in connection with a license fee paid in the form of stock which is included in unallocated other costs. In the three months ended March 31, 2015, we had an increase of $0.3 million in costs incurred in connection with the clinical trials of our OTX-DP product candidate for the treatment of ocular inflammation and pain following cataract surgery, our OTX-DP product candidate for the treatment of allergic conjunctivitis and our OTX-TP product candidate for the treatment of glaucoma and an increase of $0.8 million in unallocated personnel costs.

For the three months ended March 31, 2015, we incurred $1.3 million in direct research and development expenses for our sustained release drug delivery product candidates for the front of the eye, including $0.1 million for our OTX-DP product candidate for the treatment of ocular inflammation and pain following cataract surgery which was in Phase 3 clinical trials, $0.1 million for our OTX-DP product candidate for the treatment of allergic conjunctivitis which is expected to enter Phase 3 clinical trials in the middle of 2015 and $0.2 million for our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension which is also in Phase 2b clinical trials. In comparison, for the three months ended March 31, 2014, we incurred $1.0 million in direct research and development expenses for our punctum plug product candidates, including $0.6 million for clinical trials of OTX-DP for the treatment of allergic conjunctivitis, $0.2 million for our Phase 2 clinical trial of our OTX-TP product candidate for the treatment of glaucoma, and $0.2 million for the first of our two Phase 3 clinical trials of OTX-DP for the treatment of ocular inflammation and pain following cataract surgery. Personnel costs increased by $0.2 million due to additional hiring primarily in our clinical, regulatory and quality department and an increase in stock-based compensation expense.

Selling and Marketing Expenses

	Three Months Ended March 31,		Increase (Decrease)
	2014	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	$ 132	$ 343	$ 211
Professional, advertising and promotion costs	123	406	283
Facility related and other	55	121	66
Total selling and marketing expenses	$ 310	$ 870	$ 560

Selling and marketing expenses were $0.9 million for the three months ended March 31, 2015, compared to $0.3 million for the three months ended March 31, 2014. The increase of $0.6 million was primarily due to an increase of $0.2 million in personnel costs relating to additional hirings, an increase of $0.3 million in professional fees including consulting, recruiting and advertising and promotion costs relating to the ReSure Sealant, and an increase of $0.1 million in facility related and other costs.

General and Administrative Expenses

	Three Months Ended March 31,		Increase (Decrease)
	2014	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	$ 641	$ 1,199	$ 558
Professional, insurance and consultant fees	804	488	(316)
Facility related and other	130	207	77
Total general and administrative expenses	$ 1,575	$ 1,894	$ 319

General and administrative expenses were $1.9 million for the three months ended March 31, 2015, compared to $1.6 million for the three months ended March 31, 2014. The increase of $0.3 million was primarily due to a $0.6 million increase in personnel related costs and an increase of $0.1 million in facility related and other costs, offset by a decrease of $0.3 million in professional, insurance and consultant fees. Our personnel related costs increased due primarily to an increase in stock-based compensation expense of $0.1 million as well as hiring in our general and administrative function to support our operating as a public company. Professional, insurance and consultant fees decreased primarily to the decrease in consulting fees of $0.7 million recorded in 2014 in connection with consulting services rendered by a former member of our board of directors and current stockholder of Incept, which we paid by the issuance of 79,545 fully vested shares of our common stock for a payment having a fair value at the time of issuance of $0.7 million in addition to increased activities to support our operating as a public company including legal services and additional insurance requirements. Facility and other costs increased primarily due to general expense increases and to increased rent due to additional space under our amended lease.

Other Income (Expense), Net

Other expense, net was $0.5 million for the three months ended March 31, 2015, compared to $0.2 million for the three months ended March 31, 2014. The net increase of $0.3 million was due primarily to an increase in interest expense of $0.4 million due to increased borrowings under our new credit facility. In 2014, other expense increased by $0.1 million due to our adjustment for the fair value of the liability for our preferred stock warrants due to the increase in the value of the underlying preferred stock in 2014.

Comparison of the Years Ended December 31, 2013 and December 31, 2014

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

	Year Ended December 31, 2013	Year Ended December 31, 2014	Increase (Decrease)
	(in thousands)		
Revenue:			
Product revenue	$ —	$ 460	$ 460
Collaboration revenue	—	312	312
Total revenue	—	772	772
Operating expenses:			
Cost of product revenue	—	91	91
Research and development	10,517	18,880	8,363
Selling and marketing	625	1,982	1,357
General and administrative	1,761	6,913	5,152
Total operating expenses	12,903	27,866	14,963
Loss from operations	(12,903)	(27,094)	(14,191)
Other income (expense):			
Interest income	13	7	(6)
Interest expense	(441)	(1,119)	(678)
Other income (expense), net	14	(442)	(456)
Total other expense, net	(414)	(1,554)	(1,140)
Net loss	$ (13,317)	$ (28,648)	$(15,331)

Revenue

We generated $0.3 million of revenue from our collaboration agreements in 2014. We generated $0.5 million of product revenue during the year ended December 31, 2014 from sales of our ReSure Sealant product, for which we received FDA approval in January 2014. We did not sell any products and had no collaboration revenue during the year ended December 31, 2013.

Research and Development Expenses

	Year Ended December 31, 2013	2014	Increase (Decrease)
		(in thousands)	
Direct research and development expenses by program:			
ReSure Sealant	$ 191	$ 40	$ (151)
OTX-DP for post-surgical ocular inflammation and pain	552	2,151	1,599
OTX-DP for allergic conjunctivitis	39	1,785	1,746
OTX-TP for glaucoma	1,745	2,023	278
Unallocated expenses:			
Personnel costs	4,259	5,828	1,569
All other costs	3,731	7,053	3,322
Total research and development expenses.	$ 10,517	$ 18,880	$ 8,363

Research and development expenses were $18.9 million for the year ended December 31, 2014, compared to $10.5 million for the year ended December 31, 2013. The increase of $8.4 million was primarily due to an increase of $3.6 million in clinical trial and regulatory expenses and an increase of $4.9 million in personnel costs and other unallocated expenses.

For the year ended December 31, 2014, we incurred $6.0 million in direct research and development expenses for our punctum plug product candidates, including $2.2 million for our OTX-DP product candidate for the treatment of post-surgical ocular inflammation and pain which was in Phase 3 clinical trials, $1.8 million for our OTX-DP product candidate for the treatment of allergic conjunctivitis which was in Phase 2a clinical trials, and $2.0 million for our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension which was also in Phase 2a clinical trials. In comparison, for the year ended December 31, 2013, we incurred $1.6 million in clinical trial expenses, including $0.7 million for clinical trials of OTX-TP for glaucoma and ocular hypertension and $0.5 million for our Phase 2 clinical trial of OTX-DP for ocular inflammation and pain following cataract surgery. Unallocated research and development costs increased $4.9 million for the year ended December 31, 2014, compared to the year ended December 31, 2013, due primarily to additional license fees paid to Incept in connection with the expansion of the scope of the license to include back-of-the-eye technology, which we paid by the issuance to Incept of 189,393 fully vested shares of our common stock having a fair value of $1.7 million on the issuance date and due to an increase in testing and laboratory supply costs. In addition, unallocated personnel costs increased by $1.6 million, relating to additional hiring primarily in the clinical, regulatory and quality department.

Selling and Marketing Expenses

Selling and marketing expenses were $2.0 million for the year ended December 31, 2014, compared to $0.6 million for the year ended December 31, 2013. The increase of $1.4 million was primarily due to an increase in personnel costs and travel relating to new hires and consulting, advertising and promotion expenses relating to commercial activities in support of ReSure Sealant.

General and Administrative Expenses

	Year Ended December 31, 2013	2014	Increase (Decrease)
		(in thousands)	
Personnel related (including stock-based compensation)	$ 1,069	$ 4,469	$ 3,400
Professional fees	327	1,390	1,063
Facility related and other	365	1,054	689
Total general and administrative expenses	$ 1,761	$ 6,913	$ 5,512

General and administrative expenses were $6.9 million for the year ended December 31, 2014, compared to $1.8 million for the year ended December 31, 2013. The increase of $5.2 million was due to a $3.4 million increase in personnel related costs, an increase of $1.1 million in professional fees and an increase of $0.7 million in facility related and other costs. Our personnel related costs increased due primarily to an increase in stock-based compensation expense of $1.8 million as well as hiring in our general and administrative function. Professional fees increased primarily due to consultant fee of $0.7 million incurred in 2014 in connection with consulting services rendered by a former member of our board of directors and current stockholder of Incept, which we paid by the issuance of 79,545 fully vested shares of our common stock having a fair value of $0.7 million on the issuance date and increased activities to support our operating as a public company. Facility and other costs increased primarily due to general expense increases and to increased rent for additional space under our amended lease as well as additional insurance requirements to support operating as a public company.

Other Income (Expense), Net

Other expense, net was $1.6 million for the year ended December 31, 2014, compared to $0.4 million for the year ended December 31, 2013. The increase of $1.2 million was primarily due to an increase of $0.5 million in our adjustment for the fair value of the liability for our preferred stock warrants as compared to the year ended December 31, 2013 due to the increase in fair value of the underlying preferred stock. Interest expense also increased $0.7 million due to increased borrowings under our new credit facility.

Comparison of the Years Ended December 31, 2012 and December 31, 2013

The following table summarizes our results of operations for the years ended December 31, 2012 and 2013:

	Year Ended December 31,		Increase (Decrease)
	2012	2013	
	(in thousands)		
Product revenue	$ 10	$ —	$ (10)
Operating expenses:			
Cost of product revenue	7	—	(7)
Research and development	11,540	10,517	(1,023)
Selling and marketing	657	625	(32)
General and administrative	1,477	1,761	284
Total operating expenses	13,681	12,903	(778)
Loss from operations	(13,671)	(12,903)	768
Other income (expense):			
Interest income	4	13	9
Interest expense	(377)	(441)	(64)
Other income (expense), net	(49)	14	63
Total other expense, net	(422)	(414)	8
Net loss	$ (14,093)	$ (13,317)	$ 776

Revenue

We did not sell any products and had no revenue during the year ended December 31, 2013. We generated a small amount of product revenue during the year ended December 31, 2012 from the sale of our first-generation surgical sealant product in Europe.

Research and Development Expenses

	Year Ended December 31, 2012	Year Ended December 31, 2013	Increase (Decrease)
	(in thousands)		
Direct research and development expenses by program:			
ReSure Sealant	$ 2,186	$ 191	$ (1,995)
OTX-DP for post-surgical ocular inflammation and pain	98	552	454
OTX-DP for allergic conjunctivitis	30	39	9
OTX-TP for glaucoma	1,479	1,745	266
OTX-MP for ocular infection	108	—	(108)
Unallocated expenses:			
Personnel costs	4,167	4,259	92
All other costs	3,472	3,731	259
Total research and development expenses	$ 11,540	$ 10,517	$ (1,023)

Research and development expenses were $10.5 million for the year ended December 31, 2013, compared to $11.5 million for the year ended December 31, 2012. The decrease of $1.0 million was primarily due to incurring lower costs associated with clinical trials in 2013 than in 2012. For the year ended December 31, 2012, we incurred $3.0 million in clinical trial expenses, including $2.2 million for the pivotal clinical trials of ReSure Sealant and $0.5 million for clinical trials of OTX-TP for glaucoma and ocular hypertension. In comparison, for the year ended December 31, 2013, we incurred $1.6 million in clinical trial expenses, including $0.7 million for clinical trials of OTX-TP for glaucoma and ocular hypertension and $0.5 million for our Phase 2 clinical trial of OTX-DP for ocular inflammation and pain following cataract surgery. This decrease in clinical trial costs of $1.4 million was partially offset by an increase of $0.4 million in our unallocated expenses for product development, primarily as a result of higher personnel costs of $0.1 million due to new hires and higher product supplies expense of $0.1 million.

Selling and Marketing Expenses

Selling and marketing expenses were $0.6 million for the year ended December 31, 2013, compared to $0.7 million for the year ended December 31, 2012. The decrease of $0.1 million was primarily due to lower market consulting fees for the year ended December 31, 2013.

General and Administrative Expenses

	Year Ended December 31, 2012	Year Ended December 31, 2013	Increase (Decrease)
	(in thousands)		
Personnel related (including stock-based compensation)	$ 1,028	$ 1,069	$ 41
Professional fees	219	327	108
Facility related and other	230	365	135
Total general and administrative expenses	$ 1,477	$ 1,761	$ 284

General and administrative expenses were $1.8 million for the year ended December 31, 2013, compared to $1.5 million for the year ended December 31, 2012. The increase of $0.3 million was primarily due to increased professional fees of $0.1 million, increased facility related and other costs of $0.1 million, and increased personnel related stock-based compensation costs of $0.3 million, partially offset by decreased other personnel related costs of $0.2 million, due to ongoing business activities.

Other Income (Expense), Net

Other expense, net was $0.4 million for both the year ended December 31, 2013 and the year ended December 31, 2012. From 2012 to 2013, there was an increase of $0.1 million in interest expense on our notes payable, offset by a $0.1 million decrease in our adjustment for the fair value of the liability for our preferred stock warrants.

Liquidity and Capital Resources

Since inception, we have incurred significant operating losses. We have generated limited revenue to date and are in the early phases of commercial launch of our first FDA-approved product, ReSure Sealant. We have not yet commercialized any of our sustained drug delivery products, which are in various phases of clinical and preclinical development. We do not expect to generate revenue from sales of any product other than ReSure Sealant for several years, if at all. Through March 31, 2015, we have financed our operations primarily through private placements of our preferred stock, our IPO and borrowings under credit facilities. In July 2014, we closed our IPO, and in August 2014 the underwriters in our IPO exercised their over-allotment option in full. We received total net proceeds of approximately $66.4 million from the issuance and sale of 5,750,000 shares of common stock, including in connection with the exercise by the underwriters of their over-allotment option, after deducting underwriting discounts and offering costs.

As of March 31, 2015, we had cash, cash equivalents and marketable securities of $67.4 million. In April 2014, we borrowed $15.0 million in aggregate principal amount under a new credit facility and used $1.9 million of this amount to repay $1.7 million aggregate principal amount of indebtedness and pay $0.2 million of other amounts due in connection with our termination of a prior credit facility. The outstanding borrowings under this facility bear interest at an annual rate equal to 8.25%. See "—Contractual Obligations and Commitments" for additional information.

Cash Flows

As of March 31, 2015, we had cash, cash equivalents and marketable securities of $67.4 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31,			Three Months Ended March 31,	
	2012	2013	2014	2014	2015
			(in thousands)		
Cash used in operating activities	$(12,585)	$(12,645)	$(20,496)	$ (4,025)	$ (6,879)
Cash provided by (used in) investing activities	3,814	(387)	(38,586)	(297)	(17,854)
Cash provided by (used in) financing activities	27,295	6,683	78,970	(433)	(137)
Net increase (decrease) in cash and cash equivalents	$ 18,524	$ (6,349)	$ 19,888	$ (4,755)	$ (24,870)

Operating Activities. Net cash used in operating activities was $6.9 million for the three months ended March 31, 2015, primarily resulting from our net loss of $7.6 million and net cash used by changes in our operating assets and liabilities of $0.4 million partially offset by non-cash charges of $1.2 million. Our net loss was primarily attributed to research and development activities and our general and administrative expenses, as we had minimal product revenue in the period. Our net non-cash charges during the three months ended March 31, 2015 consisted and primarily of $0.9 million of stock-based compensation expense. Net cash used by changes in our operating assets and liabilities during the three months ended March 31, 2015 consisted primarily of a decrease in accounts payable and accrued expenses of $0.7 million and an increase in prepaid expenses and other current assets of $0.2 million. The changes in prepaid expenses and other current assets, accounts payable and accrued expenses was due to timing of vendor invoicing and payments.

Net cash used in operating activities was $4.0 million for the three months ended March 31, 2014, primarily resulting from our net loss of $7.0 million and cash used in our operating assets and liabilities of $0.1 million, partially offset by non-cash charges of $3.1 million. Our net loss was primarily attributed to research and development activities and our general and administrative expenses, as we had minimal product revenue in the period. Our net non-cash charges during the three months ended March 31, 2014 consisted primarily of $2.4 million of licensing and consultant fees paid in common stock and $0.5 million of stock-based compensation expense. Net cash used for changes in our operating assets and liabilities during the three months ended March 31, 2014 consisted primarily of an increase in inventories of $0.1 million, representing the initial capitalization of inventories purchased following the approval of ReSure Sealant, an increase in prepaid expenses and other current assets of $0.1 million and a decrease of $0.2 million in accrued expenses, primarily due to the payment of accrued bonuses, all of which were partially offset by an increase of $0.3 million in accounts payable. The increase in accounts payable was due to the timing of vendor invoicing and payments.

Net cash used in operating activities was $20.5 million for the year ended December 31, 2014, primarily resulting from our net loss of $28.6 million, partially offset by non-cash charges of $6.0 million and cash provided by changes in our operating assets and liabilities of $2.2 million. Our net loss was primarily attributed to research and development activities and our general and administrative expenses partially offset by $0.8 million of revenue in the period. Our net non-cash charges during the year ended December 31, 2014 primarily consisted of $2.4 million of licensing and consultant fees paid in common stock, $2.6 million of stock-based compensation expense and $0.5 million of depreciation expense. Net cash provided by changes in our operating assets and liabilities during the year ended December 31, 2014 consisted primarily of a $1.9 million increase in accrued expenses and deferred rent and a $0.5 million increase in accounts payable, which was due to the timing of vendor invoicing and payments, both partially offset by an increase in inventory of $0.1 million.

Net cash used in operating activities was $12.6 million for the year ended December 31, 2013, primarily resulting from our net loss of $13.3 million and cash used by changes in our operating assets and liabilities of $0.2 million, partially offset by non-cash charges of $0.9 million. Our net loss was primarily attributed to research and development activities and our general and administrative expenses, as we had no revenue in the period. Our net non-cash charges during the year ended December 31, 2013 primarily consisted of depreciation of $0.4 million and stock-based compensation expense of $0.5 million. Net cash used for changes in our operating assets and liabilities during the year ended December 31, 2013 consisted primarily of a $0.2 million decrease in accrued expenses, which was primarily due to the payment in 2013 of an accrued refund and a $0.2 million decrease in accounts payable, which was due to the timing of vendor invoicing and payments, both partially offset by a decrease in prepaid expenses and other current assets of $0.1 million. The $0.3 million increases recorded in both accounts receivable and deferred revenue during the year ended December 31, 2013 had no impact on our cash position as they were recorded in connection with the same transaction.

Net cash used in operating activities was $12.6 million for the year ended December 31, 2012, primarily resulting from our net loss of $14.1 million, partially offset by non-cash charges of $0.8 million and by cash provided from changes in our operating assets and liabilities of $0.7 million. Our net loss was primarily attributed to research and development activities and our general and administrative expenses, as we had minimal revenue in the period. Our net non-cash charges during the year ended December 31, 2012 primarily consisted of depreciation of $0.4 million and stock-based compensation expense of $0.2 million. Net cash provided by changes in our operating assets and liabilities during the year ended December 31, 2012 consisted primarily of a $0.6 million increase in accrued expenses, which were primarily due to an increase of $0.3 million in employee compensation accruals and a $0.3 million accrued refund, which was repaid in 2013.

Investing Activities. Net cash used in investing activities for the three months ended March 31, 2015 and 2014 totaled $17.9 million and $0.3 million, respectively. For the three months ended March 31, 2015, net cash used is primarily due to the purchase of marketable securities of $17.5 million. For the three months ended March 31, 2015 and 2014, the purchases of property and equipment, primarily laboratory equipment and additional investment in a manufacturing clean room was $0.4 million and $0.3 million respectively.

Net cash used by investing activities for the year ended December 31, 2014 consisted of cash used to purchase property and equipment of $1.3 million and cash used to purchase marketable securities of $37.3 million. Net cash used by investing activities for the year ended December 31, 2013 consisted of cash used to purchase property and equipment of $0.4 million. Purchases of property and equipment in 2014 and 2013 consist primarily of laboratory equipment, inclusive of building a clean room, which we commenced in 2013. Net cash provided by investing activities for the year ended December 31, 2012 of $3.8 million consisted primarily of proceeds of $4.0 million from sales or maturities of our investments, partially offset by purchases of property and equipment of $0.2 million.

Financing Activities. Net cash provided used for financing activities for the three months ended March 31, 2015 and 2014 was $0.1 million and $0.4 million, respectively. Net cash used by financing activities for the three months ended March 31, 2015 consisted primarily of payments of insurance costs financed by a third party offset by proceeds from the exercise of common stock options. Net cash used by financing activities for the three months ended March 31, 2014 consisted primarily of repayments of note payable offset by proceeds from the exercise of common stock options.

Net cash provided by financing activities for 2014 was $79.0 million and consisted primarily of proceeds of $69.5 million, net of underwriters discount related to our IPO, and $14.9 million from our new credit facility, under which we borrowed $15.0 million in aggregate principal amount in April 2014, partially offset by the payment of issuance costs of $3.0 million in connection with our IPO and the repayment of $2.3 million of outstanding principal and other amounts due in connection with our termination of a prior credit facility and repayments of principal prior to our termination of the credit facility. Net cash provided by financing activities for the year ended December 31, 2013 was $6.7 million and consisted primarily of proceeds of $8.5 million from the issuance of our Series D-1 redeemable convertible preferred stock, partially offset by repayments of $1.8 million on our outstanding notes payable. Net cash provided by financing activities for the year ended December 31, 2012 was $27.3 million and consisted primarily of net proceeds of $23.8 million from the issuance of our Series D redeemable convertible preferred stock and $4.4 million of proceeds from debt financing, partially offset by repayments of $0.9 million on our related outstanding notes payable.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the clinical trials of our products in development and increase our sales and marketing resources focused on the launch of the ReSure Sealant, our first FDA-approved product.

Our expenses will also increase as we:

- pursue the clinical development of our most advanced product candidates, the punctum plug candidates OTX-DP and OTX-TP;
- continue the research and development of our other product candidates;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical development;
- develop and expand our sales, marketing and distribution capabilities for ReSure Sealant and any of our product candidates for which we obtain marketing approval;
- scale up our manufacturing processes and capabilities to support sales of ReSure Sealant, our ongoing clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;

- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts; and
- operate as a public company.

As of March 31, 2015, we had cash, cash equivalents and marketable securities of $67.4 million. We believe that the net proceeds to us from this offering, together with our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements at least through the third quarter of 2017. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

- the level of product sales from ReSure Sealant and any additional products for which we obtain marketing approval in the future;
- the costs of manufacturing, sales, marketing, distribution and other commercialization efforts with respect to ReSure Sealant and any additional products for which we obtain marketing approval in the future;
- the progress, costs and outcome of the clinical trials of our punctum plug product candidates, in particular OTX-DP and OTX-TP;
- the scope, progress, costs and outcome of preclinical development and clinical trials of our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates by the FDA, the EMA or other regulatory authorities;
- the extent to which we choose to establish collaboration, distribution or other marketing arrangements for our products and product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or invest in other businesses, products and technologies.

Until such time, if ever, as we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through a combination of revenue from sales of ReSure Sealant, equity offerings, debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. The covenants under our existing credit facility, the pledge of our assets as collateral and the negative pledge of intellectual property limit our ability to obtain additional debt financing. If we raise additional funds through government or other third-party funding, collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Since our inception in 2006, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2014, we had federal net operating loss carryforwards of $39.2 million, which begin to expire in 2026, and state net operating loss carryforwards of $36.9 million, which begin to expire in 2030. As of December 31, 2014, we also had federal research and development tax credit carryforwards of $1.8 million and state research and development tax credit carryforwards $1.2 million, which begin to expire in 2026 and 2024, respectively. We have not completed a study to assess whether an ownership change, generally defined as a greater than 50% change (by value) in the equity ownership of our corporate entity over a three-year period, has occurred or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such studies. Accordingly, our ability to utilize our tax carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at March 31, 2015 and the effects such obligations are expected to have on our liquidity and cash flow in future periods:

	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years
			(in thousands)		
Operating lease commitments	$ 2,362	$ 807	$ 1,424	$131	$ —
Purchase commitments	7,653	7,653	—	—	—
Manufacturing commitments	2,100	2,100	—	—	—
Debt obligations	17,817	4,206	13,611	—	—
Total	$29,932	$ 14,766	$15,035	$131	$ —

In the table above, we set forth our enforceable and legally binding obligations and future commitments at March 31, 2015, as well as obligations related to contracts that we are likely to continue, regardless of the fact that they may be cancellable at March 31, 2015. Some of the figures that we include in this table are based on management's estimates and assumptions about these obligations, including their duration, and other factors. Because these estimates and assumptions are necessarily subjective, the obligations we will actually pay in future periods may vary from those reflected in the table.

Operating lease commitments represent payments due under our leases of office, laboratory and manufacturing space in Bedford, Massachusetts and of certain office equipment, all of which expire at various dates between June 2017 and June 2018.

Purchase commitments represent non-cancelable contractual commitments with CROs associated with certain of our clinical trial activities.

Manufacturing commitments generally provide for termination on notice, and therefore are cancelable contracts but are contracts that we are likely to continue, regardless of the fact that they are cancellable.

We enter into contracts in the normal course of business with other vendors to assist in the performance of our research and development activities and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts, and are not included in the table of contractual obligations and commitments.

In April 2014, we entered into a credit facility with Silicon Valley Bank and MidCap Financial SBIC, LP, pursuant to which we were able to borrow an aggregate principal amount of up to $20.0 million, of which we borrowed $15.0 million. We did not borrow the remaining $5.0 million, and this amount is no longer available to us. The credit facility carries a fixed annual interest rate of 8.25% on outstanding borrowings. In addition, upon repayment of all outstanding amounts under the credit facility, we are required to make a payment in an amount equal to 3.75% of total borrowings during the term of the credit facility. In April 2014, we issued the lenders warrants to purchase 100,000 shares of our Series D-1 redeemable convertible preferred stock with an exercise price of $3.00 per share. Upon the closing of our IPO in July 2014, the preferred stock warrants became warrants to purchase an aggregate of 37,878 shares of our common stock with an exercise price of $7.92 per share. The credit facility provides for monthly, interest-only payments on outstanding borrowings until October 1, 2015. Thereafter, we are required to pay 30 consecutive, equal monthly installments of principal and interest through March 2018. There are no financial covenants associated with the credit facility. There are negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions; encumbering our intellectual property; incurring indebtedness or liens; paying dividends; making investments; and engaging in certain other business transactions. The obligations under the credit facility are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition. The credit facility is secured by substantially all of our assets except for our intellectual property, which is subject to a negative pledge.

We have in-licensed a significant portion of our intellectual property from Incept, an intellectual property holding company, under an amended and restated license agreement that we entered into with Incept in January 2012. We are obligated to pay Incept a royalty equal to a low single-digit percentage of net sales made by us or our affiliates of any products covered by the licensed technology. Any sublicensee of ours also will be obligated to pay Incept a royalty equal to a low single-digit percentage of net sales made by it and will be bound by the terms of the agreement to the same extent as we are. We are obligated to reimburse Incept for our share of the reasonable fees and costs incurred by Incept in connection with the prosecution of the patent applications licensed to us under the agreement. Our share of these fees and costs is equal to the total amount of such fees and costs divided by the total number of Incept's exclusive licensees of the patent application. We have not included in the table above any payments to Incept under this license agreement as the amount, timing and likelihood of such payment are not known.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission, such relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40)*. The new guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. We are evaluating the effect that this guidance will have on our financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, or ASU 2014-09. ASU 2014-09 outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. In April 2015, the FASB proposed a one-year delay in the effective date of ASU 2014-09, which was originally effective for public entities for annual reporting periods beginning after December 15, 2016 and interim periods within those periods. Early adoption is not permitted. Companies may use either a full retrospective or a modified retrospective approach to adopt ASU 2014-09. We are currently assessing the impact that adopting this new accounting guidance will have on our financial statements and footnote disclosures.

In April 2015, the FASB issued ASU No. 2015-03, "*Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*" ("ASU 2015-03"). ASU 2015-03 requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. Prior to the issuance of the standard, debt issuance costs were required to be presented in the balance sheet as an asset. ASU 2015-03 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2015. We are currently assessing the impact that adopting this new accounting guidance will have on our financial statements and footnote disclosures.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. As of March 31, 2015, we had cash, cash equivalents and marketable securities of $67.4 million, which consisted of money market funds, U.S. treasury notes and government agency notes. We have policies requiring us to invest in high-quality issuers, limit our exposure to any individual issuer, and ensure adequate liquidity. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

BUSINESS

Overview of Ocular Therapeutix

We are a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using our proprietary hydrogel platform technology. Our bioresorbable hydrogel based product candidates are designed to provide sustained delivery of therapeutic agents to the eye. Our hydrogel is a bioresorbable proprietary formulation of polyethylene glycol, or PEG, which when constituted with water takes on a gelatinous consistency. The product candidates in our development pipeline have the potential to overcome many of the significant limitations of existing eye drop based therapies for ophthalmic diseases and conditions affecting the front of the eye by replacing the current standard of care regimen of weeks or months of eye drop dosing with as little as a single product application. Our lead sustained release drug delivery product candidates are OTX-DP and OTX-TP, which are inserted into the canaliculus through a natural opening called the punctum located in the inner portion of the eyelid near the nose. Our OTX-DP and OTX-TP product candidates combine our hydrogel technology with U.S. Food and Drug Administration, or FDA, approved therapeutic agents with the goal of providing sustained delivery of drug to the eye. We also have a hydrogel based drug delivery depot, which is in preclinical development for the treatment of diseases and conditions of the back of the eye, including wet age related macular degeneration, or wet AMD. Our hydrogel depot is designed to be delivered via intravitreal injection to release therapeutic agents, such as antibodies to vascular endothelial growth factor, or VEGF, over a sustained period. In addition to our ongoing product development, we have launched our first commercial product, ReSure Sealant, a hydrogel based ophthalmic wound sealant approved by the FDA in January 2014 to seal corneal incisions following cataract surgery. ReSure Sealant is the first and only surgical sealant to be approved by the FDA for ophthalmic use. Our product candidates target large and growing markets. Transparency Market Research, a provider of business information reports and services, estimates that the annual worldwide market for ophthalmic medications was nearly $16 billion as of 2012 and is expected to increase to $21.6 billion by 2018.

Poor patient compliance with eye drop regimens and the need for frequent administration of eye drops at high drug concentrations due to rapid washout by the tears can create challenges in the successful management of ocular diseases and conditions. For example, poor patient compliance can lead to diminished efficacy and disease progression and high drug concentrations can create side effects. We are developing therapies to replace standard of care eye drop regimens with our innovative drug eluting punctum plugs. Our plugs are sustained release drug delivery depots that are inserted into a natural opening called the punctum located in the inner portion of the eyelid near the nose. The plugs are designed to release a therapeutic agent to the surface of the eye over an extended period. The goal for our punctum plug product candidates is to change the management of many front-of-the-eye diseases and conditions from frequent, pulsed eye drop therapy, characterized by significant variations in drug concentration over time, to longer term, sustained delivery of therapeutic agents to improve patient outcomes.

Our most advanced product candidate, OTX-DP, incorporates the FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient in our hydrogel and is in Phase 3 clinical development for the treatment of ocular inflammation and pain following cataract surgery. We recently reported topline results from two Phase 3 clinical trials for this indication. In the first Phase 3 clinical trial, OTX-DP met both primary efficacy endpoints, absence of pain at day 8 and absence of inflammatory cells at day 14, with statistical significance. In the second Phase 3 clinical trial, OTX-DP met the primary efficacy endpoint for absence of pain at day 8 with statistical significance but did not meet the primary efficacy endpoint for absence of inflammatory cells at day 14. Although we have been conducting our Phase 3 clinical trials of OTX-DP in patients who have undergone cataract surgery, these trials are intended to support a label for all post-surgical ocular inflammation and pain. We met with the FDA in April 2015 to discuss the path forward for seeking marketing approval of OTX-DP for the treatment of ocular inflammation and pain following ophthalmic surgery. In this pre-NDA clinical meeting, the FDA indicated that the existing data from our Phase 2 and Phase 3 clinical trials are appropriate to support an NDA submission for OTX-DP solely for an ocular pain indication. The FDA further indicated that we would need additional data from a third Phase 3 clinical trial for the inflammation endpoint to support the potential labeling expansion of OTX-DP's indications for use. We plan to initiate this third Phase 3 clinical trial for OTX-DP for the treatment of post-surgical ocular inflammation and pain in the second half of 2015. We expect to submit an NDA for OTX-DP solely for the treatment of ocular pain following ophthalmic surgery in the second half of 2015. Based on our expectations regarding initiation of our third Phase 3 clinical trial of OTX-DP and design of the trial and our estimates regarding patient enrollment, we expect to have topline efficacy data available from this trial in the second half of 2016. If the results of our third Phase 3 clinical trial of OTX-DP are favorable and subject to receiving approval for the pain indication pursuant to the initial NDA, we plan to submit an NDA supplement for OTX-DP for the treatment of ocular inflammation following ophthalmic surgery in the second half of 2016. If we receive approval of our initial NDA and our NDA supplement, we expect to commercially launch OTX-DP for post-surgical ocular inflammation and pain in the United States in the first half of 2017.

In addition, we completed a Phase 2 clinical trial of OTX-DP for the treatment of allergic conjunctivitis in November 2014. Based on encouraging results from this trial, we expect to initiate two Phase 3 clinical trials of OTX-DP for this indication in the middle of 2015, with topline efficacy data from the first Phase 3 clinical trial expected to be available in the fourth quarter of 2015. We also initiated an exploratory Phase 2 clinical trial of OTX-DP for the treatment of inflammatory dry eye disease in January 2015.

We have also received conditional acceptance of the name DEXTENZA™ from the FDA for our OTX-DP product candidate. We plan to include a request for a proprietary name review for DEXTENZA as part of our NDA submission of OTX-DP for the treatment of ocular pain following ophthalmic surgery.

Our second product candidate, OTX-TP, incorporates travoprost, an FDA-approved prostaglandin analog that reduces elevated intraocular pressure, as an active pharmaceutical ingredient in our hydrogel. We completed a Phase 2a clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension in May 2014 and initiated a Phase 2b clinical trial of OTX-TP for this indication in November 2014.

In addition to OTX-DP and OTX-TP, we are engaged in the preclinical development of a sustained release hydrogel depot administered via intravitreal injection to address the large and growing markets for diseases and conditions of the back of the eye. Our initial development efforts are focused on the use of our sustained release hydrogel depot in combination with anti-VEGF compounds for the treatment of wet AMD. Our initial goal for this program is to provide sustained release of an anti-VEGF compound over a four to six month period, thereby reducing the frequency of the current monthly or bi-monthly intravitreal injection regimen for wet AMD. We also have a pipeline of earlier stage punctum plug product candidates, including OTX-MP, which has completed a Phase 1 clinical trial evaluating safety and pharmacokinetics in patients following cataract surgery.

Following our receipt of FDA approval for ReSure Sealant, we commercially launched this product in the United States in February 2014 through a network of ophthalmology focused distributors. ReSure Sealant is approved to seal corneal incisions following cataract surgery and is the first and only surgical sealant to be approved by the FDA for ophthalmic use. In the pivotal clinical trials that formed the basis for FDA approval, ReSure Sealant provided superior wound closure and a better safety profile than sutured closure. We plan to use the limited revenues we expect from sales of ReSure Sealant to contribute to the funding of our product development pipeline and commercialization efforts.

Our clinical stage product candidates and our marketed product are based on a proprietary bioresorbable hydrogel technology platform that uses PEG as a key component. Bioresorbable materials gradually break down in the body into non-toxic, water soluble compounds that are cleared by normal biological processes. PEG is used in many pharmaceutical products and is widely considered to be safe and biocompatible. Our technology platform allows us to tailor the physical properties, drug release profiles and bioresorption rates of our hydrogels to meet specific applications. We have used this platform to engineer each of our punctum plug product candidates, ReSure Sealant and our intravitreal hydrogel depot. Our technical capabilities include a deep understanding of the polymer chemistry of PEG based hydrogels and the design of the specialized manufacturing processes required to achieve a reliable, preservative free and pure product.

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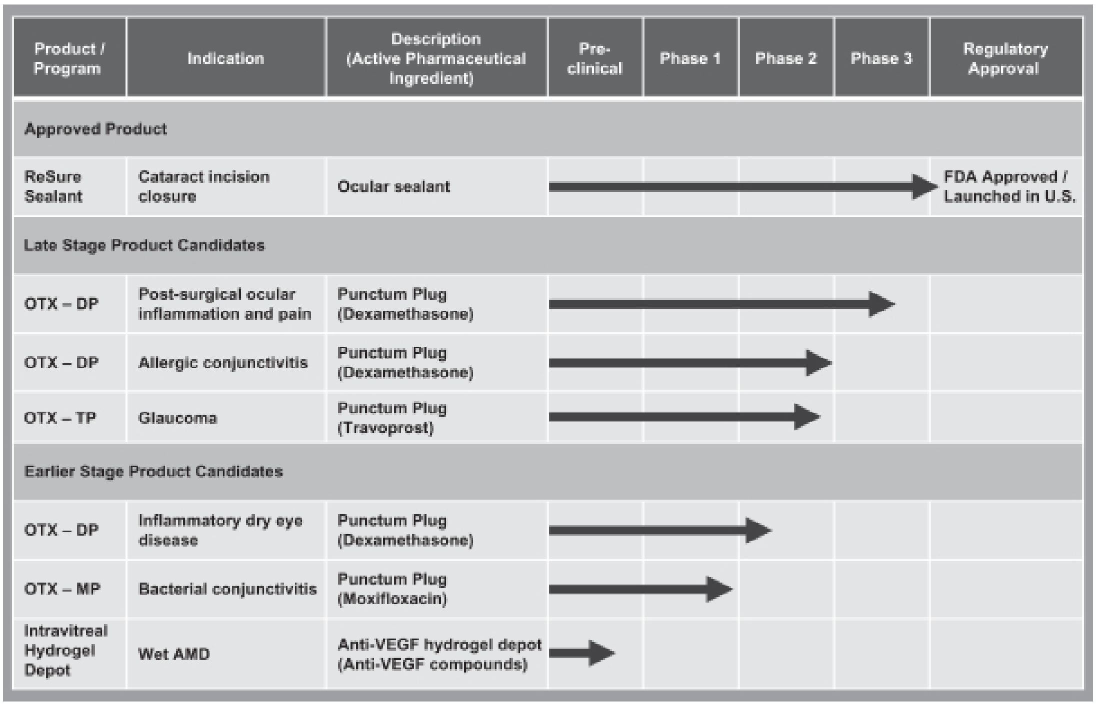
We have in-licensed all of the patent rights and a significant portion of the technology for ReSure Sealant and our hydrogel platform technology product candidates from Incept, LLC, or Incept, an intellectual property holding company. Amarpreet Sawhney, our President and Chief Executive Officer, is a general partner of Incept and has a 50% ownership stake in Incept.

Our founders and management team have significant experience in developing and commercializing medical products for other companies using bioresorbable hydrogel technology, including FDA-approved and currently marketed medical products such as DuraSeal Dural Sealant® (marketed by Integra Lifesciences, Inc.), a sealant for cranial and spine surgery, and Mynx® (marketed by Cardinal Health, Inc.), a sealant for femoral artery punctures after angiography and angioplasty. Dr. Sawhney was the founder, President and Chief Executive Officer of Confluent Surgical, Inc., the company that developed and commercialized the DuraSeal Dural Sealant and was the technology founder of AccessClosure, Inc., the company that developed and commercialized Mynx. The annual sales of Mynx were in excess of $80 million in 2013 prior to the acquisition of Mynx by Cardinal Health, Inc. in April 2014.

The following table summarizes the status of our key product development programs and our marketed product. We hold worldwide exclusive commercial rights to the core technology underlying all of our products in development.



Product / Program	Indication	Description (Active Pharmaceutical Ingredient)	Pre-clinical	Phase 1	Phase 2	Phase 3	Regulatory Approval
Approved Product							
ReSure Sealant	Cataract incision closure	Ocular sealant					FDA Approved / Launched in U.S.
Late Stage Product Candidates							
OTX – DP	Post-surgical ocular inflammation and pain	Punctum Plug (Dexamethasone)					
OTX – DP	Allergic conjunctivitis	Punctum Plug (Dexamethasone)					
OTX – TP	Glaucoma	Punctum Plug (Travoprost)					
Earlier Stage Product Candidates							
OTX – DP	Inflammatory dry eye disease	Punctum Plug (Dexamethasone)					
OTX – MP	Bacterial conjunctivitis	Punctum Plug (Moxifloxacin)					
Intravitreal Hydrogel Depot	Wet AMD	Anti-VEGF hydrogel depot (Anti-VEGF compounds)					

Our Strategy

Our goal is to change the management of many ophthalmic diseases and conditions from frequent, pulsed therapy, characterized by significant variations in drug concentration over time, to longer term, sustained delivery of therapeutic agents to improve patient outcomes. The key elements of our strategy to achieve this goal are to:

- *Create proprietary solutions for ophthalmic diseases and conditions based on our bioresorbable hydrogel technology platform combined with FDA-approved therapeutic agents to improve the delivery of these agents.* We are directing all of our development efforts towards applying our proprietary PEG based bioresorbable hydrogel technology platform to product candidates that are designed to provide sustained delivery of therapeutic agents to the eye using active pharmaceutical ingredients that are currently used in ophthalmic drugs approved by the FDA. Our technology uses a proprietary composition of PEG to make bioresorbable hydrogels that we specifically engineer for each of our product candidates. By focusing on the development of products based on FDA-approved therapeutic agents, we believe that we can advance potential products efficiently and predictably through the development cycle based on well-defined clinical and regulatory approval pathways. We believe this strategy of selecting FDA-approved therapeutic agents and improving their delivery represents an attractive risk-reward profile relative to new drug development.

- *Improve patient compliance and management of front-of-the-eye diseases and conditions by replacing standard of care eye drop therapies with our sustained release product candidates.* We are designing and developing innovative product candidates to address large markets that are currently served by a variety of competing products, all of which we believe have limitations. We are directing a significant portion of our efforts to address many of the limitations of eye drops, while still delivering the drugs to the ocular surface. Our technology platform enables sustained drug delivery to the eye, which we believe can lead to increased compliance, enhanced efficacy and reduced side effects for our product candidates as compared to existing therapies. We are designing our sustained delivery product candidates so that following a single administration of one of these product candidates performed by a healthcare professional, a patient can receive continuous exposure to a therapeutic agent over a period of weeks or months depending on the disease or condition.

- *Rapidly complete clinical development of and seek marketing approval for our most advanced punctum plug product candidates for diseases and conditions of the front of the eye.* We are focusing on completing the clinical development of our most advanced product candidates, including OTX-DP for post-surgical ocular inflammation and pain and allergic conjunctivitis and OTX-TP for glaucoma. We believe that the well-defined clinical and regulatory approval pathways for these product candidates, and the availability of large patient populations, will enable us to complete clinical development in a capital and time efficient manner. We are in the late stages of a Phase 3 clinical program for OTX-DP for ocular inflammation and pain following cataract surgery. We recently reported topline results from two Phase 3 clinical trials for this indication. We plan to initiate a third Phase 3 clinical trial for OTX-DP for the treatment of post-surgical ocular inflammation and pain in the second half of 2015. We expect to submit an NDA for OTX-DP solely for the treatment of ocular pain following ophthalmic surgery in the second half of 2015. Based on our expectations regarding initiation of our third Phase 3 clinical trial of OTX-DP and design of the trial and our estimates regarding patient enrollment, we expect to have topline efficacy data available from this trial in the second half of 2016. We completed a Phase 2 clinical trial of OTX-DP for allergic conjunctivitis in November 2014 and expect to initiate Phase 3 clinical trials of OTX-DP for this indication in the middle of 2015. We initiated a Phase 2b clinical trial of OTX-TP for glaucoma and ocular hypertension in November 2014.

- *Apply our sustained release punctum plug technology for treatment of additional diseases and conditions of the front of the eye.* We are exploring the potential use of our hydrogel punctum plugs in other front-of-the-eye diseases and conditions, such as inflammatory dry eye disease and ocular infections, incorporating active pharmaceutical ingredients that are approved by the FDA as topical ophthalmic eye drops. We initiated an exploratory Phase 2 clinical trial of OTX-DP for inflammatory dry eye disease in January 2015. Subject to further advancing our OTX-DP and OTX-TP clinical trials, we may allocate clinical development resources to later stage clinical testing of our OTX-MP punctum plug candidate, which incorporates the antibiotic moxifloxacin as an active pharmaceutical ingredient, for the treatment of ocular infections. In addition, we are exploring whether FDA-approved therapeutic agents that are not well suited to delivery by eye drops can be delivered by our hydrogel punctum plugs.

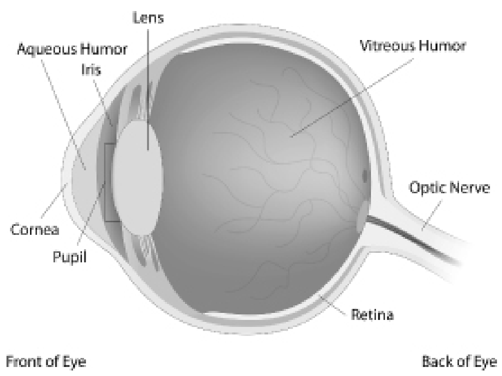
- *Pursue development of our intravitreal hydrogel depot and other technologies for back-of-the-eye diseases and conditions.* We are developing a hydrogel based drug delivery depot designed to release anti-VEGF compounds over a sustained period following administration by an intravitreal injection to address the large and growing markets for diseases and conditions of the back of the eye, including wet AMD. Our goal for this intravitreal hydrogel depot is to provide sustained release of the anti-VEGF compound over a four to six month period, thereby reducing the frequency of the current monthly or bi-monthly intravitreal injection regimen. We believe that less frequent injections will be more convenient for patients and may reduce the risk of infection and other potential side effects associated with each injection. We also believe that our drug delivery depot could potentially provide a more consistent level of therapeutic agent compared with existing therapies. In 2014, sales of the most commonly prescribed anti-VEGF drugs approved for the treatment of wet AMD totaled approximately $3.5 billion in the United States. We are working with several pharmaceutical companies with anti-VEGF compounds to explore the feasibility of delivering their compounds using our intravitreal hydrogel depot. We have established in preclinical tests the compatibility of our technology with these compounds and observed sustained delivery over four to six months in vitro and initial evidence of tolerability of the drug-loaded hydrogel depot. We believe that results to date support the continuing preclinical development of this product candidate. We plan to explore both the possibility of broader collaborations with the pharmaceutical companies we are currently working with and also an internally funded program for the development and potential commercialization of our intravitreal hydrogel depot technology to deliver anti-VEGF drugs for the treatment of back-of-the-eye diseases and conditions. We are also evaluating in early exploratory research additional opportunities beyond anti-VEGF drugs to utilize our hydrogel depot for back-of-the-eye diseases.

- *Maximize commercial potential of ReSure Sealant and any other products for which we receive marketing approval.* We hold worldwide commercial rights to ReSure Sealant and each of our product candidates. We have initiated commercialization of ReSure Sealant through a network of independent medical device distributors across the United States. These distributors are primarily exclusive to ophthalmology and focus on selling surgical products to cataract and cornea surgeons. We plan to use the expected limited revenue from sales of ReSure Sealant to contribute to the funding of our product development pipeline and commercialization efforts. If we receive approval to market any of our product candidates in the United States, we plan to then evaluate the regulatory approval requirements and commercial potential for any such product candidate in Europe, Japan and other selected geographies. We generally expect to retain commercial rights in the United States for any sustained delivery products for diseases and conditions of the front of the eye for which we may receive marketing approval and which we believe we can successfully commercialize. Outside the United States, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize any product of ours that receives marketing approval.

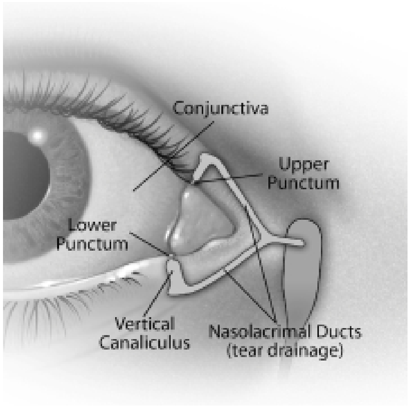
Eye Disease

The front of the human eye possesses focusing elements, consisting of the cornea on the surface of the eye, the lens and the aqueous humor, which is a transparent gelatinous fluid that fills the anterior and posterior chambers between the lens and the cornea. The tissue surrounding the eye also serves important functions. There is a natural opening, called a punctum, located in the inner portion of each eyelid near the nose. The puncta open into nasolacrimal ducts, which collect and drain tears. The conjunctiva is the membrane covering the inside of the eyelids and the white part of the eye. It helps to protect the eye from microbes and to lubricate the eye. The back of the eye contains the retina, which is the light sensing layer of tissue, the vitreous humor, which is a transparent gel that fills the vitreous chamber between the lens and the retina, and the optic nerve, which transmits visual information from the retina to the brain. Eye disease can be caused by many factors and can affect both the front and back of the eye. Diseases and conditions affecting the front of the eye are generally treated either with surgery or with medications delivered to the ocular surface by eye drops. Intravitreal injections are typically used to deliver medications to the back of the eye.

Cross Section of Eye



Tear Drainage System



Front-of-the-Eye Diseases and Conditions

Ocular Inflammation and Pain

Ocular inflammation and pain are common conditions caused by a variety of factors, including ophthalmic surgery, allergic conjunctivitis and dry eye disease.

Post-surgical Ocular Inflammation and Pain

Ocular inflammation and pain are common side effects following ophthalmic surgery. Frequently performed ophthalmic surgeries include cataract, refractive vitreoretinal, cornea and glaucoma procedures. Physicians prescribe anti-inflammatory drugs, such as corticosteroids, which are typically administered through eye drops multiple times per day, following ocular surgery as the standard of care. These drugs improve patient comfort and also accelerate recovery through disruption of the inflammatory cascade resulting in decreased inflammation and reduced activity of the immune system. Physicians also frequently prescribe non-steroidal anti-inflammatory drugs, or NSAIDs, as adjunctive or combination therapy to supplement the use of corticosteroids. If left untreated, inflammation of the eye may result in further ocular complications, including pain, scarring and vision loss. Market Scope estimates that approximately 5.3 million ocular surgeries will be performed in the United States in 2015.

Allergic Conjunctivitis

Allergic conjunctivitis is an inflammatory disease of the conjunctiva resulting primarily from a reaction to allergy-causing substances such as pollen or pet dander. The primary sign of this inflammation is redness and the primary symptom is acute itching. Allergic conjunctivitis ranges in clinical severity from relatively mild, common forms to more severe forms that can cause impaired vision. According to a study on the management of seasonal allergic conjunctivitis published in 2012 in the peer-reviewed journal *Acta Ophthalmologica*, allergic conjunctivitis affects 15% to 40% of the U.S. population. The first line of defense against allergic conjunctivitis is avoidance of the allergen. If this is not successful, physicians typically prescribe a mast cell stabilizer or antihistamine. These treatments act to reduce the signs and symptoms of the early phase allergic reaction. For the subset of patients with chronic or more severe forms of allergic conjunctivitis, antihistamines and mast cell stabilizers are often not sufficient to treat their signs and symptoms. These refractory patients are frequently treated with topical corticosteroids administered by eye drops.

Dry Eye Disease

Dry eye disease affects the ocular surface and is characterized by dryness, inflammation, pain, discomfort and irritation. The current standard of care for moderate to severe dry eye disease is the use of artificial tears and topical anti-inflammatory and immune modulating drugs administered by eye drops. The anti-inflammatory and immune modulating prescription drug market for the treatment of moderate to severe dry eye disease consists of Restasis, marketed by Allergan, and off-label use of corticosteroids and NSAIDs. Restasis is an ophthalmic formulation of the immune modulating drug cyclosporine. Restasis is a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Based on our review of industry sources, we estimate that approximately 20 million people in the United States have dry eye disease, including approximately five million people who suffer from moderate to severe dry eye disease.

Market Data

According to IMS Health data, approximately 20 million prescriptions were filled in the United States in 2014 for anti-inflammatory drugs administered by eye drops for ocular diseases and conditions, resulting in sales of approximately $2.7 billion. This consisted of approximately 8.5 million prescriptions and $747 million in sales for single-agent corticosteroids, 3.9 million prescriptions and $346 million in sales for NSAIDs, 4.4 million prescriptions and $324 million in sales for corticosteroid and antibiotic combination products and approximately 3.2 million prescriptions and $1.28 billion in sales of Restasis for dry eye disease. Additionally, according to IMS Health data, approximately 6.9 million anti-allergy eye drop prescriptions were filled in the United States in 2014, resulting in sales of approximately $868 million. The steroid market for eye drops to treat ocular diseases and conditions consists of both branded and generic products. Branded steroids include Lotemax and Alrex (loteprednol etabonate) marketed by Bausch & Lomb and Durezol (difluprednate) marketed by Alcon. Commonly used generic steroids include prednisolone, dexamethasone and fluorometholone.

Glaucoma

Glaucoma is a progressive and highly individualized disease in which elevated levels of intraocular pressure are associated with damage to the optic nerve, which results in irreversible vision loss. Glaucoma is the second leading cause of blindness in the world. Ocular hypertension is characterized by elevated levels of intraocular pressure without any optic nerve damage. Patients with ocular hypertension are at high risk of developing glaucoma.

In a healthy eye, fluid is continuously produced and drained to maintain pressure equilibrium and provide nutrients to the ocular tissue. Excess fluid production or insufficient drainage of fluid in the front of the eye or a combination of these problems causes increased intraocular pressure. The increased intraocular pressure associated with uncontrolled glaucoma results in degeneration of the optic nerve in the back of the eye. Once glaucoma develops, it is a chronic condition that requires life-long treatment. According to the Glaucoma Research Foundation, approximately 3 million people in the United States suffer from glaucoma. Open-angle glaucoma, in which the space between the iris and the cornea through which fluid drains is relatively wide, is the most common form of glaucoma. According to the Glaucoma Research Foundation, open-angle glaucoma accounts for at least 90% of all glaucoma cases.

In order to lower intraocular pressure, physicians typically initiate treatment by prescribing drugs administered as eye drops. These drugs either decrease fluid production or enhance fluid drainage. The classes of topical drugs used to treat glaucoma include prostaglandin analogs, or PGAs, beta-blockers, alpha-adrenergic agonists and carbonic anhydrase inhibitors. PGAs are the most widely prescribed class of drugs for glaucoma and are considered first-line glaucoma treatment. PGAs reduce intraocular pressure by enhancing the clearance and drainage of ocular fluid. The most frequently prescribed PGA is once-daily latanoprost, although travoprost, unoprostone and bimatoprost are also frequently used in the management of open-angle glaucoma. In cases where glaucoma is not easily managed by a drug regimen, surgical or laser treatments may be undertaken.

Market Data

According to IMS Health data, approximately 33 million prescriptions were filled in the United States in 2014 for drugs administered by eye drops for the treatment of glaucoma, resulting in sales of approximately $2.4 billion. A typical prescription provides approximately one month of treatment. We expect prescription volume to grow, in large part as a result of the aging population. According to IMS Health, PGAs account for approximately half of the prescription volume in the glaucoma market. The market for drugs administered by eye drops for the treatment of glaucoma consists of both branded and generic products. Branded products have maintained premium pricing and significant market share. These products include Travatan Z (travoprost) marketed by Alcon and Lumigan (bimatoprost) marketed by Allergan. The relevant patents covering travoprost expired in December 2014. Commonly used generic drugs include latanoprost and timolol.

Bacterial Infection

Bacterial conjunctivitis is one of the most common forms of ocular infection. It is an inflammatory disease of the eye caused by infection with bacteria such as *Haemophilus influenzae*, *Streptococcus pneumoniae* or *Staphylococcus aureus*. While bacterial conjunctivitis typically resolves on its own over time, it is often treated with antibiotics which can speed recovery, reduce relapse and potentially prevent important sight-threatening complications.

Ophthalmic bacterial infections are treated with a range of antibiotics, both branded and generic. One such example is moxifloxacin, a fourth generation fluoroquinolone marketed by Alcon under the brand names Vigamox and Moxeza. Fourth generation fluoroquinolones are favored because they offer the highest potency against gram-positive organisms while maintaining the gram-negative efficacy of previous generation antibiotics. In addition, the increased lipophilicity, or solubility in fatty tissue, of moxifloxacin allows for improved performance in ophthalmic tissue penetration studies compared to other fluoroquinolones. The relevant patents covering moxifloxacin expired in March 2014.

Market Data

According to IMS Health data, approximately 16.9 million prescriptions were filled in the United States in 2014 for ophthalmic antibiotics administered by eye drops, resulting in sales of approximately $652 million.

The Use of Eye Drops and their Limitations

Eye drops are widely used to deliver medications directly to the ocular surface and to intraocular tissue in the front of the eye. Eye drops are administrable by the patient or care provider, inexpensive to produce and treat the local tissue. However, eye drops have significant limitations, especially when used for chronic diseases or when requiring frequent administration, including:

- *Lack of patient compliance*. Eye drops require frequent administration. For example, steroids for ophthalmic use require administration as frequently as four to six times daily and require tapered dosing over the course of the therapy. As a result, patient compliance with required dosing regimens frequently suffers. According to a published third-party study, more than 50% of glaucoma patients discontinue therapy and do not refill prescriptions as required within six months of initiating therapy. Poor patient compliance can lead to diminished efficacy and disease progression.
- *Difficulty in administration*. Eye drops are difficult to administer for many patients, in particular the elderly. Difficulty in self-administering eye drops may lead to bacterial contamination in the bottle resulting from incorrect usage, limited accuracy administering the drops directly into the eye and the potential washout of drops from the eye. We believe that this also may play a large role in lack of patient compliance and resulting diminished efficacy of treatment.

- *Need for high concentrations*. After eye drops are administered to the ocular surface, the tear film rapidly renews. Most topically applied solutions are washed away by new tear fluid within 15 to 30 seconds. Because contact time with the ocular surface is short, less than 5% of the applied dose actually penetrates to reach intraocular tissues. As a result, eye drops generally require frequent administration at high drug concentrations to deliver a meaningful amount of drug to the eye. This pulsed therapy results in significant variations in drug concentrations over a treatment period, which we refer to as peak and valley dosing. At peak levels, the high concentrations can result in side effects, such as burning, stinging, redness of the clear membrane covering the white part of the eye, referred to as hyperemia, and spikes in intraocular pressure, which may lead to drug- induced glaucoma. At low concentration levels, the drug may not be effective, thus allowing the disease to progress.
- *Side effects of preservatives*. To guard against contamination, many eye drops are formulated with antimicrobial preservatives, most commonly benzalkonium chloride, or BAK. Patients on long term or chronic therapy, such as glaucoma patients, often suffer reactions, which have been linked to BAK, including burning, stinging, hyperemia, irritation and eye dryness. Less frequently, conjunctivitis or corneal damage may result.

As a result of these limitations, eye drops are often suboptimal as a therapeutic option for the treatment of many diseases and conditions of the front of the eye.

Back-of-the-Eye Diseases and Conditions

There are a range of back-of-the-eye diseases and conditions that adversely affect vision. One of the principal back of the eye conditions is wet AMD, a serious disease of the central portion of the retina, known as the macula that is responsible for detailed central vision and color perception. Wet AMD is characterized by abnormal new blood vessel formation, referred to as neovascularization, which results in blood vessel leakage and retinal distortion. If untreated, neovascularization in wet AMD patients typically results in formation of a scar under the macular region of the retina. The current standard of care for wet AMD are drugs that target VEGF, one of several proteins involved in neovascularization.

Wet AMD is the leading cause of blindness in people over the age of 55 in the United States and the European Union. According to a study on the burden of AMD published in 2006 in the peer-reviewed journal *Current Opinion in Ophthalmology*, approximately 1.2 million people in the United States suffer from wet AMD. In addition, AMD Alliance International reports that approximately 200,000 new cases of wet AMD arise each year in the United States. The incidence of wet AMD increases substantially with age, and we expect that the number of cases of wet AMD will increase with growth of the elderly population in the United States. The anti-VEGF market for the treatment of wet AMD consists predominantly of two drugs that are approved for marketing and primarily prescribed for the treatment of wet AMD, Lucentis marketed in the United States by Genentech and Eylea marketed in the United States by Regeneron, and off-label use of the cancer therapy Avastin. In 2014, sales of Lucentis and Eylea totaled approximately $3.5 billion in the United States.

Because eye drops are unable to carry effective drug concentrations to the back of the eye, intravitreal injections are used to deliver medications to this location. However, the frequency of intravitreal injections can be a significant burden on patients, caregivers and clinicians. For example, the current treatment protocol for wet AMD involves monthly or bi-monthly injections. Intravitreal injections can lead to patient discomfort, a transient increase in intraocular pressure, and ocular inflammation and infection. Although serious adverse event rates after treatment with anti-VEGF compounds are low, intravitreal injections can result in severe complications and damage to the retina and other structures of the eye, such as ocular hemorrhage and tears in the retinal pigment epithelium.

Ocular Wound Closure

According to the World Health Organization, cataracts are the leading cause of visual impairment eventually progressing to blindness. According to the American Academy of Ophthalmology Cataract and

Anterior Segment Panel's 2011 Preferred Practice Pattern Guidelines, cataract extraction is the most commonly performed eye surgery in the United States. Market Scope estimates that in 2015 there will be approximately 3.8 million cataract extractions performed in the United States.

A cataract is a clouding of the lens inside the front of the eye. During cataract surgery, a patient's cloudy natural lens is removed and replaced with a prosthetic intraocular lens. Clear corneal incisions that allow entry to the eye are the preferred method for performing cataract surgery. The most common post-surgical approach is to allow the incisions to self-seal, or close, through normal biological processes. However, self-sealing incisions can open spontaneously, especially within 12 to 24 hours following surgery, when intraocular pressure fluctuates or as a result of the application of external pressure or manipulation. In addition, incisions that are left to self-seal are often associated with fluid leakage, which can sometimes result in complications. Complications from fluid leakage include the development of hypotony, or low intraocular pressure, which can lead to corneal decompensation and vision loss, as well as the potential for infection. The implanted intraocular lens also may shift in position due to hypotony, leading to poor visual outcomes following surgery.

Sutures are the most widely used alternative method of wound closure. However, sutures do not completely prevent fluid leakage, are time-consuming to place and have been associated with patient discomfort and corneal distortion. An additional visit may be required to remove sutures, thus adding time, inconvenience and expense to the surgical process. Sutures may also lead to astigmatism, a distortion of the cornea that can result from improper suture technique. These shortcomings limit the use of sutures in ophthalmic surgery. In a 2012 survey of ophthalmologists in the United States conducted by Lachman Consulting LLC, a healthcare consulting firm, respondents indicated that they use sutures in approximately 14% of cataract surgeries.

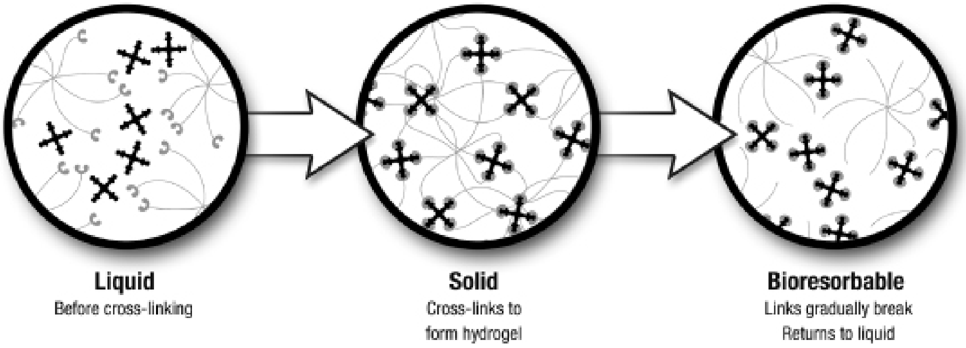
The Ocular Therapeutix Approach

Our Hydrogel Technology Platform

We apply our expertise with an established bioresorbable hydrogel technology to the development of products for sustained delivery of known, FDA-approved therapeutic agents for a variety of ophthalmic diseases and conditions and to ophthalmic wound closure. Our founders and management team have previously used this same hydrogel technology to develop FDA-approved and currently marketed medical products for other companies such as DuraSeal Dural Sealant® (marketed by Integra Lifesciences, Inc.), a sealant for cranial and spine surgery, and Mynx® (marketed by Cardinal Health), a sealant for femoral artery punctures after angiography and angioplasty.

Our bioresorbable hydrogel technology is based on the use of a proprietary form of PEG. Our technical capabilities include a deep understanding of the polymer chemistry of PEG based hydrogels and the design of the highly specialized manufacturing processes required to achieve a reliable, preservative free and pure product. We tailor the hydrogel to act as a vehicle for sustained drug delivery to the eye and as an ocular tissue sealant. We have used bioresorbable hydrogels to engineer each of our punctum plug product candidates, ReSure Sealant and our intravitreal hydrogel depot.

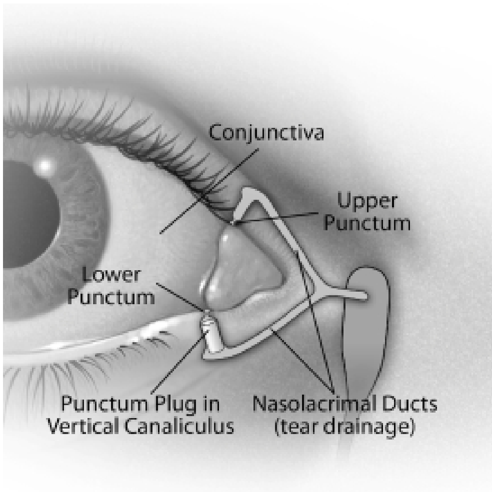
We create our hydrogels by cross-linking PEG molecules to form a network that resembles a three-dimensional mesh on a molecular level. Our PEG molecules are branched, with four to eight branches or arms. Each arm bears a reactive site on its end. Our cross-linking chemistry uses a second molecule with four arms, bearing complimentary reactive sites on each end, such that when combined with the PEG molecules, a network spontaneously forms. When swollen with water, this molecular network forms a hydrogel. We design these hydrogels to slowly degrade in the presence of water, a process called hydrolysis, by inserting a biodegradable linkage between the PEG molecule and the cross-linked molecule. By appropriately selecting the number of arms of the PEG molecule and the biodegradable linkage, we can design hydrogels with varying mechanical properties and bioresorption rates. Because the body has an abundance of water at a constant temperature and pH level, hydrolysis provides a predictable and reproducible degradation rate. Our technology enables us to make hydrogels that can bioresorb over days, weeks or several months. The figure below depicts the formation and bioresorption of the hydrogel for ReSure Sealant.



Punctum Plug Based Drug Delivery for Front-of-the-Eye Diseases and Conditions

A punctum is a natural opening located in the inner portion of the eyelid near the nose. There is a punctum in each of the lower eyelids and the upper eyelids. The puncta open into nasolacrimal ducts, which collect and drain tears produced by the eyes' lacrimal glands. Tears produced in the lacrimal glands sweep across the eye surface and drain through the puncta to the nasal cavity. The section of the nasolacrimal duct immediately beyond the puncta is called the vertical canaliculus. Punctum plugs that do not contain an active drug are commonly used for treatment of dry eye disease by physically blocking tear drainage. Because punctum plugs stay in contact with the tear film, they are well suited for sustained delivery of drug to the eye.

Punctum plug shown positioned in the vertical canaliculus

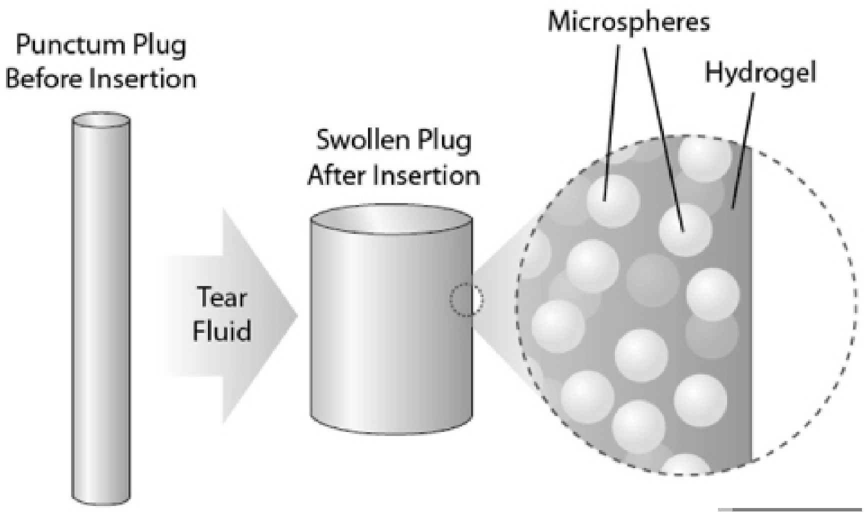


Our punctum plugs utilize our proprietary hydrogel technology and are embedded with an active drug. Following insertion through the punctum, our plugs swell in tear fluid to fill the vertical canaliculus, which secures the plugs in place. We design our plugs to release drug in a sustained fashion, tailored to each disease state, back through the punctum to the surface of the eye. Over time the plugs liquefy and are cleared through the nasolacrimal duct. If necessary due to excessive tearing, discomfort or improper placement, a healthcare professional can easily remove a punctum plug by a simple process of pushing the soft plug back through the punctum.

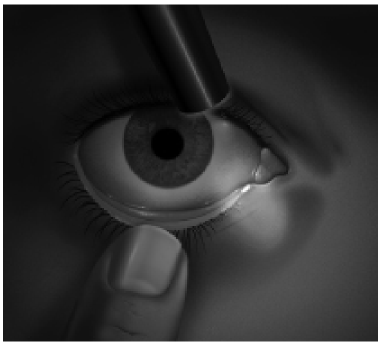
Our plugs allow incorporation of a variety of drugs with a controllable range of delivery durations and delivery rates. For acute conditions, such as post-surgical ocular inflammation and pain and allergic conjunctivitis, we have designed our punctum plugs to provide a sustained release of therapeutic levels of drug for the duration of treatment. For chronic diseases, such as glaucoma, we have designed our punctum plugs for repeat administration with extended dosing periods. We are concentrating our development efforts on plugs incorporating active pharmaceutical ingredients that are approved by the FDA for the targeted indication and that satisfy other specific selection criteria that we have developed.

We manufacture our punctum plugs from dried PEG based hydrogel formed into tiny rods that hold an active pharmaceutical ingredient in a preservative free formulation. We embed the active pharmaceutical ingredient in the pre-hydrogel liquid formulation, which then solidifies to form a hydrogel containing the drug within. The relative size of one of our punctum plugs is shown in the figure below.

We provide the punctum plug as a thin dry rod to facilitate insertion through the narrow punctal opening. Upon hydration with tear fluid, the plug swells, softens, and conforms to roughly the size and shape of the vertical canaliculus, to secure it in place. We incorporate the active pharmaceutical ingredient in the form of micronized particles embedded directly in the hydrogel or as bioresorbable microspheres.



We have included a fluorescent label, or marker, in our punctum plug hydrogel to serve as a visualization aid for the healthcare professional and patient to confirm the plug's presence. The viewer applies a blue hand held light and a clear yellow filter aid to see the plug in the eyelid as shown in the figure below.



Because punctum plugs stay in contact with the tear film, other companies have pursued the development of punctum plugs containing active drugs for sustained release to the ocular surface. However, these earlier plug designs had significant limitations with respect to drug capacity, drug release kinetics and patient comfort. The earlier plug designs used non-degradable plugs with a clear silicone hard rubber shell containing only a core with active drug. These plugs typically extended outside of the punctal opening and secured themselves in place with an external cap. The external cap was in constant contact with the surface of the eye, causing irritation and discomfort in some cases. In addition, some prior designs resorted to plugging both the upper and lower puncta, which could cause excessive tearing and patient discomfort. These designs did not incorporate a visualization agent to allow the patient and physician to assess the presence of the plug.

In contrast to these prior approaches, we have designed our punctum plugs to:

- incorporate the active pharmaceutical ingredient throughout the plug rather than just in a core to allow for higher drug capacity and better control over drug release;
- be bioresorbable so that removal is not required;
- be soft and to fit beneath the punctal opening for patient comfort; and
- include a fluorescent label to allow the healthcare professional and patient to visualize and assess the presence of the plug.

We select the active pharmaceutical ingredients for our punctum plug product candidates based on criteria we have developed through our extensive experience with hydrogel depot systems. Our active pharmaceutical ingredient selection criteria include:

- prior approval by the FDA for the targeted ophthalmic indication;
- expiration of relevant patent protection prior to or within our anticipated development timeline;
- high potency to minimize required drug load in the plug; high potency to minimize required drug load in the plug;
- availability from a qualified supplier; and
- compatibility with our drug delivery system.

Anticipated Benefits of Our Punctum Plugs Compared to Eye Drops

We believe our punctum plug product candidates may offer a range of favorable attributes as compared to eye drops, including:

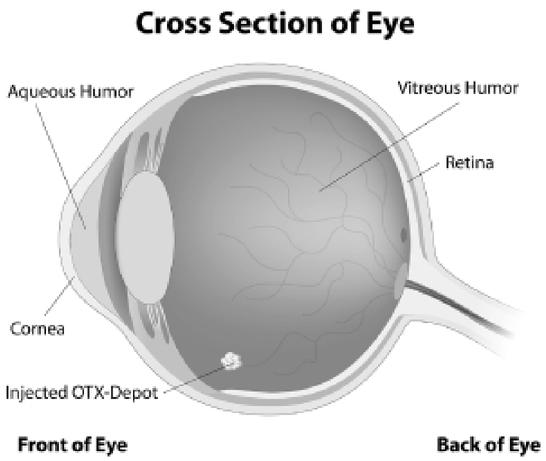
- *Improved patient compliance*. Our punctum plugs are inserted by a healthcare professional and are designed to provide sustained release of drug to the ocular surface. Because patients are not responsible for self-administration of the drug and the punctum plugs dissipate over time and do not require removal, we believe our punctum plugs address the problem of patient compliance.
- *Ease of administration*. We have designed our punctum plugs to provide the entire course of medication with a single administration by a healthcare professional for acute conditions or for several months for chronic conditions. We believe this avoids the need for frequent administration and the potential complications that could result if doses are missed.
- *Sustained delivery of drug*. We have designed our punctum plugs to deliver drug in a sustained fashion to the surface of the eye in order to avoid the peak and valley dosing and related side effects and spikes in intraocular pressure associated with eye drops. We also believe sustained dosing may improve the therapeutic profile of the active pharmaceutical ingredient because it eliminates periods of little or no drug presence between eye drop administrations. Further, we are designing our product candidates so that their drug release profiles can be tailored to match the treatment needs of the disease. For example, steroids for ophthalmic purposes generally require administration over four weeks, with tapered dosing over this period. In contrast, prostaglandin analogs require administration in a steady fashion over the duration of treatment. Our punctum plugs are designed to fully dissipate over a period of two to three times the length of the expected period of release of the therapeutic agent and can be removed if necessary by a healthcare professional.
- *Avoidance of preservative side effects*. Our punctum plugs do not involve the use of preservatives, such as BAK, which has been linked to side effects including burning, stinging, hyperemia, irritation, eye dryness and, less frequently, conjunctivitis or corneal damage.

Intravitreal Hydrogel Depot Injection for Back-of-the-Eye Diseases and Conditions

We are engaged in the preclinical development of a sustained release hydrogel depot administered via intravitreal injection to address the large and growing markets for diseases and conditions of the back of the eye. Our initial development efforts are focused on the use of our sustained release hydrogel depot in combination with anti-VEGF compounds for the treatment of wet AMD. Our initial goal for this program is to provide sustained release of an anti-VEGF compound over a four to six month period, thereby reducing the frequency of the current monthly or bi-monthly intravitreal injection regimen for wet AMD. We believe less frequent injections will be more convenient for patients and clinicians and may reduce the risk of infection and other potential side effects associated with each injection.

We are pursuing a multi-pronged strategy to seek to maximize the potential of this technology. We are collaborating with several different pharmaceutical companies using protein-based anti-VEGF agents on this program and are also conducting our own internal development using the anti-VEGF agent bevacizumab. We are exploring the delivery of small molecule drugs, such as tyrosine-kinase inhibitors, or TKIs, in our hydrogel depot and have been researching the optimal candidates for this program. We have narrowed our search down to several lead candidates. We believe this class of drugs is well suited for use with our platform given its high potency, multi-target capability, and low water solubility. In the absence of a sophisticated drug delivery system, these drugs have been difficult to deliver to the eye at therapeutic levels without causing local and systemic toxicity. We feel our local drug delivery technology gives us advantages in this regard. By selecting compounds that are compatible with our hydrogel platform technology and that will have expiration of relevant patents within the timeline of our development program, we would also avoid the need to license these molecules, thus retaining full worldwide rights to our products. We may seek to move forward on delivery of a small molecule on our own in parallel with a protein based anti-VEGF delivery program, which would require the involvement of a partner. We plan to continue working with our pharmaceutical company partners on development efforts and exploring potential business development deal structures as well as advancing our internal development efforts on our sustained release hydrogel depot for the treatment of back-of-the-eye diseases.

Our intravitreal hydrogel depot consists of a PEG based hydrogel suspension, which contains embedded micronized protein particles of an anti-VEGF compound. We designed the intravitreal hydrogel depot to be injected and retained in the vitreous humor, as depicted in the figure below, to provide sustained intravitreal delivery of anti-VEGF compounds.



We have designed our intravitreal hydrogel depot for delivery using ordinary syringes and fine gauge needles compatible with the current standard of care. Once in the vitreous humor, the hydrogel is designed to retain the anti-VEGF compound until it is released. We have designed the hydrogel to liquefy, dissolve and be cleared from the eye through hydrolysis over time. We design our hydrogels to control the hydrogel biodegradation rate and, as a result, the timing of anti-VEGF compound release.

ReSure Sealant for Ocular Wound Closure

ReSure Sealant is our bioresorbable hydrogel product for wound closure following cataract surgery. This product received marketing approval from the FDA in January 2014. We began the commercial launch of ReSure Sealant in February 2014 on a region-by-region basis in the United States through a network of independent distributors. A surgeon applies ReSure Sealant as a liquid painted onto the corneal incision. Within about 15 seconds, the sealant cross-links and transforms into a smooth, lubricious hydrogel that seals the wound. ReSure Sealant dissipates as healing progresses and does not require removal. In the pivotal clinical trials that formed the basis for FDA approval, ReSure Sealant provided superior wound closure and a better safety profile than sutured closure. However, we believe that the market opportunity for a surgical sealant following cataract surgery may be modest because sutures are used in only approximately 14% of cataract surgeries.

Development Pipeline and Marketed Product

The following table summarizes important information about our key product development programs and our marketed product, ReSure Sealant. We hold worldwide commercial rights to each of our product candidates and ReSure Sealant.

Product / Program	Indication	Description (Active Pharmaceutical Ingredient)	Stage of Development	Status
Approved Product				
ReSure Sealant	Cataract incision closure	Ocular sealant	Marketed	Approved by the FDA in January 2014; commercially launched in the United States in February 2014
Late Stage Product Candidates				
OTX-DP	Post-surgical ocular inflammation and pain	Punctum plug (Dexamethasone)	Phase 3	Two Phase 3 trials completed in the first quarter of 2015; NDA submission solely for ocular pain expected in the second half of 2015; third Phase 3 trial expected to be initiated in the second half of 2015
OTX-DP	Allergic conjunctivitis	Punctum plug (Dexamethasone)	Phase 2 completed	Phase 2 trial completed in November 2014; Phase 3 trials expected to be initiated in the middle of 2015, with efficacy data from the first Phase 3 trial expected in the fourth quarter of 2015
OTX-TP	Glaucoma	Punctum plug (Travoprost)	Phase 2b	Phase 2a trial completed in May 2014; Phase 2b trial initiated in November 2014; Phase 2b efficacy data expected in the fourth quarter of 2015
Earlier Stage Product Candidates				
OTX-DP	Inflammatory dry eye disease	Punctum plug (Dexamethasone)	Phase 2	Phase 2 trial initiated in January 2015; Phase 2 efficacy data expected in the fourth quarter of 2015
OTX-MP	Ocular Infection	Punctum plug (Moxifloxacin)	Phase 1 completed	Phase 2 planning underway
Anti-VEGF hydrogel depot	Wet AMD	Injectable hydrogel depot (Anti-VEGF compounds)	Preclinical	Ongoing preclinical studies

Dexamethasone Punctum Plug (OTX-DP)

Our OTX-DP product candidate incorporates the corticosteroid dexamethasone as an active pharmaceutical ingredient in our proprietary punctum plug. We are developing OTX-DP for the treatment of post-surgical ocular inflammation and pain, allergic conjunctivitis and inflammatory dry eye disease. We have designed OTX-DP to provide a sustained release of dexamethasone over a period of approximately 30 days. We recently reported topline results from two Phase 3 clinical trials for this indication. In the first Phase 3 clinical trial, OTX-DP met both primary efficacy endpoints, absence of pain at day 8 and absence of inflammatory cells at day 14, with statistical significance. In the second Phase 3 clinical trial, OTX-DP met the primary efficacy endpoint for absence of pain at day 8 with statistical significance but did not meet the primary efficacy endpoint for absence of inflammatory cells at day 14. Although we have been conducting our Phase 3 clinical trials of OTX-DP in patients who have undergone cataract surgery, these trials are intended to support a label for all post-surgical ocular inflammation and pain. We met with the FDA in April 2015 to discuss the path forward for seeking marketing approval of OTX-DP for the treatment of ocular inflammation and pain following ophthalmic surgery. In this pre-NDA clinical meeting, the FDA indicated that the existing data from our Phase 2 and Phase 3 clinical trials are appropriate to support an NDA submission for OTX-DP solely for an ocular pain indication. The FDA further indicated that we would need additional data from a third Phase 3 clinical trial for the inflammation endpoint to support the potential labeling expansion of OTX-DP's indications for use. We plan to initiate this third Phase 3 clinical trial for OTX-DP for the treatment of post-surgical ocular inflammation and pain in the second half of 2015. We expect to submit an NDA for OTX-DP solely for the treatment of ocular pain following ophthalmic surgery in the second half of 2015. Based on our expectations regarding initiation of our third Phase 3 clinical trial of OTX-DP and design of the trial and our estimates regarding patient enrollment, we expect to have topline efficacy data available from this trial in the second half of 2016. If the results of our third Phase 3 clinical trial of OTX-DP are favorable and subject to receiving approval for the pain indication pursuant to the initial NDA, we plan to submit an NDA supplement for OTX-DP for the treatment of ocular inflammation following ophthalmic surgery in the second half of 2016. If we receive approval of our initial NDA and our NDA supplement, we expect to commercially launch OTX-DP for post-surgical ocular inflammation and pain in the United States in the first half of 2017.

We selected dexamethasone as the active pharmaceutical ingredient for OTX-DP because it:

- is approved by the FDA and has a long history of ophthalmic use;
- is available on a generic basis;
- is highly potent and is typically prescribed for prevention of ocular inflammation and pain following ocular surgery;
- is available from multiple qualified suppliers; and
- has physical properties that are well suited for incorporation within our hydrogel punctum plugs.

Embedded within our OTX-DP punctum plug are dexamethasone drug particles that gradually erode and release the drug in a sustained fashion until the drug is depleted. As the dexamethasone drug particles erode and the hydrogel degrades by hydrolysis, the punctum plug softens, liquefies and is cleared through the nasolacrimal duct. We provide OTX-DP in a sterile, single use package without any added preservatives.

The standard regimen for dexamethasone eye drops following cataract surgery is administration four to six times daily, with a gradual tapering in the number of eye drops over a four week period. Such a regimen is often confusing to patients as they must remember to taper the number of times per day they administer the steroid, while also taking multiple drops of other drugs, such as antibiotics and NSAIDs. We believe that sustained delivery of drug to the eye may result in better control of ocular inflammation and pain as compared to eye drops and that a low dose amount may provide enhanced safety by eliminating spikes in intraocular pressure associated with high dose steroid eye drops.

Although dexamethasone is clinically effective in the treatment of late-phase inflammatory allergic reactions, the safety limitations associated with eye drop administration, including the potential to generate spikes in intraocular pressure due to the high levels of drug, have limited its widespread adoption as a treatment for this condition. These spikes in intraocular pressure can lead to drug-induced glaucoma. Further, use of oral anti-histamine medications as well as anti-histamine eye drops for allergic conjunctivitis may dry out the eye and exacerbate the discomfort to some patients. We believe, based on our clinical trial results to date, that periodic use of the OTX-DP for allergic conjunctivitis will create a low, tapered, consistent dose of dexamethasone, potentially minimizing or eliminating side effects associated with the eye drop formulation, while retaining the drug's anti-inflammatory effects.

One of the causes of dry eye disease is inflammation. Topical anti-inflammatory drugs are used as one of several therapies to treat dry eye disease and are administered by eye drops. As the understanding of dry eye disease, specifically the inflammatory components of dry eye disease, has evolved, the use of corticosteroids has become a standard to offer short-term relief of signs and symptoms of the disease. Physicians typically prescribe a topical corticosteroid for a period of two to four weeks, tapered over the course of delivery as the inflammation and symptoms subside. As with allergic conjunctivitis, there are safety limitations associated with the use of corticosteroids for inflammatory dry eye disease that have limited wide spread adoption. We believe that OTX-DP has potential as a short-term therapy for more severe cases of dry eye caused by inflammation, followed by the delivery of an immune modulating drug such as cyclosporine after the inflammation has been reduced.

Overview of OTX-DP Clinical Development

We are conducting clinical development of OTX-DP for the treatment of post-surgical ocular inflammation and pain, allergic conjunctivitis and inflammatory dry eye disease. Because OTX-DP incorporates an active pharmaceutical ingredient already approved by the FDA for the treatment of ocular inflammation and pain, we did not need to conduct Phase 1 clinical trials for this product candidate. The following summarizes our clinical development to date for OTX-DP.

- In March and April 2015, we reported topline results from two Phase 3 clinical trials for this indication. In the first Phase 3 clinical trial, OTX-DP met both primary efficacy endpoints, absence of pain at day 8 and absence of inflammatory cells at day 14, with statistical significance. In the second Phase 3 clinical trial, OTX-DP met the primary efficacy endpoint for absence of pain at day 8 with statistical significance but did not meet the primary efficacy endpoint for absence of inflammatory cells at day 14. We plan to initiate a third Phase 3 clinical trial for OTX-DP for the treatment of post-surgical ocular inflammation and pain in the second half of 2015. We expect to submit an NDA for OTX-DP solely for the treatment of ocular pain following ophthalmic surgery in the second half of 2015. Based on our expectations regarding initiation of our third Phase 3 clinical of OTX-DP and our estimates regarding patient enrollment, we expect to have topline efficacy data available from this trial in the second half of 2016. If the results of our third Phase 3 clinical trial of OTX-DP are favorable and subject to receiving approval for the pain indication pursuant to the initial NDA, we plan to submit an NDA supplement for OTX-DP for the treatment of ocular inflammation following ophthalmic surgery in the second half of 2016. If we receive approval of our initial NDA and our NDA supplement, we expect to commercially launch OTX-DP for post-surgical ocular inflammation and pain in the United States in the first half of 2017.
- In November 2014, we completed a Phase 2 clinical trial evaluating the safety and efficacy of OTX-DP for the treatment of allergic conjunctivitis. Based upon the encouraging results of this Phase 2 clinical trial and a subsequent meeting with the FDA, we expect to initiate two Phase 3 clinical trials of OTX-DP for this indication in the middle of 2015, with topline efficacy data from the first Phase 3 clinical trial expected to be available in the fourth quarter of 2015.
- In January 2015, we initiated a Phase 2 exploratory clinical trial of OTX-DP for the treatment of inflammatory dry eye disease. We expect to complete this trial in the fourth quarter of 2015 and then assess the future direction of the clinical development of this product candidate based on these results.

Clinical Trials for Post-surgical Inflammation and Pain

Completed Phase 2 Clinical Trial

In 2013, we completed a prospective, randomized parallel-arm, vehicle controlled, multicenter, double-masked Phase 2 clinical trial evaluating the safety and efficacy of OTX-DP for the treatment of ocular inflammation and pain following cataract surgery. We conducted this trial in 60 patients at four sites in the United States pursuant to an effective investigational new drug application, or IND. We randomized patients in a 1:1 ratio to receive either OTX-DP or a placebo vehicle control punctum plug without active drug. One patient randomized into the OTX-DP group was excluded from the trial because the investigator was unable to insert the plug, resulting in 29 patients in the OTX-DP group and 30 patients in the vehicle control group. We evaluated patients in this trial at days 1, 4, 8, 11, 14 and 30 following surgery.

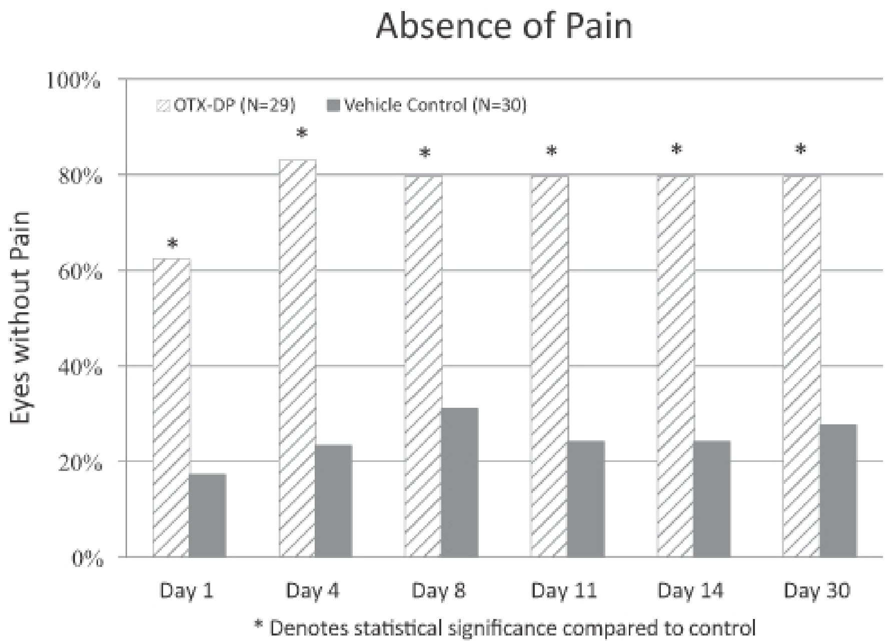
The two primary efficacy measures in this trial were absence of inflammatory cells in the anterior chamber of the study eye and absence of pain in the study eye. When viewed with a slit lamp biomicroscope, these inflammatory cells, referred to as cells in a slit lamp examination, appear like dust specks floating in a projected light beam. The presence of these cells in the anterior chamber indicates inflammation. In this trial, absence of pain was based on a patient reported score of zero on a scale from zero to ten of ocular pain assessment. The first primary efficacy endpoint was the difference in the proportion of patients in each treatment group with absence of cells in the anterior chamber of the study eye at day 8 following surgery. The second primary efficacy endpoint was the difference in the proportion of patients in each treatment group with absence of pain in the study eye at day 8 following surgery.

One of our goals for this trial was to determine appropriate primary endpoints for a subsequent Phase 3 clinical development.

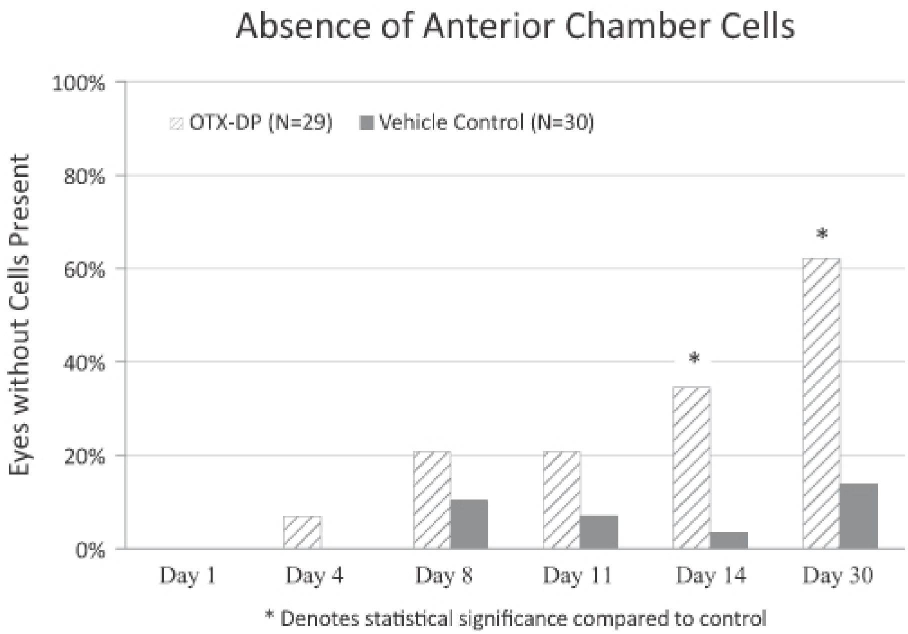
We evaluated as secondary measures the level of flare in the anterior chamber of the study eye at each evaluation date, absence of inflammatory cells in the anterior chamber of the study eye and absence of pain in the study eye at each evaluation date other than day 8 and plug retention and visualization. Flare is a scattering of light in the aqueous humor when viewed during a slit lamp biomicroscopic examination. Flare occurs when the protein content of the aqueous humor increases due to intraocular inflammation.

We enrolled patients in this trial who were at least 21 years of age undergoing unilateral clear corneal cataract surgery. We excluded patients from the trial if, among other reasons, they had intraocular inflammation or ocular pain in the study eye at screening or had glaucoma or ocular hypertension.

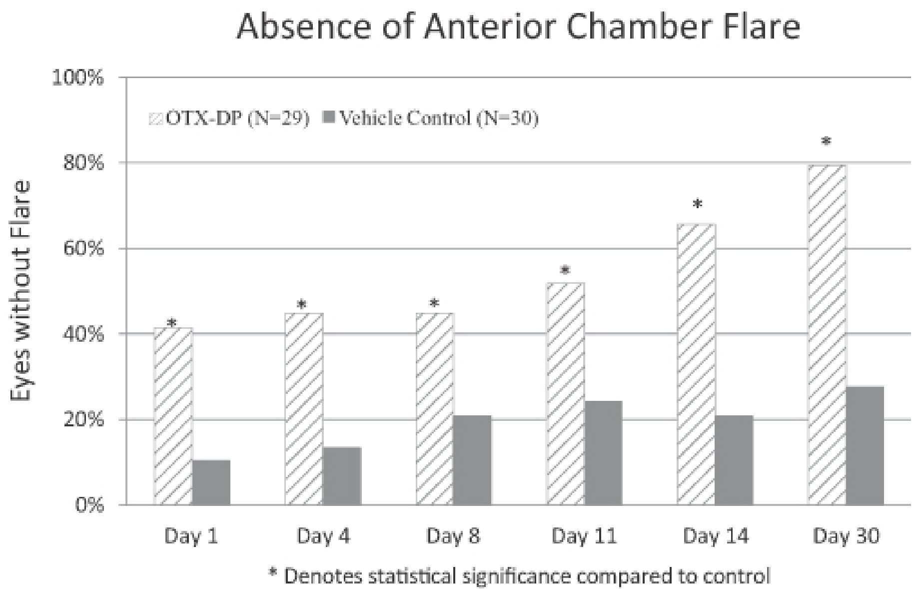
Efficacy: In this trial, OTX-DP met the primary efficacy endpoint with statistical significance for absence of pain compared to the vehicle control at day 8. 79.3% of patients receiving OTX-DP reported an absence of pain in the study eye on day 8 following insertion of the drug product, compared to 31.0% of those receiving the vehicle control punctum plug (p<0.0001). We determined statistical significance based on a widely used, conventional statistical method that establishes the p-value of clinical results. Typically, a p-value of 0.05 or less represents statistical significance. The differences between OTX-DP and the vehicle control for absence of pain also were statistically significant at each other evaluation date (p<0.0002). These results are shown in the graph below. In this graph and other graphs appearing further below, we use the abbreviation “N” to reference the number of patients in each group.



In this trial, OTX-DP did not meet the primary efficacy endpoint with statistical significance for absence of cells in the anterior chamber compared to the vehicle control at day 8. However, there was a trend of improved absence of anterior chamber cells at each evaluation date, with statistical significance at day 14. 34.5% of patients receiving OTX-DP showed an absence of inflammatory cells in the study eye on day 14 following insertion of the drug product, compared to 3.4% of those receiving the vehicle control punctum plug (p<0.0027). There was also statistical significance at day 30 (p< 0.0002). These results are shown in the graph below. The primary efficacy endpoint for inflammation in our Phase 3 clinical trials will measure the absence of anterior chamber cells at day 14. Pivotal clinical trials for other ophthalmic steroid drugs approved by the FDA for marketing in the United States also have evaluated this endpoint at day 14.



Based on post hoc analysis, OTX-DP showed statistical significance for absence of flare compared to vehicle control at each evaluation date. These results are shown in the graph below.



Safety: In this trial, there were three serious adverse events, none of which was considered related to the study treatment. The trial investigator determined the relatedness of the serious adverse events to study treatment based on his or her professional medical judgment and in accordance with the study protocol, which required the investigator to determine that a reasonable possibility did not exist that the study treatment caused the adverse event. None of the three serious adverse events, fainting, intracranial hemorrhage and bacterial skin infection, were ocular in nature. In addition, there were a variety of adverse events in both the OTX-DP group and the vehicle control group, with the adverse events in the vehicle control group outnumbering the adverse events in the OTX-DP group. In the OTX-DP group, the only adverse event that occurred more than once was reduced visual acuity, which occurred twice. The most common adverse events in the vehicle control group were reduced visual acuity, conjunctival hyperemia and corneal edema. Overall, 19 adverse events were noted in the OTX-DP group and 30 adverse events were noted in the vehicle control group. All adverse events were transient in nature and completely resolved by the end of the trial.

Phase 3 Clinical Program

In 2014, we initiated a pivotal clinical trial program that consisted of two prospective, randomized parallel-arm, vehicle controlled, multicenter, double-masked Phase 3 clinical trials evaluating the safety and efficacy of OTX-DP for the treatment of ocular inflammation and pain following cataract surgery. We initiated the first of these Phase 3 clinical trials in February 2014 and the second trial in April 2014. Patient enrollment was completed in September 2014 and the topline efficacy data from these clinical trials was reported in March and April 2015. We plan to initiate a third Phase 3 clinical trial in the second half of 2015.

We enrolled an aggregate of 488 patients in these trials at 32 sites in the United States pursuant to our effective IND. We randomized patients in a 2:1 ratio to receive either OTX-DP or a placebo vehicle control punctum plug without active drug. We enrolled 247 patients at 16 sites in the first Phase 3 clinical trial. We enrolled 241 patients at 16 sites in the second Phase 3 clinical trial. We evaluated patients at days 2, 4, 8, 14, 30 and 60 following surgery.

The two primary efficacy measures in these trials were absence of inflammatory cells in the anterior chamber of the study eye when measured with a slit lamp biomicroscope and absence of pain in the study eye. To meet the efficacy end point for absence of inflammatory cells, there needed to be a complete absence of inflammatory cells. In these trials, absence of pain was based on a patient reported score of zero on a scale from zero to ten of ocular pain assessment. The first primary efficacy endpoint for these trials is the difference in the proportion of patients in each treatment group with absence of inflammatory cells in the anterior chamber of the study eye at day 14 following surgery. The second primary efficacy endpoint for these trials is the difference in the proportion of patients in each treatment group with absence of pain in the study eye at day 8 following surgery.

We believe that the FDA will require that we demonstrate a statistically significant difference between treatment groups for each of these two primary efficacy endpoints to receive marketing approval for OTX-DP for the treatment of post-surgical ocular inflammation and pain.

We evaluated as secondary efficacy measures the level of flare in the anterior chamber of the study eye at each evaluation date other than day 60 and absence of inflammatory cells in the anterior chamber of the study eye and absence of pain in the study eye at each evaluation date other than the day used for the primary efficacy measure and day 60. The secondary analyses on primary endpoints are intended to be exploratory assessments that can be used to support the results from the primary endpoints. If we obtain favorable results showing effectiveness of OTX-DP at earlier time points for absence of cells or absence of pain, we will consider seeking to expand the labeling for OTX-DP as part of our NDA submission or following any marketing approval that we may receive. We enrolled patients in these two trials who were at least 18 years of age undergoing unilateral clear corneal cataract surgery. We excluded patients from these trials if, among other reasons, they have intraocular inflammation or ocular pain in the study eye at screening or have glaucoma or ocular hypertension.

We evaluated safety in all patients at each study visit with an assessment of general eye conditions, including visual acuity and intraocular pressure, along with any adverse events.

We plan to initiate the third Phase 3 clinical trial for OTX-DP for the treatment of post-surgical ocular inflammation and pain in the second half of 2015. We expect to enroll approximately 330 patients in this trial, with patients randomized in a 1:1 ratio to receive either OTX-DP or placebo. We plan to make modifications to the design of this third Phase 3 clinical trial compared to our two completed Phase 3 clinical trials of OTX-DP based on our learnings from these prior trials. These modifications relate to factors we believe impacted the results of the second Phase 3 clinical trial, including the use of rescue medications in patients with mild inflammation at the day 8 visit and the use of high dose oral non-steroidal anti-inflammatory drugs, or NSAIDs. Based on feedback from our meeting with the FDA, in the third Phase 3 clinical trial we plan to exclude patients receiving high doses of NSAIDs, such as Naproxen. In addition, we intend to provide additional guidance to study investigators regarding the use of rescue medications per the study protocol. Based on our expectations regarding initiation of this third Phase 3 clinical trial of OTX-DP and design of the trial and our estimates regarding patient enrollment, we expect to have topline efficacy data available from this trial in the second half of 2016.

Efficacy: In the first Phase 3 clinical trial, OTX-DP met the primary efficacy endpoint with statistical significance for absence of cells in the anterior chamber compared to the vehicle control at day 14. 33.7% of OTX-DP treated patients showed an absence of inflammatory cells in the anterior chamber of the study eye on day 14 following drug product insertion, compared to 14.6% of those receiving placebo vehicle control punctum plug ($p=0.0015$). OTX-DP also met the primary efficacy endpoint with statistical significance for absence of pain compared to the vehicle control at day 8. 76.1% of patients receiving OTX-DP reported absence of pain in the study eye on day 8 following insertion of the drug product, compared to 36.1% of those receiving placebo vehicle control punctum plug ($p< 0.0001$).

In the second Phase 3 clinical trial, OTX-DP met the primary efficacy endpoint for absence of pain at day 8 with statistical significance but did not meet the primary efficacy endpoint for absence of inflammatory cells at day 14. In the second Phase 3 clinical trial, 77.5% of patients receiving OTX-DP reported an absence of pain in the study eye on day 8 following insertion of the drug product, compared to 58.8% of those receiving placebo vehicle control punctum plug, a difference which was statistically significant (p=0.0025). However, 39.4% of OTX-DP treated patients showed an absence of inflammatory cells in the anterior chamber of the study eye on day 14 following drug product insertion, compared to 31.3% of those receiving placebo vehicle control punctum plug, a difference which was not statistically significant (p=0.2182).

Secondary analyses on primary endpoints for the two completed Phase 3 clinical trials have also been completed. In the first Phase 3 clinical trial, statistically significant differences were seen for absence of pain at all time points (days 2, 4, 8, 14, 30 and 60) in the OTX-DP treatment group compared to the vehicle control group. Statistically significant differences were seen for the absence of inflammatory cells at day 30 in the OTX-DP treatment group compared to the vehicle control group, and there were no statistically significant differences seen at the other time points.

In the second Phase 3 clinical trial, statistically significant differences were seen for absence of pain at days 2, 4, 14 and 30 in the OTX-DP treatment group compared to the vehicle control group. A similar proportion of patients in the OTX-DP treatment group and the vehicle control group were observed to have an absence of inflammatory cells at days 2, 4, 8, and 30. A statistically significant difference between treatment groups was not seen for the absence of inflammatory cells until the day 60 visit, at which time a greater proportion of patients in the OTX-DP treatment group compared to the vehicle control group were observed to have an absence of inflammatory cells at day 60 (p=0.0012).

We also performed additional retrospective post-hoc analyses that were not pre-specified in the trial protocol for our two completed Phase 3 clinical trials to provide further insight on the performance of the OTX-DP platform technology. Although post-hoc analyses performed after unblinding trial results can result in the introduction of bias, we believe that these retrospective analyses provide support for our decision to conduct a third Phase 3 clinical trial and provide additional information regarding our platform technology. The results from these post-hoc analyses are summarized as follows:

- When we pooled the aggregate results of the two completed Phase 3 clinical trials, we observed statistically significant differences between the OTX-DP treatment groups and the vehicle control groups for both the absence of pain at day 8 ($p < 0.0001$) and the absence of inflammatory cells at day 14 (p= 0.0025).
- When we combined the measures of complete absence of inflammatory cells (0.0 on a scale of zero to four) and very mild inflammation (0.5 on the same scale and defined as presence of a total of one to five inflammatory cells) for the second Phase 3 clinical trial, we observed statistically significant differences between the OTX-DP treatment group and the vehicle control group (p= 0.0004).

Although we have discussed with the FDA the results from these post-hoc analyses, these are not the primary efficacy measures to be considered by the FDA. In general, regulatory authorities give less weight to results from retrospective post-hoc analyses than pre-specified analyses.

Safety: There were no ocular or treatment related serious adverse events in the OTX-DP treatment group in either of the two completed Phase 3 clinical trials. There was one ocular serious adverse event in the vehicle control group in the two completed Phase 3 clinical trials, which was hypopyon, or inflammatory cells in the anterior chamber. There were two serious adverse events in the OTX-DP treatment group in the first Phase 3 clinical trial (1.2% incidence), compared with three serious adverse events in the vehicle control group (3.6% incidence). There were two serious adverse events in the OTX-DP treatment group in the second Phase 3 clinical trial (1.3% incidence), compared with three serious adverse events in the vehicle control group (3.8% incidence). In the first Phase 3 clinical trial, 98 adverse events were noted in the OTX-DP group and 59 adverse events were noted in the vehicle control group. In the second Phase 3 clinical trial, 74 adverse events were noted in the OTX-DP group and 47 adverse events were noted in the vehicle control group. Patients were randomized in a 2:1 ratio between the treatment group and the vehicle control group. All adverse events were either resolved or considered chronic/stable at the time of subject exit from the study. We expect to be able to use the safety data from these Phase 3 trials to support our other OTX-DP clinical development programs, including for allergic conjunctivitis.

Regulatory Pathway

We expect to finalize the clinical study reports for our pivotal Phase 3 OTX-DP clinical program for ocular inflammation and pain following cataract surgery and submit an NDA to the FDA for OTX-DP solely for ocular pain following ophthalmic surgery in the second half of 2015. Prior to submitting this NDA, we will also need to complete process validation for the manufacture of OTX-DP and obtain stability data for 12 months for OTX-DP. If the results of our third Phase 3 clinical trial of OTX-DP are favorable and subject to receiving approval for the pain indication pursuant to the initial NDA, we plan to submit an NDA supplement for OTX-DP for the treatment of ocular inflammation following ophthalmic surgery in the second half of 2016. We expect that we would submit these NDAs under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA. See "—Government Regulation—Section 505(b)(2) NDAs" for additional information. Although we conducted our Phase 3 clinical trials of OTX-DP in patients who have undergone cataract surgery, these trials are intended to support a label for all post-surgical ocular inflammation and pain.

Clinical Trials for Allergic Conjunctivitis

Completed Phase 2 Clinical Trial

In November 2014, we completed a prospective, randomized parallel-arm, vehicle controlled, multicenter, double-masked Phase 2 clinical trial evaluating the safety and efficacy of OTX-DP for the treatment of allergic conjunctivitis. We conducted this trial using a controlled exposure model commonly used to assess anti-allergy medications known as the Conjunctival Allergen Challenge model, or CAC™, which is a proprietary model owned by ORA, Inc., the clinical research organization we used to manage the trial. The CAC achieves a very high transient dose exposure by placing allergen directly into the space between the eyelid and the surface of the eye of the patient. We initially exposed patients to specified allergens to determine which allergens resulted in an allergic response for the patients. If patient was responsive to a particular allergen, we continued to expose the patient to that same allergen prior to each evaluation.

We enrolled 68 patients at two sites in the United States pursuant to our effective IND. We randomized patients in a 1:1 ratio to receive either OTX-DP or a placebo vehicle control punctum plug without active drug. We evaluated patients using three allergen challenges in series for each of the two efficacy measures at days 14, 28 and 42 following punctum plug insertion.

The primary efficacy measures for this trial were ocular itching graded by the patient and conjunctival redness graded by the trial investigator, in each case based on a five point scale from zero to four. The primary efficacy measures were differences between treatment groups of at least 0.5 units on the five point scale on day 14 for all three time points measured in a day for both ocular itching and conjunctival redness and differences between treatment groups of at least 1.0 unit for the majority of the three time points measured on day 14 for both ocular itching and conjunctival redness. The secondary endpoints for this trial were similar to the primary efficacy endpoints, except that each variable was assessed at days 28 and 42 following insertion of the punctum plug.

We enrolled patients in this trial who were at least 18 years of age with a positive history of ocular allergies and a positive skin test reaction to a perennial allergen and a seasonal allergen. We excluded patients from this trial if, among other reasons, they had an active ocular infection or itching or conjunctival redness at screening.

We evaluated safety in all patients at each study visit with an assessment of general eye conditions, including visual acuity and intraocular pressure, along with any adverse events.

Efficacy: In this trial, there was a statistically significant mean difference (p<0.05) between the OTX-DP treatment group and the vehicle group for both ocular itching and conjunctival redness at all three time points measured on days 14, 28, and 42 following insertion of the punctum plug. OTX-DP met one of the two primary efficacy measures. The OTX-DP treatment group achieved a mean difference compared to the vehicle control group of more than 0.5 units on a five point scale on day 14 for all three time points measured in a day for both ocular itching and conjunctival redness. The OTX-DP group did not achieve a mean difference compared to the vehicle control group of 1.0 unit for the majority of the three time points measured on day 14 for either ocular itching or conjunctival redness. However, in a pre-specified analysis group of a second site in the clinical trial, in which OTX-DP punctum plugs were inserted 48 to 72 hours following exposure to the allergen, rather than on the same day, we observed a mean difference in ocular itching between the OTX-DP group and the vehicle control group of approximately 1.0 unit for the majority of three time points measured on day 14.

The results of this trial for each of the three time points on day 14 for the OTX-DP group and the vehicle control group are shown in the table below:

Parameter	Time point	OTX-DP	Vehicle	Treatment Difference (P value)
Ocular Itching	3 min	1.80 (1.068)	2.58 (0.823)	-0.78 (0.0031)
	5 min	1.72 (0.998)	2.70 (0.865)	-0.98 (0.0002)
	7 min	1.65 (0.989)	2.53 (0.880)	-0.88 (0.0007)
Conjunctival Redness	7 min	1.60 (0.753)	2.11 (0.727)	-0.51 (0.0100)
	15 min	1.53 (0.753)	2.23 (0.708)	-0.70 (0.0006)
	20 min	1.54 (0.739)	2.21 (0.696)	-0.67 (0.0008)

Safety: In this trial, there was one serious adverse event in the treatment arm, which was depression. The trial investigator determined the relatedness of the serious adverse event to study treatment based on his or her professional medical judgment and in accordance with the study protocol, which required the investigator to determine that a reasonable possibility did not exist that the study treatment caused the adverse event. The serious adverse event was not ocular in nature. In addition, there were a variety of adverse events in both the OTX-DP group and the vehicle control group, with nine ocular related adverse events and two non-ocular adverse events in the OTX-DP group and eight ocular adverse events and two non-ocular adverse events in the vehicle control group. In the OTX-DP group, the only adverse event that occurred more than once was reduction in visual ocuity and increased intraocular pressure, both of which occurred twice. The most common adverse events in the vehicle control group were erythera of the eyelid, discharge from the eye and an increase in lacrimation, all of which occurred twice. All adverse events were transient in nature and completely resolved by the end of the trial.

Planned Phase 3 Clinical Program

We met with the FDA in December 2014 to review the Phase 2 clinical trial results of OTX-DP for the treatment of allergic conjunctivitis and to discuss our planned Phase 3 clinical development program. Based on these discussions, we plan to initiate two prospective, randomized parallel-arm, vehicle controlled, multicenter, double-masked Phase 3 clinical trials in the middle of 2015 to evaluate the safety and efficacy of OTX-DP for the treatment of allergic conjunctivitis. We plan to conduct this trial using the CAC model. We plan to enroll 72 patients in each of the Phase 3 clinical trials and randomize patients in a 1:1 ratio to receive either OTX-DP or a placebo vehicle control punctum plug without active drug. We plan to evaluate patients using three allergen challenges in series for each of two efficacy measures at days 7, 14 and 28 following punctum plug insertion.

As in the Phase 2 trial, we expect that the primary efficacy measures for this trial will be ocular itching graded by the patient and conjunctival redness graded by the trial investigator, in each case based on a five point scale from zero to four. We expect that the primary efficacy endpoints will be differences between the treatment group and the vehicle group of at least 0.5 units on the five point scale on day 7 for all three time points measured in a day for both ocular itching and conjunctival redness and differences of at least 1.0 unit for the majority of the three time points measured on day 7 for both ocular itching and conjunctival redness. We expect that the secondary endpoints for this trial will be similar to the primary efficacy endpoints, except that each variable will be assessed at day 28 following insertion of the punctum plug. In our Phase 3 clinical trials, we plan to insert the punctum plugs 48 to 72 hours after exposure to the allergen. In our completed Phase 2 clinical trial, we obtained better efficacy results when OTX-DP punctum plugs were inserted 48 to 72 hours following exposure to the allergen, rather than on the same day, as noted in the description of the Phase 2 efficacy results above.

We plan to enroll patients in this trial who are at least 18 years of age with a positive history of ocular allergies and a positive skin test reaction to a perennial allergen and a seasonal allergen. We plan to exclude patients from this trial if, among other reasons, they have an active ocular infection or itching or conjunctival redness at screening.

We plan to evaluate safety in all patients at each study visit with an assessment of general eye conditions, including visual acuity and intraocular pressure, along with any adverse events.

Regulatory Pathway

We reviewed our Phase 2 results with the FDA during a meeting in December 2014 and based on these discussions expect to initiate two Phase 3 clinical trials evaluating OTX-DP for the treatment of allergic conjunctivitis in the middle of 2015, with topline efficacy data from the first Phase 3 clinical trial expected to be available in the fourth quarter of 2015. If we obtain favorable results on one or both primary efficacy endpoints, we plan to submit an NDA supplement, or sNDA, to the FDA for OTX-DP for this indication. Depending on the results of our Phase 3 clinical trials and further discussions with the FDA, we could determine to seek approval for both ocular itching and conjunctival redness or only one of these indications. We expect that we would submit this sNDA under Section 505(b)(2) of the FDCA. See “—Government Regulation—Section 505(b)(2) NDAs” for additional information. Based on discussions with the FDA, we expect to use safety results from our Phase 3 clinical trials of OTX-DP for post-surgical ocular inflammation and pain to support the sNDA for OTX-DP for allergic conjunctivitis.

Clinical Trial for Inflammatory Dry Eye

Phase 2 Clinical Trial

In January 2015, we initiated a prospective, randomized parallel-arm, vehicle controlled, multicenter, bilateral, double-masked Phase 2 feasibility study evaluating the safety and efficacy of OTX-DP for the treatment of inflammatory dry eye disease. We enrolled 43 patients, and will evaluate 86 eyes, at two sites in the United States pursuant to our effective IND. We randomized patients in a 1:1 ratio to receive either OTX-DP or a placebo vehicle control punctum plug without active drug.

Designed as a serial phase exploratory study, patients are initially administered a placebo vehicle plug for 30 days to establish a baseline for the investigational drug treatment. Patients who respond to the placebo plug in treatment of their dry eye disease are excluded from the trial. Patients who continue to exhibit symptoms of dry eye disease during the initial 30 days are qualified for enrollment in the treatment phase of the trial. Qualified patients are then randomized to either OTX-DP or a placebo vehicle plug. Primary efficacy measures include corneal and conjunctival staining, tear osmolarity, tear film break-up time, presence of the plug, ease of product use and visualization, and resorption of the plug following therapy. We expect to complete this trial in the second half of 2015 and assess the future direction of the clinical development of this product candidate based on these results. Our long term strategy for the treatment of dry eye may be to use OTX-DP as an initial mode of therapy to reduce inflammation followed by a punctum plug containing an immunosuppressant drug such as cyclosporine. For more chronic treatment of dry eye, we continue to conduct early stage research to identify product candidates that would be suitable for this multifactorial disease.

Travoprost Punctum Plug (OTX-TP)

Our OTX-TP product candidate incorporates the prostaglandin analog travoprost as an active pharmaceutical ingredient in our proprietary punctum plug. We are developing OTX-TP for the treatment of glaucoma and ocular hypertension. We have completed a Phase 2a clinical trial of OTX-TP and initiated a Phase 2b clinical trial of OTX-TP in the United States in November 2014. We expect to complete enrollment of this trial in the third quarter of 2015, with topline efficacy data expected to be available in the fourth quarter of 2015.

Travoprost is a synthetic prostaglandin analog that reduces intraocular pressure by enhancing the clearance and drainage of ocular fluid.

We selected travoprost as the active pharmaceutical ingredient for OTX-TP because it:

- is approved by the FDA for the treatment of glaucoma and ocular hypertension;
- has relevant patent protection that expired in December 2014;
- is a highly potent PGA molecule;
- is available from multiple qualified suppliers; and
- has physical properties that are well suited for incorporation within our hydrogel punctum plugs.

We have designed OTX-TP to provide a sustained release of therapeutic levels of travoprost for up to three months. We have tested versions of OTX-TP that are capable of sustained delivery over a one-month, a two-month and a three-month period. The retention time of our punctum plugs varies from patient to patient due to various physiological factors and particular stresses to which the punctum plugs may be subjected. We have conducted a series of non-significant risk, or NSR, investigational device exemption, or IDE, studies with improved product designs and placement procedures with the goal of achieving higher retention rates. We have achieved successive improvements in retention, with as high as a 92% retention rate at day 90 in one of these NSR studies. Our completed pilot studies evaluated one-month and two-month versions of OTX-TP. In our Phase 2a clinical trial, we evaluated two-month and three-month versions of OTX-TP. In our Phase 2b clinical trial, we are evaluating an improved three-month version of OTX-TP. In our pilot studies, the OTX-TP plugs we evaluated were violet to provide a visual assessment of plug position. In our subsequent Phase 2 clinical trials, we switched to a fluorescent yellow color to improve visibility and are using this same fluorescent marker in our Phase 2b clinical trial.

In addition to the PEG based hydrogel, OTX-TP contains bioresorbable microparticles which contain encapsulated travoprost. We designed OTX-TP to provide a sustained release of travoprost at therapeutic levels for the duration of therapy as the microparticles degrade. We provide OTX-TP in a sterile, single use package without any added preservatives.

Overview of OTX-TP Clinical Development

We are conducting clinical development of OTX-TP for glaucoma and ocular hypertension. Because OTX-TP incorporates an active pharmaceutical ingredient already approved by the FDA for the treatment of glaucoma and ocular hypertension, we did not need to conduct Phase 1 clinical trials for this product candidate. However, we did conduct two pilot studies to assess safety and to obtain initial efficacy data. The following summarizes our clinical development to date for OTX-TP.

- In 2012, we conducted two pilot studies evaluating the safety and efficacy of two versions of OTX-TP for the treatment of glaucoma and ocular hypertension over a 30 to 60 day period.

- In 2014, we completed a Phase 2a clinical trial of two versions of OTX-TP for the treatment of glaucoma and ocular hypertension to evaluate reduction in intraocular pressure over a 60 to 90 day period. This completed trial provided important information regarding the effects in patients of the drug delivery rates for our plugs that informed the design of the OTX-TP plug that we are using in our Phase 2b clinical trial for this indication.
- In the November 2014, we initiated a Phase 2b clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension to evaluate reduction in intraocular pressure over a 60 to 90 day period. We expect to complete enrollment of this trial in the third quarter of 2015, with topline efficacy data expected to be available in the fourth quarter of 2015.
- We are conducting ongoing studies of punctum plugs without active drug to assess compositional and dimensional parameters of the punctum plug in an effort to optimize retention.

Clinical Trials for Glaucoma and Ocular Hypertension

Completed Singapore Pilot Study

In 2012, we completed a prospective, single arm, open label pilot study evaluating the initial safety and efficacy of the one-month version of OTX-TP for the treatment of glaucoma and ocular hypertension. We conducted this trial in 17 patients, and in 26 eyes, at two sites in Singapore.

We enrolled patients in this trial who were at least 21 years of age with a documented diagnosis of ocular hypertension or open-angle glaucoma, baseline intraocular pressure within a specified range and a specified minimum level of visual acuity in each eye. The trial protocol provided that if the participant's intraocular pressure was high despite treatment with OTX-TP, rescue medication would be made available to the patient. For patients who were currently under treatment for ocular hypertension or glaucoma, we required a drug washout period for these medications between screening and first visit.

We evaluated patients at days 3, 10, 20 and 30 following insertion of the plug and made the following assessments:

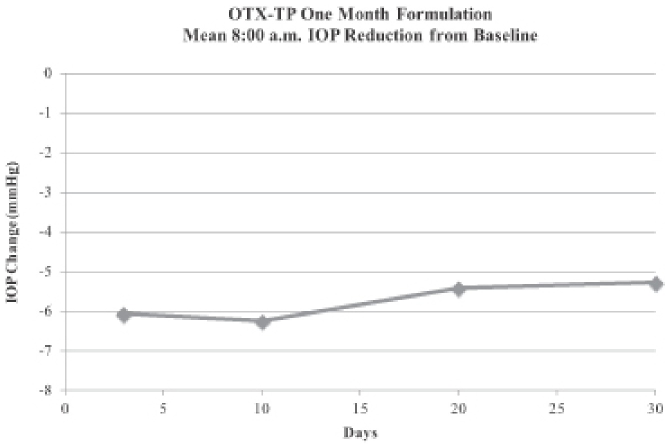
- mean intraocular pressure at 8:00 a.m. at each evaluation date as measured in millimeters of mercury, or mmHg;
- mean intraocular pressure at 12:00 p.m. and 4:00 p.m. at days 10, 20 and 30;
- change in mean intraocular pressure from baseline at each time point measured; and
- retention of the plug in the canaliculus at days 10, 20 and 30.

We assessed intraocular pressure at multiple time points on each evaluation date because intraocular pressure naturally varies over the course of the day.

For patients who are affected bilaterally, if both eyes met all eligibility criteria, both eyes were treated, but only the eye with the higher mean intraocular pressure at baseline was included in the efficacy analysis.

Efficacy: On day 10, 100% of the plugs were retained, on day 20, 88% of the plugs were retained, and on day 30, 79% of the plugs were retained.

We observed a clinically meaningful reduction in mean intraocular pressure over the 30 day trial period. For eyes that retained the plug, from a mean baseline intraocular pressure of 27.2 mmHg, the mean intraocular pressure during treatment was maintained at or below 22 mmHg at each evaluation date and time point. The mean reduction in intraocular pressure from baseline ranged from 5.3 mmHg (20%) to 8.2 mmHg (30%) across all evaluation dates and time points. In studies conducted by third parties, a sustained 5.0 mmHg reduction in intraocular pressure reduced risk of disease progression by approximately 50%. The results for change in mean intraocular pressure from baseline at 8:00 a.m. on each evaluation date are set forth in the graph below.



Safety: In this trial, there were no serious adverse events or unanticipated adverse events. There was only one adverse event, bilateral epiphora, or excess tearing of both eyes, which was transient in nature and completely resolved after plug removal. There were no significant changes in hyperemia scores from baseline through day 30. There were no notable observations of clinical relevance among the slit lamp biomicroscopy assessments.

Completed South Africa Pilot Study

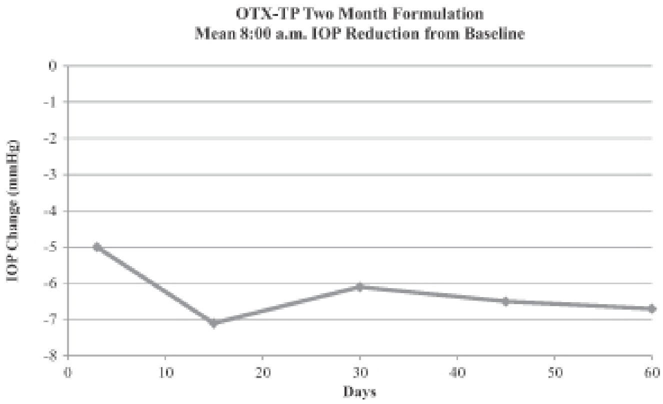
In 2012, we completed a prospective, single arm, open label pilot study evaluating the initial safety and efficacy of the two-month version of OTX-TP for the treatment of glaucoma and ocular hypertension. We conducted this trial in 20 patients, and in 36 eyes, at two sites in South Africa.

Enrollment criteria were comparable to our Phase 1 Singapore trial described above, except that the minimum patient age was 18.

We evaluated patients at days 3, 15, 30, 45 and 60 following insertion of the plug and made the same assessments with respect to mean intraocular pressure, change in mean intraocular pressure from baseline and retention of the plug in the canaliculus at each evaluation date following day 3 as in our Phase 1 Singapore trial described above.

Efficacy: On day 15, 97% of the plugs were retained, on day 30, 92% of the plugs were retained, on day 45, 78% of the plugs were retained, and on day 60, 59% of the plugs were retained. Because of the limitations of the visualization of the violet color through pigmented eyelids, it is possible that punctum plugs identified as not being retained were in fact retained but not visible, particularly given the sustained reduction in intraocular pressure through day 60 described below. We have since eliminated the violet colorant in favor of a fluorescent PEG hydrogel, resulting in greatly improved visualization.

We observed a clinically meaningful reduction in mean intraocular pressure over the 60 day trial period. For eyes that retained the plug, from a mean baseline intraocular pressure of 28.7 mmHg, the mean intraocular pressure during treatment was maintained at or below 22.0 mmHg beginning on day 15 and at all subsequent evaluation dates. The mean reduction in intraocular pressure from baseline ranged from 5.0 mmHg (18%) to 7.1 mmHg (25%) across all evaluation dates and time points. The results for change in mean intraocular pressure from baseline at 8:00 a.m. on each evaluation date are set forth in the graph below for patients who retained the plug on such date.



There were only two cases in which intraocular pressure remained high even though the plug was confirmed to be present. In each of these cases, the investigator prescribed rescue medication at the end of the visit. It is possible that this elevated intraocular pressure was the result of the participants not responding to travoprost.

Safety: In this trial, there were no serious adverse events or unanticipated adverse events. The most common adverse event was inflammatory reaction, which was noted in three patients. All adverse events were transient in nature and completely resolved by the end of the trial. There were no significant changes in hyperemia scores from baseline through day 60. There were no notable observations of clinical relevance among the slit lamp biomicroscopy assessments.

Completed South Africa Phase 2a Clinical Trial

In May 2014, we completed a prospective, randomized multi-arm, active controlled, multicenter, double masked Phase 2 clinical trial evaluating the safety and efficacy of two versions of OTX-TP for the treatment of glaucoma and ocular hypertension. The OTX-TPa version was intended to release travoprost over a two-month period, and the OTX-TPb version was intended to release travoprost at a slower rate over a three-month period. Based on in vitro testing, the OTX-TPa version had an average daily drug delivery rate of 3.5 micrograms per day and the OTX-TPb version had an average daily drug delivery rate of 2.8 micrograms per day. We conducted this trial in 41 patients at four sites in South Africa. In this trial, we randomized 11 patients for treatment with OTX-TPa and placebo eye drops, 17 patients for treatment with OTX-TPb and placebo eye drops and 13 patients for treatment with a placebo vehicle control punctum plug without active drug and timolol eye drops. One patient randomized into the timolol group was excluded from the trial because the investigator was unable to insert the plug. We randomized more patients in the OTX-TPb group than in the OTX-TPa group because we ceased enrolling patients in the OTX-TPa group during the trial based on an amendment to our trial protocol intended to facilitate the completion of the trial and to allow us to evaluate a larger number of patients being treated with a three-month version of the plug. Timolol is the most commonly prescribed non-PGA drug for the treatment of glaucoma and has been used as a comparator drug in pivotal clinical trials for other approval glaucoma products.

The primary efficacy endpoints in this trial are differences between treatment groups in:

- mean change in intraocular pressure from baseline on each evaluation date and at each time point;

- mean percent change in intraocular pressure from baseline on each evaluation date and at each time point; and
- mean intraocular pressure on each evaluation date and at each time point.

We designed our Phase 2a clinical trial to assess clinically meaningful response to treatment, and did not power the trial to measure any efficacy endpoints with statistical significance. We expect that our planned Phase 3 clinical trials for OTX-TP described below will be the first clinical trials for OTX-TP to be powered with an appropriate number of patients to allow us to measure with statistical significance the non-inferiority of OTX-TP compared to a vehicle control punctum plug plus timolol eye drops for the treatment of glaucoma and ocular hypertension based on the primary efficacy endpoint. We are also evaluating retention of the plug as a secondary endpoint.

We enrolled patients in this trial who were at least 18 years of age with a documented diagnosis of ocular hypertension or open-angle glaucoma, baseline intraocular pressure within a specified range and a specified minimum level of visual acuity in each eye. We excluded patients from this trial if, among other reasons, they had a history of inadequate response to treatment with prostaglandins or beta-blockers. For patients who were currently under treatment for ocular hypertension or glaucoma, we required a drug washout period for these medications between screening and first visit.

We evaluated patients at days 3, 15, 30, 45, 60, 75 and 90 following insertion of the plug and made the following assessments:

- mean intraocular pressure at 8:00 a.m. at each evaluation date;
- mean intraocular pressure at 12:00 p.m. and 4:00 p.m. at days 30, 60 and 90;
- change in mean intraocular pressure from baseline at each time point measured; and
- retention of the plug in the canaliculus at each evaluation date.

For patients who are affected bilaterally, if both eyes met all eligibility criteria, both eyes were treated, but only the eye with the higher mean intraocular pressure at baseline was included in the primary efficacy analysis.

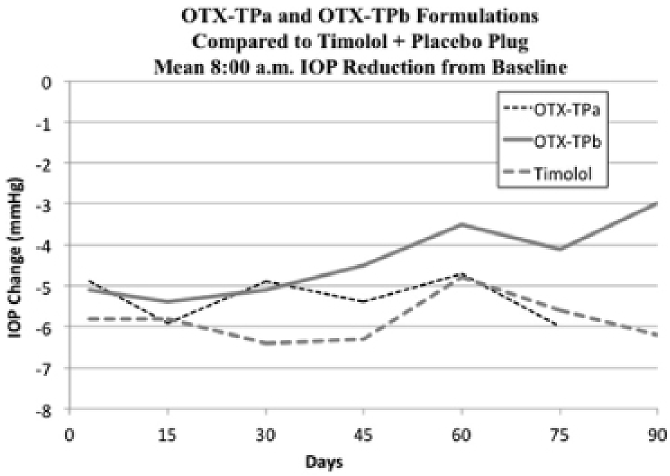
We evaluated safety in all patients at each study visit with an assessment of general eye conditions, including visual acuity, along with any adverse events.

Efficacy: In the timolol group, for eyes that retained the plug, from a mean baseline intraocular pressure of 26.1 mmHg, the mean intraocular pressure during treatment was maintained at or below 21.3 mmHg beginning on day 15 and at all subsequent evaluation dates and time points. The mean reduction in intraocular pressure from baseline ranged from 3.2 mmHg (13%) to 6.4 mmHg (25%) across all evaluation dates and time points through day 75.

In the OTX-TPa group, for eyes that retained the plug, from a mean baseline intraocular pressure of 25.8 mmHg, the mean intraocular pressure during treatment was maintained at or below 21.1 mmHg beginning on day 15 and at all subsequent evaluation dates and time points through day 75. The OTX-TPa formulation, originally intended to deliver drug over a two-month period, exceeded our expectations, delivering drug for 75 days. The mean reduction in intraocular pressure from baseline ranged from 3.2 mmHg (19%) to 6.0 mmHg (23%) across all evaluation dates and time points through day 75.

In OTX-TPb group, for eyes that retained the plug, from a mean baseline intraocular pressure of 26.4 mmHg, the mean intraocular pressure during treatment was maintained at or below 23.4 mmHg beginning on day 15 and at all subsequent evaluation dates and time points. The mean reduction in intraocular pressure from baseline ranged from 2.0 mmHg (8%) to 5.4 mmHg (20%) across all evaluation dates and time points.

The results for change in mean intraocular pressure for patients in the OTX-TPa group, for patients in the OTX-TPb group and for patients in the timolol group from baseline at 8:00 a.m. on each applicable evaluation date are set forth in the graph below, in each case for patients who retained the plug on such date. We believe that the lower average daily drug delivery rate in the OTX-TPb group resulted in less reduction of mean intraocular pressure in this group as compared to the OTX-TPa group. As discussed below, we plan to evaluate an improved three-month version of OTX-TP in our Phase 2b clinical trial.



Safety: In this trial, there were no serious adverse events. The most common adverse event was inflammatory reaction, which was noted in five patients. All adverse events were transient in nature and resolved by the end of the trial. There were no significant changes in hyperemia scores from baseline through day 90. There were no notable observations of clinical relevance among the slit lamp biomicroscopy assessments.

Ongoing U.S. Phase 2b Clinical Trial

In November 2014, we initiated a prospective, randomized, parallel-arm, active controlled, multicenter, double-masked Phase 2b clinical trial to evaluate the safety and efficacy of OTX-TP for the treatment of glaucoma and ocular hypertension after submitting an IND to the FDA for this indication. We plan to conduct this trial in 80 patients, and in up to 160 eyes, at 10 sites in the United States pursuant to our effective IND. As of May 31, 2015, we had enrolled 70 patients in this Phase 2b clinical trial of OTX-TP. We expect to complete enrollment of this trial in the third quarter of 2015, with topline efficacy data expected to be available in the fourth quarter of 2015. We are randomizing patients in a 1:1 ratio to receive either OTX-TP and placebo eye drops or a placebo vehicle control punctum plug without active drug and eye drops containing timolol. Patients are being instructed to use the placebo drops or timolol drops twice daily for the duration of the trial. Based on the results of our completed Phase 2a clinical trial, we designed the OTX-TP plug for use in our Phase 2b clinical trial to deliver drug over a 90 day period at the same daily rate as the OTX-TPa plug used in the Phase 2a clinical trial. To achieve this, we modified the design of the OTX-TP plug to enlarge it in order to enable the plug to carry a greater amount of drug. We previously evaluated in our Phase 1 clinical trial of OTX-MP in patients following cataract surgery a plug of similar length to the plug we are using in our Phase 2b clinical trial. These structural changes were previously evaluated in NSR studies that we describe below.

The study endpoint measures in this trial are the following:

- difference between treatment groups in the mean change in intraocular pressure from baseline at day 60, calculated by averaging the change from baseline across the three time points at the assessment date, which is known as diurnal intraocular pressure;

- difference between treatment groups in the mean change from baseline in average diurnal intraocular pressure at day 90;
- difference between treatment groups in the mean change from baseline in intraocular pressure at each individual time point at day 60 and day 90;
- difference between treatment groups in the mean change in average diurnal intraocular pressure and intraocular pressure at each individual time point at day 60 and day 90; and
- difference between treatment groups in the mean percent change from baseline in average diurnal intraocular pressure and intraocular pressure at each individual time point at day 60 and 90.

We are designing our Phase 2b clinical trial to assess clinically meaningful response to treatment, and will not be powering the trial to measure any efficacy endpoints with statistical significance.

We are enrolling patients in this trial who are at least 18 years of age with a documented diagnosis of ocular hypertension or open-angle glaucoma, baseline intraocular pressure within a specified range and a specified minimum level of visual acuity in each eye. We are excluding patients from this trial if, among other reasons, they have a history of inadequate response to treatment with prostaglandins or beta-blockers. For patients under treatment for ocular hypertension or glaucoma, we are requiring a drug washout period for these medications between screening and first visit.

We evaluate patients at days 3, 15, 30, 45, 60, 75 and 90 (with insertion of the plug on day 1) and make the following assessments:

- mean intraocular pressure and change in mean intraocular pressure from baseline at 8:00 a.m. at days 3, 15, 45 and 75; and
- mean intraocular pressure and change in mean intraocular pressure from baseline at 8:00 a.m., 12:00 p.m. and 4:00 p.m. at days 30, 60 and 90.

We are evaluating safety in all patients at each study visit with an assessment of general eye conditions, including visual acuity, along with any adverse events.

We are also collecting data on punctum plug presence along with visualization of the punctum plug by both the study patient and the investigator. The patients are instructed to assess plug presence on a daily basis and report the absence of a plug immediately. This provides a method to assess the accuracy of patient self-examination for plug presence. In addition, if the investigator confirms the plug is no longer present at any time prior to day 90, a new plug will be inserted. We expect that this will maximize the consistency of dosing.

Non-Significant Risk Retention Studies

We conduct NSR IDE studies on an ongoing basis for the purpose of refining our punctum plug product and placement procedure. We conduct these NSR studies under FDA IDE regulations, although no specific FDA approval is required. We are able to conduct NSR studies because punctum plugs without active drug are well established ophthalmic medical devices. The NSR study process allows us to make relatively quick evaluations of our punctum plug design and placement procedure in human subjects.

In a series of completed NSR studies, we have effected compositional and dimensional adjustments to our punctum plug to optimize retention. We have also used these studies to evaluate punctum plug placement, as well as removal and repeat placements.

As discussed above, we plan to conduct additional NSR studies on different versions of our punctum plug in an effort to improve plug retention rates and the placement procedure over time. We have seen a range of results in NSR studies to date, with one recent study achieving a retention rate as high as 92% at day 90.

We believe that with the current level of retention with our punctum plug design and given the ability of patients to assess the presence of the plug as a result of the fluorescent label, our current product design offers a potentially significant improvement over the current standard of care with patients receiving prostaglandin analogs. The compliance rate with prostaglandin analog eye drops has been shown to be only approximately 50% after six months of therapy due to the challenges of administration and side effects including hyperemia, or red eye.

Regulatory Pathway

We anticipate that the results of our Phase 2b clinical trial of OTX-TP will provide important information to inform the design of later stage clinical trials of this product candidate. We will be required to successfully complete two well controlled Phase 3 clinical trials of OTX-TP conducted under an IND to obtain marketing approval from the FDA. The FDA has indicated that we will need to study 500 treated patients for an exposure duration of three months in these pivotal clinical trials, with 300 of these patients studied further up to six months and with 150 of these patients studied up to 12 months for safety evaluations. We expect patients to be randomized in a 1:1 ratio to receive either OTX-TP or a placebo vehicle control punctum plug without active drug. We expect that the primary efficacy endpoints for these pivotal clinical trials will be similar to our ongoing Phase 2b clinical trial, as described above. However, unlike our Phase 2b clinical trial, we expect that the pivotal clinical trials will be adequately powered with an appropriate number of patients to measure with statistical significance the non-inferiority of OTX-TP compared to a vehicle control punctum plug plus timolol eye drops based on the primary efficacy endpoint. If we obtain favorable results from these pivotal clinical trials, we would plan to submit an NDA to the FDA for marketing approval of OTX-TP for the treatment of glaucoma. We expect that we would submit this NDA under Section 505(b)(2) of the FDCA. See "—Governmental Regulation—Section 505(b)(2) NDAs" for additional information.

Moxifloxacin Punctum Plug (OTX-MP)

Our OTX-MP product candidate incorporates the antibiotic moxifloxacin as an active pharmaceutical ingredient. We have completed a Phase 1 clinical trial of OTX-MP evaluating safety and pharmacokinetics in patients following cataract surgery. Although we believe that OTX-MP has potential to treat bacterial conjunctivitis and corneal ulcers, we are currently prioritizing our allocation of resources to the clinical development of our OTX-DP and OTX-TP clinical development programs and do not have plans currently to allocate clinical development resources to later stage clinical testing of OTX-MP. We will continue to assess our strategy and, if resources are available to fund this program, we would expect to initiate additional clinical trials to evaluate OTX-MP for a particular ocular infection indication. If we determine to proceed with later stage clinical testing of OTX-MP, we expect to select the specific indication for clinical development based on our assessment of clinical and regulatory pathways, including the relative expected costs and availability of our resources.

We selected moxifloxacin as the active pharmaceutical ingredient for OTX-MP because it:

- is approved by the FDA for bacterial conjunctivitis;
- is available on a generic basis;
- offers high lethality against gram-positive organisms while maintaining gram-negative lethality;
- is available from multiple qualified suppliers; and
- has physical properties that are well suited for incorporation within our hydrogel punctum plugs.

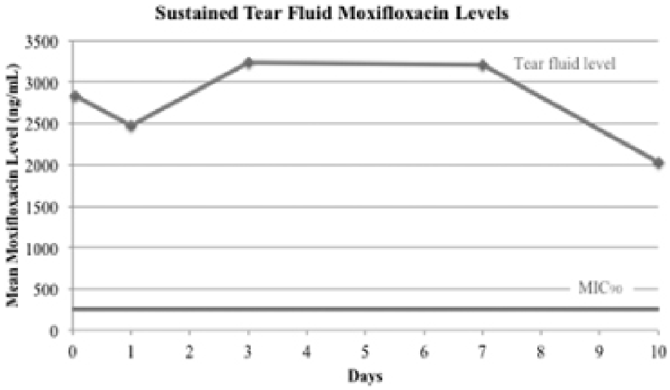
Completed Phase 1 Clinical Trial

In 2010, we completed a prospective, single center, single arm, open label Phase 1 clinical trial evaluating the initial safety and pharmacokinetics of OTX-MP in post-cataract surgery patients. We conducted the trial in 10 patients at one site in Singapore.

We enrolled patients in this trial who were at least 21 years of age undergoing clear corneal cataract surgery. We evaluated patients at days 1, 3, 7, 10, 20 and 30 following insertion of the plug and made the following assessments:

- retention of the plug in the canaliculus on each evaluation date;
- moxifloxacin level in tear fluid on each evaluation date; and
- ease of use.

Efficacy: We have designed our OTX-MP product candidate to provide for the release of moxifloxacin over a period of up to two weeks and to be fully resorbed by day 30. In this trial, the plug was present in 100% of eyes through day 10 and 0% of eyes at day 30. This indicates the plug functioned as designed for retention and for resorption. The mean concentration level of moxifloxacin in tear fluid at each post-surgical evaluation date through day 10 was above the MIC_{90} potency threshold. The MIC_{90} measurement establishes the concentration of a drug needed to inhibit the growth of 90% of a panel of bacterial strains isolated from patients. OTX-MP was able to maintain effective concentration levels of moxifloxacin in the tear fluid over the target 7 to 10 day period, as shown in the chart below. No drug was detectable at day 30.



The investigator who administered the OTX-MP rated the product as “easy” to use for nine of 10 (90%) cases and as “difficult” to use in one (10%) of the cases.

Safety: There were no serious adverse ocular events or other significant adverse ocular events in this trial.

Regulatory Pathway

If we were to advance the clinical development of our OTX-MP product candidate for the treatment of a particular ocular infection indication, we would expect to initiate a Phase 2 clinical trial to evaluate OTX-MP for such indication. We would then be required to successfully complete two well controlled Phase 3 clinical trials conducted under an IND to obtain marketing approval from the FDA. At least one of the Phase 3 clinical trials would be conducted in the United States. If we were to obtain favorable results from these two pivotal clinical trials, we would plan to submit an NDA to the FDA for marketing approval of OTX-MP for such indication. We expect that we would submit this NDA under Section 505(b)(2) of the FDCA. See “—Government Regulation—Section 505(b)(2) NDAs.”

Intravitreal Hydrogel Depot

We are engaged in the preclinical development of a sustained release hydrogel depot administered via intravitreal injection to address the large and growing markets for diseases and conditions of the back of the eye.

Our initial development efforts are focused on the use of our sustained release hydrogel depot in combination with anti-VEGF compounds for the treatment of wet AMD. Our initial goal for this program is to provide sustained release of an anti-VEGF compound over a four to six month period, thereby reducing the frequency of the current monthly or bi-monthly intravitreal injection regimen for wet AMD.

Our intravitreal hydrogel depot consists of a PEG based hydrogel suspension, which contains embedded micronized protein particles of an anti-VEGF compound. We designed the injection to be delivered to the vitreous chamber of the eye using ordinary syringes and fine gauge needles. The wet hydrogel is soft and flowable, allowing it to be easily injected through the needle.

We are pursuing a multi-pronged strategy to seek to maximize the potential of this technology. We are collaborating with several different pharmaceutical companies using protein-based anti-VEGF agents on this program and are also conducting our own internal development using the anti-VEGF agent bevacizumab. We are exploring the delivery of small molecule drugs, such as tyrosine-kinase inhibitors, or TKIs, in our hydrogel depot and have been researching the optimal candidates for this program. We have narrowed our search down to several lead candidates. We believe this class of drugs is well suited for use with our platform given its high potency, multi-target capability, and low water solubility. In the absence of a sophisticated drug delivery system, these drugs have been difficult to deliver to the eye at therapeutic levels without causing local and systemic toxicity. We feel our local drug delivery technology gives us advantages in this regard. By selecting compounds that are compatible with our hydrogel platform technology and that will have expiration of relevant patents within the timeline of our development program, we would also avoid the need to license these molecules, thus retaining full worldwide rights to our products. We may seek to move forward on delivery of a small molecule on our own in parallel with a protein based anti-VEGF delivery program, which would require the involvement of a partner. We plan to continue working with our pharmaceutical company partners on development efforts and exploring potential business development deal structures as well as advancing our internal development efforts on our sustained release hydrogel depot for the treatment of back-of-the-eye diseases.

To date, in *in-vitro* tests and preclinical studies, we have been able to incorporate anti-VEGF drugs within our hydrogels, and our collaborators have been testing release rates and the integrity and activity of their compounds. We have demonstrated *in-vitro* release over a four to six month duration. The released proteins have been stable, with no chemical or functional changes observed. In preclinical animal models, we have observed delivery of anti-VEGF drugs up to three months, with studies ongoing. In preclinical testing, our hydrogel depot has shown initial tolerability and acceptable pharmacokinetics.

Additionally, we conducted an *in vivo* study to measure ocular tissue concentrations of bevacizumab after injection with and without our sustained release hydrogel depot. The injection of bevacizumab without our hydrogel depot resulted in a first order rate of drug clearance. As expected, the concentrations of bevacizumab in the ocular tissues decreased with distance from the intravitreal injection site. The injection of bevacizumab in our hydrogel depot showed the same decrease of tissue concentration of bevacizumab in successively distant tissues. However, the injection of bevacizumab in our hydrogel depot resulted in a sustained level of drug over the course of the 30 day study. Further, a slight increase in levels of drug was observed in ocular tissues with the bevacizumab injection in our hydrogel depot over the course of the study, which was consistent with our *in vitro* release data. After two weeks, the drug concentrations of bevacizumab injected with our hydrogel depot exceeded those of bevacizumab injected without our hydrogel depot. This early feasibility study has provided us with initial encouraging data for our sustained release hydrogel depot with bevacizumab and its potential capability of delivering active drug to ocular tissues in a sustained fashion and informs the additional preclinical activities we plan to pursue. Although these results have been encouraging, we will need to further optimize our hydrogels for the particular anti-VEGF molecules with which we are working. We are conducting additional studies to confirm these results and more consistently demonstrate sustained delivery and tolerability. We believe we have demonstrated initial feasibility sufficient to support the continuing preclinical development of this program and, if we obtain additional favorable preclinical results, advancement into Phase 1 clinical trials.

We plan to continue working with our current pharmaceutical company collaborators for our back-of-the-eye program, with the goal of confirming the initial results that we have observed. We are also conducting our own internal preclinical development program and have seen encouraging results to date. If we successfully complete our preclinical feasibility programs, we plan to explore a broader development and commercialization collaboration with one of the pharmaceutical companies we are currently working with or advance our internal development efforts through additional preclinical development and initial clinical trials. Given the initial positive results in feasibility studies with our intravitreal hydrogel depot containing anti-VEGF drugs for the treatment of back-of-the-eye diseases, including wet AMD, and the size of the market opportunity, we plan to commit additional resources to this program. We also believe there are other opportunities beyond anti-VEGF drugs to utilize our hydrogel depot for back-of-the-eye diseases, and we are conducting early exploratory research initiatives on certain of these opportunities.

ReSure Sealant

ReSure Sealant is a topical liquid hydrogel that creates a temporary, adherent, soft and lubricious sealant to prevent post-surgical leakage from clear corneal incisions that are made during cataract surgery. The main components of ReSure hydrogel are water and PEG. ReSure hydrogel is completely synthetic, with no animal or human derived components. The FDA granted marketing approval for ReSure Sealant in January 2014. We commercially launched ReSure Sealant in the United States in February 2014 through a network of ophthalmology focused distributors.

We previously commercialized in Europe an earlier version of ReSure Sealant that was approved and marketed as an ocular bandage. However, we ceased our commercialization of the product in 2012 to focus on the ongoing clinical development of ReSure Sealant pursuant to FDA requirements after the FDA requested that we withdraw an application for the earlier version of ReSure Sealant that we had submitted under Section 510(k) of the FDCA because the FDA believed that the technical characteristics of the earlier version of ReSure Sealant were not substantially equivalent to a predicate device. After withdrawing our 510(k) application, we filed an IDE application to conduct a pivotal clinical trial to support approval of ReSure Sealant as an ocular sealant and subsequently received premarket approval, or PMA, from the FDA.

Product Design

A surgeon forms ReSure Sealant hydrogel by combining three components: PEG, a cross-linker and a diluent buffer solution. The cross-linker interacts with the PEG molecules to form a molecular network that comprises the hydrogel. The components are mixed to initiate the cross-linking reaction to form a biocompatible, resorbable hydrogel. The hydrogel is approximately 90% water and is blue in color to help the surgeon visualize the sealant during application. The surgeon applies the sealant to the corneal incision as a liquid using a soft foam-tipped applicator. The sealant forms a conformal coating that adheres to the ocular tissue through mechanical interlocking of the hydrogel with the tissue surfaces. The blue color fades within a few hours following surgery. The soft, pliable hydrogel remains on the corneal surface during the critical wound healing period of one to three days and provides a barrier to fluid leakage. ReSure Sealant softens over time, detaches and is sloughed off in the tears as a liquid or extremely soft gel pieces. ReSure Sealant is designed to completely liquefy over a five to seven day duration. Complete epithelial healing takes place over this time period, providing long-term wound closure.

We provide ReSure Sealant in a sterile, single patient use package. The package contains a tray with two elongated mixing wells. Each well contains dried deposits of reactants, separated within the well. The package also contains one plastic dropper bottle filled with diluent solution and two applicators. The device is stored at room temperature for easy access.

Commercial Strategy

Our goals for ReSure Sealant are to provide a novel means of definitive wound closure in situations in which the surgeon would otherwise use sutures and to increase the number of procedures in which surgeons close the wound following cataract surgery, instead of leaving the wound to self-seal. In a 2012 survey of ophthalmologists in the United States conducted by Lachman Consulting LLC, a healthcare consulting firm, respondents indicated that they use sutures in approximately 14% of cataract surgeries. As a result, the market opportunity for a surgical sealant following cataract surgery may be modest. However, we believe ReSure Sealant offers important benefits over sutures, including superior wound closure, a better safety profile and less follow-up. We sell ReSure Sealant through a network of independent medical device distributors across the United States. ReSure Sealant is not separately reimbursed when used as part of a cataract surgery procedure.

We believe that the key factors affecting commercial demand for ReSure Sealant will be:

- *Fewer complications*. We believe that surgeons will be more likely to use ReSure Sealant in complicated cases or cases involving immune-compromised patients in order to avoid the risk of a return patient visit, for which surgeons generally are not separately reimbursed. In complicated cases, the surgeon often must manipulate the eye more extensively in a procedure that takes more time, which results in a greater likelihood that the wound may not close properly. Immune-compromised patients, such as the elderly, are at greater risk of infection, which can require a return visit. According to Medicare data reported by the Centers for Medicare and Medicaid Services, complicated cases and immune-compromised patients represented approximately 8% of all Medicare cataract extraction procedures in 2013.
- *Less follow-up*. We believe that surgeons may elect to use ReSure Sealant because, in contrast with sutures, there is no need for removal. This eliminates the need for a return patient visit for which the surgeon is not separately reimbursed. Removal of sutures also uses valuable clinic time and resources. In addition, ReSure Sealant does not induce astigmatism, a distortion of the cornea that can result from improper suture technique, thus further reducing the potential for a return patient visit.
- *Premium procedures*. We believe surgeons will be more likely to use ReSure Sealant in cases in which patients opt for replacement intraocular lenses that are in a premium category because of the high quality closure it enables. Surgeons face less pricing pressure in these procedures because the patient is responsible for payment and reimbursement from insurance does not cover the cost of the procedure. In addition, because some premium procedures are particularly complicated, there is a greater likelihood that the wound may not close properly. According to Market Scope, premium lens cases represent approximately 14% of all cataract extraction procedures in the United States.

ReSure Sealant Clinical Development

We conducted a pivotal clinical trial evaluating the safety and effectiveness of ReSure Sealant compared to sutures for preventing incision leakage from clear corneal incisions. In connection with FDA approval of ReSure Sealant in January 2014, we have agreed to conduct two post-approval studies. The first post-approval study is designed to confirm whether ReSure Sealant can be used safely by physicians in a standard cataract surgery practice and to confirm the incidence of pre-specified adverse ocular events in eyes treated with ReSure Sealant. The second post-approval study is designed to ascertain the incidence of endophthalmitis in patients treated with ReSure Sealant.

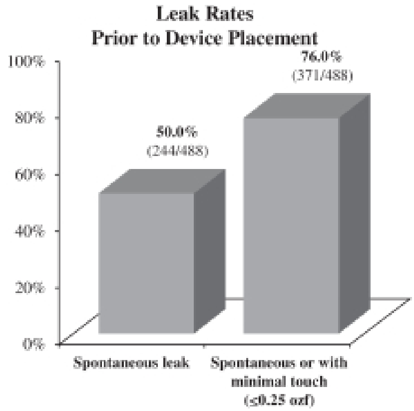
Pivotal Clinical Trial

In 2013, we completed a prospective, randomized parallel arm, controlled, multicenter, subject-masked pivotal clinical trial evaluating the safety and effectiveness of ReSure Sealant. In this trial, we enrolled 488 patients at 24 sites across the United States. One patient was excluded prior to treatment because the surgeon was unable to achieve a dry ocular surface for application of ReSure Sealant. As a result, we randomized 304 patients for treatment with ReSure Sealant and 183 patients for treatment with sutures. Based on the trial protocol, 295 patients treated with the ReSure Sealant and 176 patients treated with sutures completed study follow-up without a significant protocol deviation that directly affected the primary efficacy endpoint.

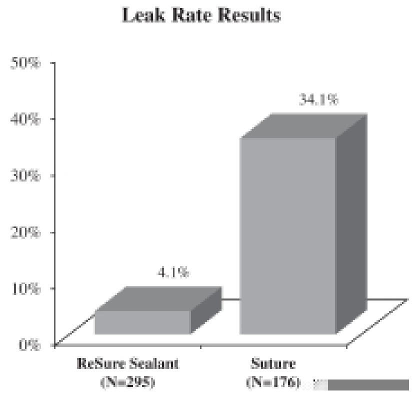
The primary efficacy endpoint was non-inferiority of ReSure Sealant to sutures for preventing incision leakage from clear corneal incisions within the first seven days following cataract surgery. A non-inferiority determination requires that the test product is not worse than the comparator by more than a small pre-specified margin. The non-inferiority margin for the ReSure Sealant pivotal clinical trial was a percentage difference in leak rates between ReSure Sealant and sutures of 5%.

We randomized patients in a 5:3 ratio to receive either ReSure Sealant or sutures. All patients received a standardized self-sealing incision.

Surgeons assessed incision leakage during the operation and during follow-up visits on days 1, 3, 7 and 28 after the procedure. During the pre-randomization intraoperative evaluation, the surgeons assessed whether there was any leakage based on a standard test called a Seidel test in conjunction with an application of force near the incision using a standardized tool and technique. The surgeon slowly applied force using the standardized tool that we provided until a leak was observed or until a pre-specified maximum force of one ounce of force was reached. In the assessments conducted during the operation, approximately 50% of leaks occurred spontaneously without application of force and 76% of leaks occurred with the application of 0.25 ounces of force or less.



Based on assessments conducted immediately following surgery, using the same standardized leak testing tool and technique, eyes receiving sutures leaked more frequently than eyes sealed with ReSure Sealant by a statistically significant margin of more than 8 to 1 (p<0.0001). In this trial, ReSure Sealant demonstrated both non-inferiority and superiority relative to the suture control based on the proportion of eyes with leakage within the first seven days after surgery. These results are shown in the figures below.



ReSure Sealant treated patients had significantly lower adverse event and device-related adverse event rates than patients treated with suture wound closure. We determined statistical significance based on a widely used, conventional statistical method that establishes the p-value of clinical results. Typically, a p-value of 0.05 or less represents statistical significance. In adverse events related to the study device, ReSure Sealant had a lower occurrence rate by a statistically significant margin of 1.6% for ReSure Sealant compared to 30.6% for sutures ($p<0.0001$). There were no significant or clinically relevant differences in the other safety endpoints, including slit lamp examination findings, between ReSure Sealant and suture patients, thus indicating that ReSure Sealant is well tolerated. Only one ReSure Sealant treated patient out of 299 (0.3%) had a wound healing assessment characterized as outside of normal limits at the day 7 assessment due to the presence of mild stromal edema. No ReSure Sealant treated subjects were outside of normal limits at the day 28 assessment. In this trial, surgeons rated ReSure Sealant as “easy” or “very easy” to use for 94.1% of patients treated with ReSure Sealant.

Post-Approval Studies

ReSure Sealant is classified in the United States as a class III medical device subject to the rules and regulation of premarket approval by the FDA. Following our submission of a PMA application to the FDA for review and during the review process, the FDA completed compliance audits of our manufacturing facility and several of our pivotal clinical trial sites. Before granting approval of the PMA application, the FDA sought input from the Ophthalmic Devices Advisory Committee, a panel of physicians charged with reviewing results from our pivotal clinical trial. Upon the Advisory Committee’s favorable recommendation, the FDA-approved our PMA application for ReSure Sealant in January 2014. The FDA included two post-approval studies as a condition of the PMA application approval. We are required to provide periodic reports to the FDA on the progress of each post-approval study over the next four to five years.

The first post-approval study is a prospective multicenter observational registry study that we will conduct at up to 40 centers in the United States. We are required to enroll at least 598 patients treated with ReSure Sealant. We may enroll a maximum of 120 patients at any one site. The goals of this study are to confirm that ReSure Sealant can be used safely by physicians in a standard cataract surgery practice and confirm the incidence in eyes treated with ReSure Sealant of the most prevalent adverse ocular events identified in the pivotal study. Enrollment in this post-approval study was initiated in December 2014.

The second post-approval study is a prospective multicenter observational single arm registry study that we will conduct at up to 100 centers in the United States. We are required to enroll at least 4,857 patients treated with the ReSure Sealant. Patients having undergone cataract surgery will receive treatment with ReSure Sealant. Data from patients in this trial will be linked to a Medicare database. We will use the Medicare database link to ascertain if patients are diagnosed or treated for endophthalmitis within 30 days following the procedure. All patients that received at least one application of the ReSure Sealant on the operative eye will be enrolled in the device exposure registry. Follow-up will consist of acquiring patient results from the Medicare database to report on the outcome of interest on at least an annual basis starting from the date Medicare data is available, for at least one year after completion of enrolling the last patient. In connection with ongoing discussions with the FDA and the Centers for Medicare and Medicaid Services, or CMS, we submitted an application to CMS seeking a tracking or research code for ReSure Sealant commercial use. CMS has preliminarily indicated that it is not likely to issue such a tracking or research code.

Foreign Approvals

Outside the United States, we plan to assess whether to seek regulatory approval for ReSure Sealant in markets such as the European Union, Australia and Japan based on the market opportunity, particularly pricing, and the requirements for marketing approval. Given our prioritization of the clinical development of our drug delivery product candidates and our planned commercialization efforts for our initial punctum plug product candidates in the United States, we do not currently plan to seek CE Mark approval to commercialize ReSure Sealant in the European Union. Outside of the United States and the European Union, we will need to engage a third party to assist us in the approval process. If we obtain regulatory approval to market and sell ReSure Sealant in international markets, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize ReSure Sealant. See "—Government Regulation—Review and Approval of Medical Devices in the European Union" for additional information.

Sales, Marketing and Distribution

We began the commercial launch of ReSure Sealant in the United States in February 2014. We sell ReSure Sealant through a network of independent medical device distributors across the United States. These distributors are primarily exclusive to ophthalmology and focus on selling surgical products to cataract and cornea surgeons. We train each independent distributorship before it is permitted to sell the product to surgeons. In addition, surgeons must complete an online training session before ordering the product. We continue to build a marketing presence for the ReSure Sealant in the ophthalmic marketplace through podium presence at major conventions, such as the American Society of Cataract and Refractive Surgery and the American Academy of Ophthalmology. We expect that our marketing organization will develop more promotional and educational initiatives while continuing to foster relationships with thought leaders to further build awareness of ReSure Sealant.

We generally expect to retain commercial rights in the United States for any sustained delivery products for which we may receive marketing approvals and which we believe we can successfully commercialize. If the results of our third Phase 3 clinical trial of OTX-DP are favorable and subject to receiving approval of our planned initial NDA and our NDA supplement for OTX-DP, we expect to commercially launch OTX-DP under the marketing name DEXTENZA for post-surgical ocular inflammation and pain in the United States in the first half of 2017. Within the United States, we plan to use our own direct sales force that we plan to establish to commercialize OTX-DP, potentially in addition to the network of independent agents that we use to sell ReSure Sealant. We expect that we will collaborate with a pharmaceutical company for the commercialization of our intravitreal hydrogel depot for the delivery of anti-VEGF drugs for the treatment of back-of-the-eye diseases, including wet AMD, if approved for marketing. Alternatively, we may elect to pursue the internal development of an intravitreal hydrogel depot and commercialization of this product with a direct sales force calling on retinal specialists.

If we receive approval to market any of our product candidates in the United States, we plan to then evaluate the regulatory approval requirements and commercial potential for any such product candidate in Europe, Japan and other selected geographies. If we decide to commercialize our products outside of the United States, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize any product of ours that receives marketing approval. These may include independent distributors, pharmaceutical companies or our own direct sales organization.

Manufacturing

We fabricate devices and drug depot products for use in our clinical trials, research and development and commercial efforts for all of our therapeutic product candidates using current good manufacturing practices, or cGMP, at our multi-product facility located in Bedford, Massachusetts.

We purchase active pharmaceutical ingredient drug substance from independent suppliers on a purchase order basis for incorporation into our drug depot products. We purchase our PEG and other raw materials from different vendors on a purchase order basis according to our specifications. Multiple vendors are available for each component we purchase. We qualify vendors according to our quality system requirements. We do not have any long term supply agreements in place for any raw materials or drug substances. We do not license any technology or pay any royalties to any of our drug or raw material vendors for the front-of-the-eye products.

We believe that our strategic investment in manufacturing capabilities allows us to advance product candidates at a more rapid pace and with more flexibility than a contract manufacturer, although we will continue to evaluate outsourcing unit operations for cost advantages. Our manufacturing capability also enables us to produce products in a cost-effective manner while retaining control over the process and prioritize the timing of internal programs.

Our manufacturing capabilities encompass the full manufacturing process through quality control and quality assurance and are integrated with our project teams from discovery through development and commercial release. This structure enables us to efficiently transfer research stage product concepts into manufacturing. We have designed our manufacturing facility and processes to provide maximum flexibility and rapid changeover for the manufacture of different product candidates. We outsource sterilization services for our products.

We believe that we can scale our manufacturing processes to support ReSure Sealant sales as well as development of our punctum plug product candidates and our intravitreal hydrogel depot and the potential commercialization of such product candidates.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our products, product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We rely on patent protection, trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We have in-licensed all of our patent rights from Incept. The license from Incept is limited to the field of human ophthalmic diseases and conditions. As of May 31, 2015, we have licensed from Incept a total of 19 U.S. patents, seven U.S. patent applications and foreign counterparts of some of these patents and patent applications. Eleven of the 19 licensed U.S. patents and six of the seven licensed U.S. patent applications cover the technology that underlies our punctum plug product candidates, ReSure Sealant or our intravitreal hydrogel depot.

Punctum Plug Product Candidates

In the United States, we have licensed from Incept four patent families related to our punctum plug product candidates, comprised of an aggregate of six U.S. patents and one U.S. patent application. The first patent family, which is licensed on an exclusive basis, is comprised of two U.S. patents that will expire in 2030 and covers composition and method claims specific to the drug delivery and design of the punctum plugs. The second and third patent families, which are licensed on an exclusive basis, are comprised of three U.S. patents that will expire between 2018 and 2020 and cover the hydrogel composition of the punctum plugs and methods of making and using hydrogel implants that swell in tissue tracts. The fourth patent family, which is licensed on a non-exclusive basis, is comprised of one U.S. patent that will expire in 2018 and one U.S. patent application that, if granted, will expire in approximately 2018 and covers the hydrogel composition of OTX-TP and OTX-MP in combination with certain drug release particles.

In the European Union and some other areas outside of the United States, we have licensed from Incept three patent families related to our punctum plug product candidates, comprised of an aggregate of two patents and nine patent applications. The first patent family, which is licensed on an exclusive basis, is comprised of one issued patent that will expire in approximately 2027 and one patent application that, if granted, will expire in approximately 2027; this family covers certain drug release features of the punctum plugs in combination with their hydrogel composition. The second patent family, which is licensed on an exclusive basis, is comprised of six patent applications that, if granted, will expire in approximately 2030 and covers composition and method claims related to the drug delivery and design of the punctum plugs, in combination with their hydrogel composition. The third patent family, which is licensed on a non-exclusive basis, is comprised of two patents that will expire in approximately 2019 and one patent application that, if granted, will expire in approximately 2019 and covers the hydrogel composition of the OTX-TP and OTX-MP punctum plugs in combination with certain drug release particles.

ReSure Sealant

In the United States, we have exclusively licensed from Incept two patent families comprised of six U.S. patents related to ReSure Sealant. One U.S. patent that will expire in 2024 covers the process of making and using compositions of the hydrogel. A second U.S. patent that will expire in 2032 covers certain features of the ReSure Sealant package. A third U.S. patent that expires in 2019 covers the hydrogel composition. The remaining three U.S. patents, which expire between 2017 and 2018, cover compositions and methods of making or using the hydrogel, in combination with a visualization agent.

Outside of the United States, we have exclusively licensed only one patent in Canada that expires in 2019 that is directed to a medical kit for use with ReSure Sealant.

Intravitreal Hydrogel Depot

In the United States, we have exclusively licensed from Incept three patent families related to the intravitreal hydrogel depot, comprised of an aggregate of one U.S. patent and two U.S. patent applications. We have further licensed three U.S. provisional patent applications. The first patent family is comprised of a U.S. patent application that, if granted will expire in approximately 2027, and covers certain drug-release features of the hydrogel depot in combination with its hydrogel composition. The second patent family is comprised of one U.S. patent application that, if granted will expire in approximately 2032, and covers the process of making the hydrogel depot with its drug release features and the resultant compositions. The third patent family, comprised of a U.S. patent that expires in 2019, covers the hydrogel composition of the hydrogel depot. The three U.S. provisional patent applications are expected to be filed as three U.S. utility patent applications in 2015 and 2016 and, if issued, will expire in approximately 2035 and 2036.

In the European Union and some other areas outside of the United States, we have exclusively licensed from Incept two patent families related to the intravitreal hydrogel depot. The first patent family is comprised of one patent and one patent application that if the application is granted, will expire in approximately 2027, and covers certain drug-release features of the hydrogel depot in combination with its hydrogel composition. The second patent family is comprised of seven patent applications that, if granted, will expire in approximately 2032. The U.S. provisional patent applications are expected to serve as the basis for filings in multiple countries outside of the U.S. and, if granted, will expire in approximately 2035 and 2036.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review while the patent is in force. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended.

Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each drug and other factors. The expiration dates referred to above are without regard to potential patent term extension or other market exclusivity that may be available to us.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data.

Licenses

Incept, LLC

In January 2012, we entered into an amended and restated license agreement with Incept under which we hold an exclusive, worldwide, perpetual, irrevocable license under specified patents and technology owned or controlled by Incept to make, have made, use, offer for sale, sell, sublicense, have sublicensed, offer for sublicense and import, products delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to all human ophthalmic diseases or conditions. This license covers all of the patent rights and a significant portion of the technology for ReSure Sealant and our hydrogel platform technology product candidates. The agreement supersedes an April 2007 license agreement between us and Incept. Amar Sawhney, our President and Chief Executive Officer, is a general partner of Incept.

Financial Terms. In connection with the agreement, we issued to Incept 443,068 shares of our common stock. In addition, on February 12, 2014, we issued to Incept 189,393 shares of our common stock in connection with the expansion of the scope of the license to include back-of-the-eye technology held by Incept. We are obligated to pay Incept a royalty equal to a low single-digit percentage of net sales made by us or our affiliates. Any sublicensee of ours also will be obligated to pay Incept a royalty equal to a low single-digit percentage of net sales made by it and will be bound by the terms of the agreement to the same extent as we are.

We are obligated to reimburse Incept for our share of the reasonable fees and costs incurred by Incept in connection with the prosecution of the patent applications licensed to us under the agreement. Our share of these fees and costs is equal to the total amount of such fees and costs divided by the total number of Incept's exclusive licensees of the patent application.

Assignment of Our Patents. Under the terms of the agreement, we have agreed to assign to Incept our rights in any patent application filed at any time in any country for which one or more inventors are under an obligation of assignment to us. These assigned patent applications and any resulting patents are included within the specified patents owned or controlled by Incept to which we receive a license under the agreement. Incept has retained rights to practice the patents and technology licensed to us under the agreement for all purposes other than for researching, designing, developing, manufacturing and commercializing products that are delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to ophthalmic diseases or conditions.

Patent Prosecution and Litigation. The agreement provides that, with limited exceptions, Incept has sole control and responsibility for ongoing prosecution for the patents covered by the license agreement. We have the right to bring suit against third parties who infringe the patents covered by the license agreement, but we have agreed, if requested by Incept, to enter into a joint defense and prosecution agreement for the purpose of allowing the parties to share confidential and attorney-client privileged information regarding the possible infringement of one or more patents covered by the license agreement. We are responsible for all costs incurred in prosecuting any infringement action we bring.

Term and Termination. The agreement, unless earlier terminated by us or Incept, will remain in effect until the expiration of the last to expire patent or patent application licensed to us under the agreement. The agreement provides that either party may terminate the agreement in the event of the other party's insolvency, bankruptcy or comparable proceedings, or if the other party materially breaches the agreement and does not cure such breach during a specified cure period.

Competition

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

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

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

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors' establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third party payors seeking to encourage the use of generic products.

Our product candidates target markets that are already served by a variety of competing products based on a number of active pharmaceutical ingredients. Many of these existing products have achieved widespread acceptance among physicians, patients and payors for the treatment of ophthalmic diseases and conditions. In addition, many of these products are available on a generic basis, and our product candidates may not demonstrate sufficient additional clinical benefits to physicians, patients or payors to justify a higher price compared to generic products. In many cases, insurers or other third-party payors, particularly Medicare, seek to encourage the use of generic products. Given that we are developing products based on FDA-approved therapeutic agents, our product candidates, if approved, will face competition from generic and branded versions of existing drugs based on the same active pharmaceutical ingredients that are administered in a different manner, typically through eye drops.

Because the active pharmaceutical ingredients in our product candidates are available on a generic basis, or are soon to be available on a generic basis, competitors will be able to offer and sell products with the same active pharmaceutical ingredient as our products so long as these competitors do not infringe the patents that we license. For example, our licensed patents related to our punctum plug product candidates largely relate to the hydrogel composition of the punctum plugs and certain drug-release features of the punctum plugs. As such, if a third party were able to design around the formulation and process patents that we license and create a different formulation using a different production process not covered by our licensed patents or patent applications, we would likely be unable to prevent that third party from manufacturing and marketing its product.

Competitors of Punctum Plug Product Candidates

Several competitors are developing sustained drug release products for the same ophthalmic indications as our punctum plug product candidates, as set forth below.

Competitors of OTX-DP

Icon Biosciences, Inc. is conducting Phase 3 clinical development of IBI-10090, a biodegradable therapeutic for injection of dexamethasone into the anterior chamber of the eye to treat inflammation associated with cataract surgery.

Competitors of OTX-TP

Allergan, Inc. is conducting Phase 2 clinical development of Bimatoprost Sustained Release, a biodegradable intraocular implant consisting of a PGA and a biodegradable polymer matrix to treat glaucoma. ForSight VISION5 is conducting Phase 2 clinical development of the Helios insert, a sustained release ocular insert placed below the eyelid, for the treatment of glaucoma. In addition, several other companies have announced their intention to develop products for treatment of glaucoma using sustained release therapy, although each of these is at an early stage of development. Mati Therapeutics is conducting Phase 2 clinical development of a punctum plug for the treatment of glaucoma.

Competitors of ReSure Sealant

ReSure Sealant is the first and only surgical sealant approved for ophthalmic use in the United States. Outside the United States, Beaver Visitec is commercializing its product OcuSeal, which is designed to provide a protective hydrogel film barrier to stabilize ocular wounds. This product is not currently available in the United States. Sutures are the primary alternative for closing ophthalmic wounds. In addition, a technique called stromal hydration, which involves the localized injection of a balanced salt solution at the wound edges, is often used to facilitate the self-sealing of a wound.

Competitors of our Intravitreal Hydrogel Depot

Our intravitreal hydrogel depot will compete with anti-VEGF compounds administered in their current formulation and prescribed for the treatment of wet AMD, including Lucentis, Eylea and off-label use of the cancer therapy Avastin. Multiple companies are exploring ways to deliver anti-VEGF products in a sustained release fashion, although all are in early stages of development. Alcon is developing the Replenish pump to deliver its anti-VEGF agent. In addition, Ophthotech Corporation is currently conducting Phase 3 clinical trials of Fovista, an anti-PDGF product candidate to be administered in combination with anti-VEGF compounds for the treatment of wet AMD.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, clearance, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products and medical devices. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drugs under the FDCA and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of an NDA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND.

Companies usually must complete some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Human Clinical Studies in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence. For our punctum plug product candidates, we have typically conducted our initial and earlier stage clinical trials outside the United States. We generally plan to conduct our later stage and pivotal clinical trials of our punctum plug product candidates in the United States. To date, we have submitted two INDs to the FDA. The first IND was submitted in August 2012 and relates to OTX-DP for the treatment of post-surgical ocular inflammation and pain and, pursuant to subsequent amendments submitted in February and November 2014, allergic conjunctivitis and dry eye disease. We submitted a second IND to the FDA relating to OTX-TP for the treatment of glaucoma and ocular hypertension in the second half of 2014 prior to initiating our Phase 2b clinical trial of OTX-TP for this indication.

In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or IND so long as the clinical trial is conducted in compliance with an international guideline for the ethical conduct of clinical research known as the Declaration of Helsinki or the laws and regulations of the country or countries in which the clinical trial is performed, whichever provides the greater protection to the participants in the clinical trial. Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into a small number of healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Phase 3 clinical trials are commonly referred to as “pivotal” trials, which typically denotes a trial which presents the data that the FDA or other relevant regulatory agency will use to determine whether or not to approve a drug.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA’s previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application “were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.”

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA’s previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

If we obtain favorable results in our clinical trials, we plan to submit NDAs for our punctum plug product candidates under Section 505(b)(2).

Submission of an NDA to the FDA

NDAs for most new drug products are based on two full clinical studies that must contain substantial evidence of the safety and efficacy of the proposed new product. Assuming successful completion of required clinical testing and other requirements, the results of the preclinical and clinical studies, together with detailed information relating to the product’s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, currently exceeding $2.1 million, and the sponsor of an approved NDA is also subject to annual product and establishment user fees, currently exceeding $104,000 per product and $554,000 per establishment. These fees are typically increased annually.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for various reasons, including three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, which can materially affect the potential market and profitability of the product. In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, referred to as ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

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

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is “bioequivalent” to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if “the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug.”

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Hatch-Waxman Patent Certification and the 30 Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application to the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, a NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be 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 the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product 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 another application.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of a NDA, plus the time between the submission date of a NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Review and Approval of Medical Devices in the United States

Medical devices in the United States are strictly regulated by the FDA. Under the FDCA, a medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug. If not, it is generally a medical device.

Unless an exemption applies, a new medical device may not be marketed in the United States unless and until it has been cleared through filing of a 510(k) premarket notification, or 510(k), or approved by the FDA pursuant to a PMA application. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness.

Class I devices are low risk devices for which reasonable assurance of safety and effectiveness can be provided by adherence to the FDA's general controls for medical devices, which include applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events and malfunctions and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Many Class I devices are exempt from premarket regulation; however, some Class I devices require premarket clearance by the FDA through the 510(k) premarket notification process.

Class II devices are moderate risk devices and are subject to the FDA's general controls, and any other special controls, such as performance standards, post-market surveillance, and FDA guidelines, deemed necessary by the FDA to provide reasonable assurance of the devices' safety and effectiveness. Premarket review and clearance by the FDA for Class II devices are accomplished through the 510(k) premarket notification procedure, although some Class II devices are exempt from the 510(k) requirements. Premarket notifications are subject to user fees, unless a specific exemption applies.

Class III devices are deemed by the FDA to pose the greatest risk, such as those for which reasonable assurance of the device's safety and effectiveness cannot be assured solely by the general controls and special controls described above and that are life-sustaining or life-supporting. A PMA application must provide valid scientific evidence, typically extensive preclinical and clinical trial data and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications (and supplemental PMA applications) are subject to significantly higher user fees than are 510(k) premarket notifications.

510(k) Premarket Notification

To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is "substantially equivalent" to a predicate device, which is a previously cleared 510(k) device or a pre-amendment device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of a PMA application. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the application is submitted and filed with the FDA, but it can take significantly longer and clearance is never assured. The FDA has issued guidance documents meant to expedite review of a 510(k) and facilitate interactions between applicants and the agency. To demonstrate substantial equivalence, a manufacturer must show that the device has the same intended use as a predicate device and the same technological characteristics, or the same intended use and different technological characteristics and does not raise new questions of safety and effectiveness than the predicate device.

Most 510(k)s do not require clinical data for clearance, but the FDA may request such data.

The FDA seeks to review and act on a 510(k) within 90 days of submission, but it may take longer if the agency finds that it requires more information to review the 510(k). If the FDA determines that the device is substantially equivalent to a predicate device, the subject device may be marketed. However, if the FDA concludes that a new device is not substantially equivalent to a predicate device, the new device will be classified in Class III and the manufacturer will be required to submit a PMA application to market the product. Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III by operation of section 513(f)(1) of the FDCA, regardless of the level of risk they pose. To avoid requiring PMA review of low- to moderate-risk devices classified in Class III by operation of law, Congress enacted section 513(f)(2) of the FDCA. This provision allows the FDA to classify a low- to moderate-risk device not previously classified into Class I or II, a process known as the *de novo* process. A company may apply directly to the FDA for classification of its device as *de novo* or may submit a de novo petition within 30 days of receiving a not substantially equivalent determination.

Modifications to a 510(k)-cleared medical device may require the submission of another 510(k). Modifications to a 510(k)-cleared device frequently require the submission of a traditional 510(k), but modifications meeting certain conditions may be candidates for FDA review under a Special 510(k). If a device modification requires the submission of a 510(k), but the modification does not affect the intended use of the device or alter the fundamental technology of the device, then summary information that results from the design control process associated with the cleared device can serve as the basis for clearing the application. A Special 510(k) allows a manufacturer to declare conformance to design controls without providing new data. When the modification involves a change in material, the nature of the "new" material will determine whether a traditional or Special 510(k) is necessary.

Any modification to a 510(k)-cleared product that would constitute a major change in its intended use or any change that could significantly affect the safety or effectiveness of the device may, in some circumstances, requires the submission of a PMA application, if the change raises complex or novel scientific issues or the product has a new intended use. A manufacturer may be required to submit extensive pre-clinical and clinical data depending on the nature of the changes.

The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. If the FDA disagrees with the manufacturer's determination and requires new 510(k) clearances or PMA application approvals for modifications to previously cleared products for which the manufacturer concluded that new clearances or approvals are unnecessary, the manufacturer may be required to cease marketing or distribution of the products or to recall the modified product until it obtains clearance or approval, and the manufacturer may be subject to significant regulatory fines or penalties. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements.

Premarket Approval Application

The PMA application process for approval to market a medical device is more complex, costly, and time- consuming than the 510(k) clearance procedure. A PMA application must be supported by extensive data, including technical information regarding device design and development, preclinical studies, clinical trials, manufacturing and controls information and labeling information that demonstrate the safety and effectiveness of the device for its intended use. After a PMA application is submitted, the FDA has 45 days to determine whether it is sufficiently complete to permit a substantive review. If the PMA application is complete, the FDA will file the PMA application. If the FDA accepts the application for filing, the agency will begin an in-depth substantive review of the application. By statute, the FDA has 180 days to review the application although, generally, review of the application often takes between one and three years, and may take significantly longer. If the FDA has questions, it will likely issue a first major deficiency letter within 150 days of filing. It may also refer the PMA application to an FDA advisory panel for additional review, and will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the QSR, either of which could extend the 180-day response target. In addition, the FDA may request additional information or request the performance of additional clinical trials in which case the PMA application approval may be delayed while the trials are conducted and the data acquired are submitted in an amendment to the PMA. Even with additional trials, the FDA may not approve the PMA application.

If the FDA's evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter authorizing commercial marketing or an approvable letter that usually contains a number of conditions that must be met in order to secure final approval. If the FDA's evaluations are not favorable, the FDA will deny approval of the PMA application or issue a not approvable letter. The PMA application process, including the gathering of clinical and nonclinical data and the submission to and review by the FDA, can take several years, and the process can be expensive and uncertain. Moreover, even if the FDA approves a PMA application, the FDA may approve the device with an indication that is narrower or more limited than originally sought. The FDA can impose post-approval conditions that it believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. After approval of a PMA application, a new PMA application or PMA application supplement may be required for a modification to the device, its labeling, or its manufacturing process. PMA application supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel. The time for review of a PMA application supplement may vary depending on the type of change, but it can be lengthy. In addition, in some cases the FDA might require additional clinical data.

Investigational Device Exemption

A clinical trial is typically required for a PMA application and, in a small percentage of cases, the FDA may require a clinical study in support of a 510(k) submission. A manufacturer that wishes to conduct a clinical study involving the device is subject to the FDA's IDE regulation. The IDE regulation distinguishes between significant and non-significant risk device studies and the procedures for obtaining approval to begin the study differ accordingly. Also, some types of studies are exempt from the IDE regulations. A significant risk device presents a potential for serious risk to the health, safety, or welfare of a subject. Significant risk devices are devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. Studies of devices that pose a significant risk require both FDA and an IRB approval prior to initiation of a clinical study. Non-significant risk devices are devices that do not pose a significant risk to the human subjects. A non-significant risk device study requires only IRB approval prior to initiation of a clinical study.

An IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. An IDE application is considered approved 30 days after it has been received by the FDA, unless the FDA otherwise informs the sponsor prior to 30 calendar days from the date of receipt, that the IDE is approved, approved with conditions, or disapproved. The FDA typically grants IDE approval for a specified number of subjects to be enrolled at specified study centers. The clinical trial must be conducted in accordance with applicable regulations, including but not limited to the FDA's IDE regulations and GCP. The investigators must obtain subject informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and record keeping requirements. A clinical trial may be suspended or terminated by the FDA, the IRB or the sponsor at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the trial. Approval of an IDE does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

Post-Marketing Restrictions and Enforcement

After a device is placed on the market, numerous regulatory requirements apply. These include but are not limited to:

- submitting and updating establishment registration and device listings with the FDA;

- compliance with the QSR, which require manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;
- unannounced routine or for-cause device inspections by the FDA, which may include our suppliers' facilities labeling regulations, which prohibit the promotion of products for uncleared or unapproved or "off-label" uses and impose other restrictions on labeling; and
- post-approval restrictions or conditions, including requirements to conduct post-market surveillance studies to establish continued safety data or tracking products through the chain of distribution to the patient level.

Under the FDA medical device reporting, or MDR, regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or a similar device of such manufacturer were to recur. The decision to file an MDR involves a judgment by the manufacturer. If the FDA disagrees with the manufacturer's determination, the FDA can take enforcement action.

Additionally, the FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated.

The failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions or civil penalties;
- recalls, detentions or seizures of products;
- operating restrictions;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- delay or refusal of the FDA or other regulators to grant 510(k) clearance or PMA application approvals of new products;
- withdrawals of 510(k) clearance or PMA application approvals; or
- in the most serious cases, criminal prosecution.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of subcontractors.

Review and Approval of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities, and frequently by different Centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products;
- a drug or device packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug or device where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug or device packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a device-drug combination product is attributable to the drug product, the FDA Center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a drug under European Union regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the European Medicines Agency, or EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not received marketing approval in any European Union member states before. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Review and Approval of Medical Devices in the European Union

The European Union has adopted numerous directives and standards regulating, among other things, the design, manufacture, clinical trials, labeling, approval and adverse event reporting for medical devices. In the EU, medical devices must comply with the Essential Requirements in Annex I to the EU Medical Devices Directive (Council Directive 93/42/EEC), or the Essential Requirements. Compliance with these requirements is a prerequisite to be able to affix the CE Mark of Conformity to medical devices, without which they cannot be marketed or sold in the European Economic Area, or EEA, comprised of the European Union member states plus Norway, Iceland, and Liechtenstein. Actual implementation of these directives, however, may vary on a country-by-country basis.

To demonstrate compliance with the Essential Requirements a manufacturer must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices, where the manufacturer can issue a CE Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements, a conformity assessment procedure requires the intervention of a third-party organization designated by competent authorities of a European Union country to conduct conformity assessments, or a Notified Body. Notified Bodies are independent testing houses, laboratories, or product certifiers typically based within the European Union and authorized by the European member states to perform the required conformity assessment tasks, such as quality system audits and device compliance testing. The Notified Body would typically audit and examine the product's Technical File and the quality system for the manufacture, design and final inspection of the product before issuing a CE Certificate of Conformity demonstrating compliance with the relevant Essential Requirements.

Medical device manufacturers must carry out a clinical evaluation of their medical devices to demonstrate conformity with the relevant Essential Requirements. This clinical evaluation is part of the product's Technical File. A clinical evaluation includes an assessment of whether a medical device's performance is in accordance with its intended use, and that the known and foreseeable risks linked to the use of the device under normal conditions are minimized and acceptable when weighed against the benefits of its intended purpose. The clinical evaluation conducted by the manufacturer must also address any clinical claims, the adequacy of the device labeling and information (particularly claims, contraindications, precautions and warnings) and the suitability of related Instructions for Use. This assessment must be based on clinical data, which can be obtained from clinical studies conducted on the devices being assessed, scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or both clinical studies and scientific literature.

With respect to implantable devices or devices classified as Class III in the European Union, the manufacturer must conduct clinical studies to obtain the required clinical data, unless relying on existing clinical data from similar devices can be justified. As part of the conformity assessment process, depending on the type of devices, the Notified Body will review the manufacturer's clinical evaluation process, assess the clinical evaluation data of a representative sample of the device's subcategory or generic group, or assess all the clinical evaluation data, verify the manufacturer's assessment of that data and assess the validity of the clinical evaluation report and the conclusions drawn by the manufacturer.

Even after a manufacturer receives a CE Certificate of Conformity enabling the CE mark to be placed on it products and the right to sell the products in the EEA countries, a Notified Body or a competent authority may require post-marketing studies of the products. Failure to comply with such requirements in a timely manner could result in the withdrawal of the CE Certificate of Conformity and the recall or withdrawal of the subject product from the European market.

A manufacturer must inform the Notified Body that carried out the conformity assessment of the medical devices of any planned substantial changes to the devices which could affect compliance with the Essential Requirements or the devices' intended purpose. The Notified Body will then assess the changes and verify whether they affect the product's conformity with the Essential Requirements or the conditions for the use of the devices. If the assessment is favorable, the Notified Body will issue a new CE Certificate of Conformity or an addendum to the existing CE Certificate of Conformity attesting compliance with the Essential Requirements. If it is not, the manufacturer may not be able to continue to market and sell the product in the EEA.

In the European Union, medical devices may be promoted only for the intended purpose for which the devices have been CE marked. Failure to comply with this requirement could lead to the imposition of penalties by the competent authorities of the European Union Member States. The penalties could include warnings, orders to discontinue the promotion of the medical device, seizure of the promotional materials and fines. Promotional materials must also comply with various laws and codes of conduct developed by medical device industry bodies in the European Union governing promotional claims, comparative advertising, advertising of medical devices reimbursed by the national health insurance systems and advertising to the general public.

Additionally, all manufacturers placing medical devices in the market in the European Union are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the competent authority in whose jurisdiction the incident occurred. In the European Union, manufacturers must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant authorities of the European Union countries, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its European Authorized Representative to its customers and to the end users of the device through Field Safety Notices. In September 2012, the European Commission adopted a proposal for a regulation which, if adopted, will change the way that most medical devices are regulated in the European Union, and may subject products to additional requirements.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. 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. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state 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, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

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

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits 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;
- the federal transparency requirements under the Patient Protection and Affordable Care Act will require manufacturers of drugs, devices, drugs and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Employees

As of May 31, 2015, we had 77 full-time employees. Of these full-time employees, 64 employees are primarily engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

Our facilities consist of office space, laboratory space and manufacturing facilities in Bedford, Massachusetts. We occupy approximately 32,000 square feet of space. The lease for approximately 20,000 square feet of space expires in 2018 and the lease for the remaining approximately 12,000 square feet of space expires in 2017.

Legal Proceedings

We are not currently subject to any material legal proceedings.

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MANAGEMENT

The following table sets forth the name, age as of May 31, 2015 and position of each of our executive officers and directors.

Name	Age	Position
Amarpreet Sawhney, Ph.D.	48	President and Chief Executive Officer and Chairman of the Board of Directors
Bradford Smith	59	Chief Financial Officer
James Fortune	56	Chief Operating Officer
Eric Ankerud	58	Executive Vice President, Clinical, Regulatory and Quality
Jaswinder Chadha	47	Director
James Garvey(1)(3)	68	Director
Richard Lindstrom, M.D.(2)(3)	67	Director
Bruce Peacock(1)(2)	63	Director
Charles Warden(1)(2)	46	Director

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating and Corporate Governance Committee.

Amarpreet Sawhney, Ph.D. has served as our President and Chief Executive Officer and as a member of our board of directors since 2006. He has served as the Chairman of our board of directors since June 2014. From 2008 to April 2014, Dr. Sawhney also served as Chief Executive Officer of Augmenix, Inc., a biopharmaceutical company, which was, up until April 2014, an affiliate of Ocular through Dr. Sawhney's service as Chief Executive Officer of both entities. Dr. Sawhney is also a general partner of Incept, LLC, an intellectual property holding company. Prior to joining Ocular Therapeutix, Dr. Sawhney founded and served as the President and Chief Executive Officer of Confluent Surgical, Inc., a medical device company, from 1998 to 2006 when it was acquired by Covidien plc. He served as a member of the board of directors of AccessClosure, Inc., a medical device company, from 2002 to 2009. Previously, he was a technical founder of Focal, Inc., a biopharmaceutical company subsequently acquired by Genzyme Corporation. Dr. Sawhney holds a Ph.D. and M.S. in Chemical Engineering from the University of Texas at Austin and a B.Tech. in Chemical Engineering from the Indian Institute of Technology, Delhi, India. We believe that Dr. Sawhney is qualified to serve on our board of directors because of his extensive executive leadership experience in the life sciences industry and his extensive knowledge of our company based on his position as President and Chief Executive Officer.

Bradford Smith has served as our Chief Financial Officer since March 2014. Prior to joining Ocular Therapeutix, Mr. Smith served as the Chief Financial Officer of OmniGuide, Inc., a medical device company, from 2008 to March 2014. Previously, Mr. Smith served as the Chief Financial Officer of several other life sciences companies, including NeuroMetrix, Inc., a medical device company, Synarc, Inc., a clinical research organization company, PatientKeeper, Inc., a healthcare information technology company, Focal, Inc. and CytoTherapeutics, Inc., a biopharmaceutical company, Mr. Smith holds a B.S. in Biology from Tufts University and an M.B.A. from the Whittemore School at the University of New Hampshire.

James Fortune has served as our Chief Operating Officer since 2008. Mr. Fortune also served as the Chief Operating Officer of Augmenix, Inc. from 2008 to April 2014 and of AccessClosure, Inc. from 2008 to 2010. Prior to joining Ocular Therapeutix, Mr. Fortune served as the Chief Operating Officer of Intrinsic Therapeutics, Inc. and the Chief Operating Officer of Confluent Surgical, Inc. Previously, he held various senior management roles with the orthopedic and neurosurgical divisions of Johnson & Johnson. Mr. Fortune holds a B.S. in Mechanical Engineering from Rensselaer Polytechnic Institute.

Eric Ankerud has served as our Executive Vice President, Clinical, Regulatory and Quality, since 2007. From 2008 to April 2014, Mr. Ankerud also served as Executive Vice President, Clinical, Regulatory and Quality, of Augmenix, Inc. Prior to joining Ocular Therapeutix, Mr. Ankerud served as the Vice President, Clinical, Regulatory and Quality, of Confluent Surgical, Inc., the Vice President, Corporate Regulatory Affairs, of Boston Scientific Corporation, the Vice President, Quality, Regulatory and Clinical Affairs, of Summit Technology, Inc., a medical device company, and the Director, Corporate Regulatory Affairs, of Bausch & Lomb. Previously, he held various senior management roles with the surgical products and infusion pump divisions of C.R. Bard, a medical device manufacturer. Mr. Ankerud holds a B.A. in Economics from St. Lawrence University and a J.D. from the State University of New York at Buffalo.

Jaswinder Chadha has served as a member of our board of directors since 2013. Mr. Chadha founded and has served as the President and Chief Executive Officer of Axtria, Inc., an analytics company, since 2009. Prior to founding Axtria, Mr. Chadha was a co-founder and served as President and Chief Executive Officer of marketRx Inc., a market research and analytics firm subsequently acquired by Cognizant Technology Solutions, from 2000 to 2009. Mr. Chadha holds a B.Tech. in Mechanical Engineering from the Indian Institute of Technology, Delhi, India. We believe that Mr. Chadha is qualified to serve on our board of directors because of his extensive experience in sales and marketing strategy in the life sciences industry.

James Garvey has served as a member of our board of directors since 2010. Mr. Garvey was Chief Executive Officer of SV Life Sciences Advisers, LLC from 1995 to 2005, was Managing Partner and Chief Executive Officer from 2006 to 2009, was Chairman from 2010 to 2014 and assumed the role of Chairman Emeritus in 2014. Previously, he was Managing Director for the venture capital division of Allstate Corporation, an insurance provider, President of National Teledata, a healthcare information technology company, and President and Chief Executive Officer of Allegheny International Medical Technology, a medical device company. Mr. Garvey has also held senior management positions at Millipore Corporation, a biopharmaceutical company. He serves as a member of the boards of directors of several privately-held life sciences companies and previously served as a member of the boards of directors of the publicly-traded companies Achillion Pharmaceuticals, Inc. and Shire plc. Mr. Garvey holds a B.S. in Education from Northern Illinois University. We believe that Mr. Garvey is qualified to serve on our board of directors because of his service on the boards of directors of other life sciences companies and his extensive executive leadership experience.

Richard Lindstrom, M.D. has served as a member of our board of directors since 2012. Dr. Lindstrom is a founder and director and has been an attending surgeon at Minnesota Eye Consultants P.A., a provider of eye care services, since 1989. He has served as a member of the boards of directors of Imprimis Pharmaceuticals, Inc., a pharmaceutical company, since 2014 and TearLab Corporation, a diagnostics company, since 2010 and served as a member of the board of directors of Onpoint Medical Diagnostics, Inc. from 2010 to 2013. Dr. Lindstrom has served as associate director of the Minnesota Lions Eye Bank since 1987. He is a medical advisor for several medical device and pharmaceutical manufacturers and serves on the boards of several privately-held life sciences companies. Dr. Lindstrom previously served as president of the International Society of Refractive Surgery, the International Intraocular Implant Society, the International Refractive Surgery Club and the American Society of Cataract and Refractive Surgery. From 1980 to 1989, he served as a professor of ophthalmology at the University of Minnesota, where he is currently adjunct professor emeritus. Dr. Lindstrom holds a B.A. in Pre-Medical Studies, a B.S. in Medicine and an M.D. from the University of Minnesota. We believe that Dr. Lindstrom is qualified to serve on our board of directors because of his service on the board of directors of other life sciences companies and his background in ophthalmology, which gives him a perspective that is helpful to the board for understanding our product market.

Bruce A. Peacock has served as a member of our board of directors since 2014. From August 2013 to September 2014, Mr. Peacock served as the Chief Financial and Business Officer of Ophthotech Corporation, a biopharmaceutical company. He served as the Chief Business Officer of Ophthotech from September 2010 to August 2013. Since May 2006, Mr. Peacock also has served as a Venture Partner at SV Life Sciences. Mr. Peacock served as President and Chief Executive Officer of Alba Therapeutics, a biopharmaceutical company, from April

2008 to February 2011, and has served as Co-Chairman of the board of directors of Alba Therapeutics since April 2008. Prior to joining SV Life Sciences as a Venture Partner, Mr. Peacock served as Chief Executive Officer and a director of The Little Clinic, a medical care services company. Previously, Mr. Peacock served as President and Chief Executive Officer and a director of Adolor Corporation, a publicly-traded biotechnology company, as President, Chief Executive Officer and a member of the board of directors of Orthovita, Inc., a publicly-traded orthopedic biomaterials company, as Executive Vice President, Chief Operating Officer and a member of the board of directors of Cephalon, Inc., as Chief Financial Officer of Cephalon, Inc. and as Chief Financial Officer of Centocor, Inc. Mr. Peacock serves as a member of the boards of directors of Applied Genetic Technologies Corporation, Dicerna Pharmaceuticals, Inc., Discovery Laboratories, Inc., and Invisible Sentinel Inc. and has served as a member of the boards of directors of Ocean Power Technologies, Inc., Ligand Pharmaceuticals Incorporated and NeurogesX, Inc. Mr. Peacock holds a B.A. in Business Administration from Villanova University and is a certified public accountant. We believe that Mr. Peacock is qualified to serve on our board of directors because of his extensive executive leadership experience, finance and accounting background, knowledge of the life sciences industry and service on the boards of directors of other life sciences companies.

Charles Warden has served as a member of our board of directors since 2008. Mr. Warden has served as a Managing Director at Versant Ventures since 2004. Prior to Versant, he was a General Partner at Schroder Ventures Life Sciences (now SV Life Sciences), where he worked from 1996 to 2004. Previously, Mr. Warden served as an associate with Boston Capital Ventures and as a consultant with Monitor Company. He serves on the boards of several privately-held life sciences companies and also has been involved with ForSight Labs, an ophthalmic incubator, The Foundry, a medical device incubator, and The Innovation Factory, a medical devices incubator. Mr. Warden holds a B.A. in Economics and Classics from Beloit College and an M.B.A from Harvard University. We believe that Mr. Warden is qualified to serve on our board of directors due to his significant experience as an investor in life sciences companies.

Board Composition and Election of Directors

Board Composition

Our board of directors is currently authorized to have seven members. Our board currently consists of six members and one vacancy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

Our certificate of incorporation and by-laws provide that the authorized number of directors may be changed only by resolution of our board of directors. Our certificate of incorporation and by-laws also provide that our directors may be removed only for cause by the affirmative vote of the holders of 75% of the votes which all of our stockholders would be entitled to vote in any annual election of directors or class of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Our board of directors is divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. The members of the classes are divided as follows:

- the class I directors are James Garvey and Charles Warden, and their term expires at the 2015 Annual Meeting;
- the class II directors are Jaswinder Chadha and Richard Lindstrom, M.D., and their term expires at the annual meeting of stockholders to be held in 2016; and
- the class III directors are Bruce Peacock and Amarpreet Sawhney their term expires at the annual meeting of stockholders to be held in 2017.
- Any new director appointed or elected to fill our board's vacancy will be a class III director.

Upon the expiration of the term of a class of directors, directors in that class are eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

Director Independence

Applicable NASDAQ rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the NASDAQ rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under applicable NASDAQ rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In June and July 2014 and again in March 2015, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Dr. Sawhney and Mr. Chadha, is an "independent director" as defined under applicable NASDAQ rules, including, in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act. In making such determination, our board of directors considered the relationships that each such non-employee director has with Ocular Therapeutix, including each of the transactions described in "Transactions With Related Person," and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Dr. Sawhney is not an independent director under these rules because he is our President and Chief Executive Officer. Mr. Chadha is not an independent director under these rules because of a compensation committee interlock with Axtria, Inc., or Axtria. See "—Compensation Committee Interlocks and Insider Participation" for additional information. In determining the independence of the members of our audit committee, our board of directors also considered that SV Life Sciences, an entity in which Mr. Garvey serves as Managing Partner and Chairman, was the beneficial owner of approximately 12.1% of our outstanding common stock as of December 31, 2014 and that Versant Ventures, an entity in which Mr. Warden serves as Managing Director, was the beneficial owner of approximately 13.9% of our outstanding common stock as of December 31, 2014.

There are no family relationships among any of our directors or executive officers, except for between Dr. Sawhney and Mr. Chadha, who are cousins.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates under a charter that has been approved by our board.

Audit Committee

The members of our audit committee are Bruce Peacock, James Garvey and Charles Warden. Mr. Peacock is the chair of the audit committee. Our audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from that firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our internal audit function;
- overseeing our risk assessment and risk management policies;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our internal auditing staff, if any, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by Securities and Exchange Commission, or SEC, rules.

All audit and non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Our board of directors has determined that Mr. Peacock is an "audit committee financial expert" as defined in applicable SEC rules. We believe that the composition of our audit committee meets the requirements for independence under current NASDAQ and SEC rules and regulations.

Compensation Committee

The members of our compensation committee are Charles Warden, Richard Lindstrom, M.D. and Bruce Peacock. Mr. Warden is the chair of the compensation committee. Our compensation committee's responsibilities include:

- reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our chief executive officer and our other executive officers;
- overseeing an evaluation of our senior executives;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis" disclosure if and to the extent then required by SEC rules; and
- preparing the compensation committee report if and to the extent then required by SEC rules.

We believe that the composition of our compensation committee meets the requirements for independence under current NASDAQ and SEC rules and regulations.

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are James Garvey and Richard Lindstrom, M.D. Mr. Garvey is the chair of the nominating and corporate governance committee. Our nominating and corporate governance committee's responsibilities include:

- identifying individuals qualified to become members of our board of directors;
- recommending to our board of directors the persons to be nominated for election as directors and to each of our board's committees;
- reviewing and making recommendations to our board with respect to our board leadership structure;
- reviewing and making recommendations to our board with respect to management succession planning;
- developing and recommending to our board of directors corporate governance principles; and
- overseeing an annual evaluation of our board of directors.

We believe that the composition of our nominating and corporate governance committee meets the requirements for independence under current NASDAQ and SEC rules and regulations.

Compensation Committee Interlocks and Insider Participation

For 2014, following the effectiveness, on July 24, 2014, of the registration statement filed in connection with our initial public offering, the members of our compensation committee were Charles Warden, Richard Lindstrom, M.D. and Bruce Peacock. Prior to July 24, 2014, Alan Crane, Richard Lindstrom, M.D. and Charles Warden served on our compensation committee. None of the members of our compensation committee is, or has ever been, an officer or employee of Ocular Therapeutix. Dr. Sawhney, our President and Chief Executive Officer, is a member of the board of directors of Axtria. Axtria does not have a standing compensation committee or other board committee performing equivalent functions. Mr. Chadha, who serves on our board of directors, is a director, President and Chief Executive Officer of Axtria. In 2014, Mr. Chadha was not a member of our compensation committee. Except for Dr. Sawhney, none of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee.

EXECUTIVE COMPENSATION

This section describes the material elements of compensation awarded to, earned by or paid to each of our named executive officers. Our named executive officers for 2014 are Amarpreet Sawhney, Ph.D., our President and Chief Executive Officer; Bradford Smith, our Chief Financial Officer; and James Fortune, our Chief Operating Officer. This section also provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our executive officers and is intended to place in perspective the data presented in the tables and narrative that follow.

Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by or paid to our named executive officers during the years ended December 31, 2014 and December 31, 2013.

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(2)	All Other Compensation ($)(3)	Total ($)
Amarpreet Sawhney, Ph.D.(4)	2014	500,000(5)	288,750	900,176(6)	696,782	135	2,385,843
President and Chief Executive Officer	2013	254,894(7)	—	—	260,627	—	515,521
Bradford Smith(8)	2014	248,750	76,781	—	732,622	1,215	1,059,368
Chief Financial Officer							
James Fortune	2014	375,215	135,077	—	438,992(9)	1,915	951,199
Chief Operating Officer	2013	362,527	—	—	76,904	—	439,431

(1) The amount reported in the “Stock Awards” column reflects the aggregate grant date fair value of stock-based awards granted during the year or in connection with the year’s performance, computed in accordance with the provisions of the Financial Accounting Standards Board’s Accounting Standards Codification Topic 718. See Note 11 to our audited financial statements included elsewhere in this prospectus, regarding assumptions underlying the valuation of equity awards.

(2) The amounts reported in the “Option Awards” column reflect the aggregate fair value of share-based compensation awarded during the year computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standard Codification, or ASC, Topic 718. See Note 11 to our audited financial statements included elsewhere in this prospectus, regarding assumptions underlying the valuation of equity awards.

(3) The compensation included in the “All Other Compensation” column consists of “gross-ups” for the payment of taxes we paid to each of our named executive officers for a group term life insurance policy.

(4) Dr. Sawhney also serves as a member of our board of directors but does not receive any additional compensation for his service as a director.

(5) In lieu of a portion of his 2014 salary, we granted Dr. Sawhney 94,696 shares of our restricted common stock, which had an aggregate fair market value of $832,491 at the time of grant. The shares vested on an equal monthly basis over 12 months starting on January 1, 2014.

(6) Consists of (i) a stock grant to Dr. Sawhney of 25,094 shares of our common stock in February 2014 in recognition of his performance during 2013, (ii) a stock grant to Dr. Sawhney of 28,437 shares of our restricted common stock in lieu of payment of a portion of the base salary to which Dr. Sawhney will be entitled in 2015, and (iii) the incremental value of $429,574 received by Dr. Sawhney for the grant to him of 94,696 shares of our restricted common stock in excess of the $402,917 portion of his 2014 salary foregone.

(7) In lieu of his 2013 salary of $254,894, we granted to Dr. Sawhney 100,378 shares of our restricted common stock, which had an aggregate fair market value of $249,100 at the time of grant. The shares vested on an equal monthly basis over 12 months starting on January 1, 2013.

(8) Mr. Smith was appointed as our Chief Financial Officer in March 2014.

(9) Includes an option granted to Mr. Fortune to purchase 7,339 shares of our common stock in February 2014 in recognition of his performance during 2013.

Narrative Disclosure to Summary Compensation Table

Base Salary

In 2014, we paid annualized base salaries of $233,000, which was increased to $500,000 in June 2014, to Dr. Sawhney; $325,000 to Mr. Smith; and $375,000 to Mr. Fortune. In 2015 we increased the base salaries of these officers as follows: Dr. Sawhney: $522,500; Mr. Smith: $333,531; and Mr. Fortune: $388,348. In 2013, we compensated Dr. Sawhney with an equity award in lieu of his base salary. In 2014, we compensated Dr. Sawhney with an equity award in lieu of a portion of his base salary. None of our named executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary.

Annual Performance-Based Compensation

We do not have a formal performance-based bonus plan. From time to time, our board of directors has approved discretionary annual cash bonuses to our named executive officers with respect to their prior year performance. We did not pay any discretionary annual cash bonuses to our named executive officers for their 2013 performance. In the first quarter of 2015, we paid discretionary annual cash bonuses of $288,750 to Dr. Sawhney; $76,781 to Mr. Smith; and $135,077 to Mr. Fortune in recognition of their performance in 2014.

Equity Incentive Awards

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incents our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our named executive officers and from time to time may grant equity incentive awards to them in the form of stock options.

We have historically granted stock options with exercise prices that are set at no less than the fair market value of shares of our common stock on the date of grant as determined by contemporaneous valuations and reviewed and approved by our compensation committee or our board of directors.

In February 2014, we granted to Mr. Fortune an option to purchase 7,339 shares of our common stock in recognition of his performance during 2013 and a stock award to Dr. Sawhney of 25,094 shares of our common stock in recognition of his performance during 2013. In March 2014, we granted Mr. Smith an option to purchase 123,105 shares of our common stock upon his appointment as our Chief Financial Officer, Dr. Sawhney an option to purchase 75,757 shares of our common stock, and Mr. Fortune an option to purchase 66,287 shares of our common stock. In April 2014, we granted Dr. Sawhney an option to purchase 47,348 shares of our common stock. The following table sets forth information regarding our option grants in 2014 to Dr. Sawhney, Mr. Smith and Mr. Fortune.

Name	Equity Award(#)	Exercise Price per share
Amarpreet Sawhney	13,882(1)	$ 9.68
	61,875(2)	$ 8.80
	47,348(3)	$ 8.80
Bradford Smith	41,819(4)	$ 8.80
	81,286(5)	$ 8.80
James Fortune	7,339(6)	$ 8.80
	21,814(7)	$ 8.80
	44,473(8)	$ 8.80

(1) This option vests over four years, with (i) approximately 11.4% of the shares underlying the option vesting on January 31, 2017, (ii) approximately 11.4% vesting monthly from February 28, 2017 to May 31, 2017, (iii) approximately 9.0% vesting on June 30, 2017, and (iv) approximately 11.4% vesting monthly from January 31, 2018 to March 31, 2018.

(2) This option vests over four years, with (i) approximately 30.6% of the shares underlying the option vesting on March 31, 2015, (ii) approximately 2.6% vesting monthly from April 30, 2015 to December 31, 2016, (iii) approximately 0.5% vesting on June 30, 2017, and (iv) approximately 2.6% vesting monthly from July 31, 2017 to December 31, 2017.

(3) This option vests over four years, with 25% of the shares underlying the option vesting on March 31, 2015, and 2.0833% vesting monthly thereafter.

(4) This option vests over four years, with (i) approximately 27.2% of the shares underlying the option vesting on March 26, 2015, (ii) approximately 6.1% vesting monthly from January 26, 2016 to April 26, 2016, (iii) approximately 2.7% vesting on May 26, 2016, (iv) approximately 6.1% vesting monthly from January 26, 2017 to April 26, 2017, (v) approximately 2.7% vesting on May 26, 2017, and (vi) approximately 6.1% vesting monthly from January 26, 2018 to March 26, 2018.

(5) This option vests over four years, with (i) approximately 23.9% of the shares underlying the option vesting on March 26, 2015, (ii) approximately 3.2% vesting monthly from April 26, 2015 to December 26, 2015, (iii) approximately 1.8% vesting on May 26, 2016, (iv) approximately 3.2% vesting monthly from June 26, 2016 to December 26, 2016, (v) approximately 1.8% vesting on May 26, 2017, and (vi) approximately 3.2% vesting monthly from June 26, 2016 to December 26, 2016.

(6) This option vests over four years, with 25% of the shares underlying the option vesting on January 1, 2015 and 2.0833% of the shares vesting thereafter.

(7) This option vests over four years, with (i) approximately 13.6% of the shares underlying the option vesting on March 31, 2015, (ii) approximately 6.3% vesting monthly from January 31, 2016 to April 30, 2016, (iii) approximately 1.1% vesting on May 31, 2016, (iv) approximately 6.3% vesting monthly from January 31, 2017 to June 30, 2017, (v) approximately 3.1% vesting on July 31, 2017, and (vi) approximately 6.3% vesting monthly from January 31, 2018 to March 31, 2018.

(8) This option vests over four years, with (i) approximately 30.6% of the shares underlying the option vesting on March 31, 2015, (ii) approximately 3.1% vesting monthly from April 30, 2015 to December 31, 2015, (iii) approximately 2.6% vesting on May 31, 2016, (iv) approximately 3.1% vesting monthly from June 30, 2016 to December 31, 2016, (v) approximately 1.6% vesting on July 31, 2017, and (vi) approximately 3.1% vesting monthly from August 31, 2017 to December 31, 2017.

On February 4, 2015, our board of directors granted stock options under the 2014 Plan to each of our named executive officers. Beginning on the one-month anniversary of the grant date, each of these option awards will vest in approximately equal monthly installments through the fourth anniversary of the grant date. Each of the option awards has an exercise price of $30.07 per share, the last reported sale price of our common stock on The NASDAQ Global Market on the date of grant, and a grant date fair value of $19.25 per share, as determined in accordance with ASC Topic 718. The following table sets forth the number of shares of common stock issuable upon exercise of the stock options granted to our named executive officers on February 4, 2015:

Name	Option Award (#)
Amarpreet Sawhney	170,000
Bradford Smith	55,000
James Fortune	79,000

Outstanding Equity Awards as of December 31, 2014

The following table sets forth information regarding outstanding stock options held by our named executive officers as of December 31, 2014:

	Option Awards				Stock Awards	
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date	Number of shares of stock that have not vested (#)	Market value of shares of stock that have not vested($)
Amarpreet Sawhney, Ph.D.	91,539	18,309(1)	1.35	8/11/2016		
	26,857	79,525(2)	2.73	1/30/2018		
	59,947	23,064(3)	2.49	1/30/2023		
		13,882(4)	9.68	3/30/2019		
		61,875(5)	8.80	3/30/2024		
		47,348(6)	8.80	4/13/2024		
					28,437(7)	668,838
Bradford Smith		41,819(8)	8.80	3/25/2024		
		81,286(9)	8.80	3/25/2024		
James Fortune	14,835	316(10)	1.22	6/15/2021		
	31,564	6,314(11)	1.22	8/11/2021		
	4,573	1,699(12)	1.22	1/25/2022		
	20,833	24,621(13)	2.49	1/30/2023		
	3,800	4,131(14)	2.49	6/5/2023		
		7,339(15)	8.80	2/11/2024		
		21,814(16)	8.80	3/30/2024		
		44,473(17)	8.80	3/30/2024		

(1) Dr. Sawhney's option to purchase 109,848 shares of common stock vests over four years, with 25% of the shares underlying the option vesting on August 12, 2012 and 2.0833% of the shares vesting monthly thereafter.

(2) Dr. Sawhney's option to purchase 106,382 shares of common stock vests over four years, with (i) approximately 25.2% of the shares underlying the option vesting on February 1, 2014, (ii) approximately 3.7% vesting monthly from January 1, 2015 to July 1, 2015, (iii) approximately 3.5% vesting on August 1, 2015, (iv) approximately 3.7% vesting monthly from January 1, 2016 to October 1, 2016, (v) approximately 0.8% vesting on November 1, 2016, and (vi) approximately 3.7% vesting monthly from January 1, 2017 to February 1, 2017.

(3) Dr. Sawhney's option to purchase 83,011 shares of common stock vests over four years, with (i) approximately 24.7% of the shares underlying the option vesting on February 1, 2014, (ii) approximately 4.8% vesting monthly from March 1, 2014 to December 1, 2014, (iii) approximately 0.3% vesting on August 1, 2015, (iv) approximately 4.8% vesting monthly from September 1, 2015 to December 1, 2015, (v) approximately 3.7% vesting on November 1, 2016, and (vi) approximately 4.8% vesting on December 1, 2016.

(4) Dr. Sawhney's option to purchase 13,882 shares of common stock vests over four years, with (i) approximately 11.4% of the shares underlying the option vesting on January 31, 2017, (ii) approximately 11.4% vesting monthly from February 28, 2017 to May 31, 2017, (iii) approximately 9.0% vesting on June 30, 2017, and (iv) approximately 11.4% vesting monthly from January 31, 2018 to March 31, 2018.

(5) Dr. Sawhney's option to purchase 61,875 shares of common stock vests over four years, with (i) approximately 30.6% of the shares underlying the option vesting on March 31, 2015, (ii) approximately 2.6% vesting monthly from April 30, 2015 to December 31, 2016, (iii) approximately 0.5% vesting on June 30, 2017, and (iv) approximately 2.6% vesting monthly from July 31, 2017 to December 31, 2017.

(6) Dr. Sawhney's option to purchase 47,348 shares of common stock vests over four years, with 25% of the shares underlying the option vesting on March 31, 2015, and 2.0833% vesting monthly thereafter.

(7) On April 14, 2014, we granted Dr. Sawhney 28,437 shares of restricted common stock, which grant is in lieu of payment of a portion of the base salary to which Dr. Sawhney will be entitled for 2015.

(8) Mr. Smith's option to purchase 41,819 shares of common stock vests over four years, with (i) approximately 27.2% of the shares underlying the option vesting on March 26, 2015, (ii) approximately 6.1% vesting monthly from January 26, 2016 to April 26, 2016, (iii) approximately 2.7% vesting on May 26, 2016, (iv) approximately 6.1% vesting monthly from January 26, 2017 to April 26, 2017, (v) approximately 2.7% vesting on May 26, 2017, and (vi) approximately 6.1% vesting monthly from January 26, 2018 to March 26, 2018.

(9) Mr. Smith's option to purchase 81,286 shares of common stock vests over four years, with (i) approximately 23.9% of the shares underlying the option vesting on March 26, 2015, (ii) approximately 3.2% vesting monthly from April 26, 2015 to December 26, 2015, (iii) approximately 1.8% vesting on May 26, 2016, (iv) approximately 3.2% vesting monthly from June 26, 2016 to December 26, 2016, (v) approximately 1.8% vesting on May 26, 2017, and (vi) approximately 3.2% vesting monthly from June 26, 2016 to December 26, 2016.

(10) Mr. Fortune's option to purchase 15,151 shares of common stock vests over four years, with 25% of the shares underlying the option vesting on January 3, 2012 and 2.0833% of the shares vesting monthly thereafter.

(11) Mr. Fortune's option to purchase 37,878 shares of common stock vests over four years, with 25% of the shares underlying the option vesting on August 12, 2012 and 2.0833% of the shares vesting monthly thereafter.

(12) Mr. Fortune's option to purchase 6,272 shares of common stock vests over four years, with 25% of the shares underlying the option vesting on January 3, 2013 and 2.0833% of the shares vesting monthly thereafter.

(13) Mr. Fortune's option to purchase 45,454 shares of common stock vests over four years, with 25% of the shares underlying the option vesting on February 1, 2014 and 2.0833% of the shares vesting monthly thereafter.

(14) Mr. Fortune's option to purchase 7,931 shares of common stock vests over four years, with 25% of the shares underlying the option vesting on January 1, 2014 and 2.0833% of the shares vesting thereafter.

(15) Mr. Fortune's option to purchase 7,339 shares of common stock vests over four years, with 25% of the shares underlying the option vesting on January 1, 2015 and 2.0833% of the shares vesting thereafter.

(16) Mr. Fortune's option to purchase 21,814 shares of common stock vests over four years, with (i) approximately 13.6% of the shares underlying the option vesting on March 31, 2015, (ii) approximately 6.3% vesting monthly from January 31, 2016 to April 30, 2016, (iii) approximately 1.1% vesting on May 31, 2016, (iv) approximately 6.3% vesting monthly from January 31, 2017 to June 30, 2017, (v) approximately 3.1% vesting on July 31, 2017, and (vi) approximately 6.3% vesting monthly from January 31, 2018 to March 31, 2018.

(17) Mr. Fortune's option to purchase 44,473 shares of common stock vests over four years, with (i) approximately 30.6% of the shares underlying the option vesting on March 31, 2015, (ii) approximately 3.1% vesting monthly from April 30, 2015 to December 31, 2015, (iii) approximately 2.6% vesting on May 31, 2016, (iv) approximately 3.1% vesting monthly from June 30, 2016 to December 31, 2016, (v) approximately 1.6% vesting on July 31, 2017, and (vi) approximately 3.1% vesting monthly from August 31, 2017 to December 31, 2017.

Employment Agreements with Executive Officers

In June and July 2014, we entered into an amended and restated employment agreement with Dr. Sawhney and employment agreements with Mr. Smith, Mr. Fortune and Mr. Ankerud. Each of these agreements provides that employment will continue until either we or the executive provides written notice of termination in accordance with the terms of the agreement. In addition, each of these agreements prohibits the executives from disclosing confidential information and competing with us during the term of their employment and for a specified time thereafter.

Pursuant to their respective employment agreements, each of these executives is entitled to receive a minimum annual base salary as follows: Dr. Sawhney: $500,000; Mr. Smith: $325,000; Mr. Fortune: $375,000; and Mr. Ankerud: $330,000. On February 12, 2014, we granted to Dr. Sawhney 94,696 shares of restricted common stock, which grant is in lieu of payment of a portion of Dr. Sawhney's base salary for 2014. On April 14, 2014, we granted to Dr. Sawhney 28,437 shares of restricted common stock, which grant is in lieu of payment of a portion of the base salary to which Dr. Sawhney will be entitled for 2015.

In addition, each of these executives is eligible to receive an annual cash bonus, which is based on the achievement of individual and corporate performance objectives that are determined by our Compensation Committee following the end of each year, calculated as a percentage of the executive's annual base salary, and which will be determined by our board of directors, in its sole discretion. The target annual bonus, as a percentage of annual base salary, for each of these executives is as follows: Dr. Sawhney: 55%; Mr. Smith: 35%; Mr. Fortune: 40%; and Mr. Ankerud: 35%.

Dr. Sawhney's amended and restated employment agreement provides for the assignment of all intellectual property he solely or jointly develops to Incept, LLC.

Potential Payments Upon Termination or Change in Control Transaction

Upon execution and effectiveness of a release of claims, each of our executives will be entitled to severance payments if his employment is terminated under specified circumstances.

Dr. Sawhney. If we terminate Dr. Sawhney's employment without cause, as defined in his employment agreement, or if Dr. Sawhney terminates his employment with us for good reason, as defined in his employment agreement, absent a change in control, or "corporate change," as defined in his employment agreement, we are obligated to pay Dr. Sawhney's base salary for a period of 18 months and, to the extent allowed by applicable law and the terms of the applicable policies, to continue to provide Dr. Sawhney and certain of his dependents with group health insurance for a period of 18 months. In addition, to the extent any shares of restricted stock granted to Dr. Sawhney in lieu of his base salary, as described above, remain unvested as of his termination, such shares will continue to vest during the 18-month severance period as if Dr. Sawhney had continued to be employed through the end of such period.

If we terminate Dr. Sawhney's employment without cause or if Dr. Sawhney terminates his employment with us for good reason, in each case within 12 months following a corporate change, we are obligated to pay Dr. Sawhney in a lump sum an amount equal to his base salary for 24 months, to pay Dr. Sawhney an amount equal to two times his target annual bonus for the year of termination, to accelerate in full the vesting of all of Dr. Sawhney's outstanding equity awards and, to the extent allowed by applicable law and the terms of the applicable policies, to continue to provide Dr. Sawhney and certain of his dependents with group health insurance for a period of 24 months.

Other Executive Officers. For each of Mr. Smith, Mr. Fortune and Mr. Ankerud, if we terminate such executive's employment without cause, as defined in such executive's employment agreement, or if the executive terminates his employment with us for good reason, as defined in such executive's employment agreement, absent a change in control, or "corporate change," as defined in such executive's employment agreement, we are obligated to pay such executive's base salary for a period of 12 months and, to the extent allowed by applicable law and the terms of the applicable policies, to continue to provide such executive and certain of his dependents with group health insurance for a period of 12 months.

If we terminate Mr. Smith, Mr. Fortune or Mr. Ankerud without cause or if such executive terminates his employment with us for good reason, in each case within 12 months following a corporate change, we are obligated to pay to such executive in a lump sum an amount equal to his base salary for 18 months, to pay to such executive an amount equal to one and one-half times his target annual bonus for the year of termination, to accelerate in full the vesting of all outstanding equity awards held by such executive and, to the extent allowed by applicable law and the terms of the applicable policies, to continue to provide such executive and certain of his dependents with group health insurance for a period of 18 months.

Taxation. To the extent that any severance or other compensation payment to any of Dr. Sawhney, Mr. Smith, Mr. Fortune or Mr. Ankerud pursuant to his employment agreement or any other agreement constitutes an "excess parachute payment" within the meaning of Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended, or the Code, then such executive will receive the full amount of such severance and other payments, or a reduced amount intended to avoid the application of Sections 280G and 4999, whichever provides the executive with the highest amount on an after-tax basis.

Equity Incentive Plans

The three equity incentive plans described in this section are our 2006 Stock Incentive Plan, as amended, or the 2006 Plan; our 2014 Stock Incentive Plan, or the 2014 Plan; and our 2014 Employee Stock Purchase Plan, or the 2014 ESPP. Prior to our initial public offering, which closed on July 30, 2014, we granted awards to eligible participants under the 2006 Plan. Following the closing of our initial public offering, we ceased granting awards under the 2006 Plan and started granting awards to eligible participants under the 2014 Plan and the 2014 ESPP.

2006 Stock Incentive Plan

The 2006 Plan provided for the grant of incentive stock options within the meaning of Section 422 of the Code, non-statutory stock options and stock grants. Our key employees, officers, directors, and consultants, as well as key employees, officers, directors, and consultants of our affiliates and certain other strategic partners, were eligible to receive awards under our 2006 Plan. However, incentive stock options could only be granted to our key employees. The terms of awards were set forth in the applicable award agreements. Our board of directors may amend our 2006 Plan at any time, subject in certain circumstances to stockholder approval. Stockholders may terminate our 2006 Plan at any time. Subject to certain limitations with respect to incentive stock options, our board of directors may accelerate the exercise date of any installment of any option under the 2006 Plan, and may amend the terms or conditions of an outstanding option or stock grant under the 2006 Plan, subject to participant consent of any amendment that is adverse to the participant.

Awards under our 2006 Plan are subject to adjustment in the event of certain corporate transactions affecting our common stock such as stock splits, stock dividends or similar transactions. In the event of a recapitalization or reorganization (other than an Acquisition, as described below) pursuant to which our securities or securities of another corporation are issued with respect to outstanding shares of our common stock, a participant, upon exercising or accepting an option or stock grant under the 2006 Plan, will be entitled to receive, for the purchase price, if any, paid upon such exercise or acceptance, the securities which would have been received if such option or stock grant had been exercised or accepted prior to such recapitalization or reorganization.

In the event of an Acquisition (as defined in the 2006 Plan) of us, our board of directors (or the board of the entity assuming our obligations under the 2006 Plan) shall take one of the following actions pursuant to the 2006 Plan, as to outstanding options:

- make appropriate provision for the continuation of outstanding options by substituting on an equitable basis for the shares then subject to outstanding options either the consideration payable with respect to the outstanding shares of common stock in connection with the Acquisition or securities of any successor or acquiring entity;
- upon written notice to participants, provide that all outstanding options must be exercised (to the extent then exercisable after taking into account any applicable acceleration of vesting) and that unexercised options will terminate within a specified time period of such notice; or

- terminate all outstanding options in exchange for a cash payment equal to the excess of the fair market value of the shares subject to such options (to the extent then exercisable after taking into account any applicable acceleration of vesting) over the exercise price thereof.

In the event of an Acquisition of us, our board of directors (or the board of the entity assuming our obligations under the 2006 Plan) shall take one of the following actions pursuant to the 2006 Plan, as to outstanding stock grants:

- make appropriate provisions for the continuation of outstanding stock grants by substituting on an equitable basis for the shares then subject to outstanding stock grants either the consideration payable with respect to the outstanding shares of common stock in connection with the Acquisition or securities of any successor or acquiring entity;
- upon written notice to participants, provide that all outstanding stock grants must be accepted (to the extent then subject to acceptance) and that unaccepted stock grants will terminate within a specified number of days of the date of such notice; or
- terminate all outstanding stock grants in exchange for a cash payment equal to the excess of the fair market value of the shares subject to such stock grant over the purchase price thereof, if any.

In addition, in the event of an Acquisition of us, our board of directors may waive all or any repurchase rights with respect to outstanding stock grants.

As of March 31, 2015, under our 2006 Plan, there were options to purchase an aggregate of 1,512,312 shares of common stock outstanding at a weighted average exercise price of $4.95 per share. We will grant no further stock options or other awards under our 2006 Plan. However, any shares of common stock subject to awards under our 2006 Plan that expire, terminate, or are otherwise surrendered, cancelled, forfeited or repurchased without having been fully exercised or resulting in any common stock being issued will become available for issuance under our 2014 Plan, up to a specified number of shares.

2014 Stock Incentive Plan

Our 2014 Plan, which became effective on July 30, 2014, was adopted by our board of directors and approved by our stockholders in June 2014. The 2014 Plan is administered by our board of directors or by a committee appointed by our board of directors. The 2014 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The number of shares of our common stock that are currently reserved for issuance under the 2014 Plan is the sum of (1) 1,244,413 shares, 92,494 shares reserved for issuance under the 2006 Plan that remained available for grant under the 2006 Plan immediately prior to the closing of our initial public offering, and the number of shares of our common stock subject to outstanding awards under our 2006 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right, plus (2) an annual increase, to be added on the first day of each fiscal year, continuing until, and including, the fiscal year ending December 31, 2024, equal to the least of 1,659,218 shares of our common stock, 4% of the number of shares of our common stock outstanding on the first day of the applicable fiscal year and an amount determined by our board of directors. On December 23, 2014, the board of directors increased the number of shares authorized for issuance under the 2014 Plan by an additional 790,000 shares, effective as of January 1, 2015.

Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2014 Plan. However, incentive stock options may only be granted to our employees.

Subject to any limitation in the 2014 Plan, our board of directors or any committee or officer to which our board of directors has delegated authority will select the recipients of awards and determine:

- the number of shares of common stock covered by options and stock appreciation rights and the dates upon which those awards become exercisable;
- the type of options to be granted;
- the exercise price of options and measurement price of stock appreciation rights, neither of which may be less than 100% of the fair market value of our common stock on the grant date;
- the duration of options and stock appreciation rights, which may not be in excess of ten years;
- the methods of payment of the exercise price of options; and
- the number of shares of common stock subject to any restricted stock awards, restricted stock units or other stock-based awards and the terms and conditions of such awards, including the issue price, conditions for repurchase, repurchase price and performance conditions, if any.

Our board of directors has delegated authority to our Chief Executive Officer to grant awards under the 2014 Plan to all new hires, other than executive officers, subject to any limitations under the 2014 Plan. Our board of directors has established the terms of the awards to be granted by our Chief Executive Officer, including the exercise price of such awards (which may include a formula by which the exercise price will be determined), and the maximum number of shares subject to awards that such executive officer may make.

Awards under the 2014 Plan are subject to adjustment in the event of a stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in our capitalization or event or any dividend or distribution to holders of our common stock other than an ordinary cash dividend.

Upon a merger or other reorganization event (as defined in the 2014 Plan), our board of directors, may, in its sole discretion, take any one or more of the following actions pursuant to the 2014 Plan, as to some or all outstanding awards, other than restricted stock:

- provide that all outstanding awards will be assumed, or substantially equivalent awards shall be substituted, by the acquiring or successor corporation or an affiliate thereof;
- upon written notice to a participant, provide that the participant's unvested and/or unexercised options or awards will terminate immediately prior to the consummation of such transaction unless exercised by the participant;
- provide that outstanding awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the reorganization event;
- in the event of a reorganization event pursuant to which holders of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to the participants with respect to each award held by the participant equal to (1) the number of shares of our common stock subject to the vested portion of the award, after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event, multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such awards; and
- provide that, in connection with a liquidation or dissolution, awards convert into the right to receive liquidation proceeds.

In the case of specified restricted stock units, no assumption or substitution is permitted, and the restricted stock units will instead be settled in accordance with the terms of the applicable restricted stock unit agreement.

Upon the occurrence of a reorganization event other than a liquidation or dissolution, the repurchase and other rights under each outstanding restricted stock award will continue for the benefit of the successor company and will, unless our board of directors may otherwise determine, apply to the cash, securities or other property into which our common stock is converted pursuant to the reorganization event. Upon the occurrence of a reorganization event involving a liquidation or dissolution, all restrictions and conditions on each outstanding restricted stock award will automatically be deemed terminated or satisfied, unless otherwise provided in the agreement evidencing the restricted stock award.

At any time, our board of directors may, in its sole discretion, provide that any award under the 2014 Plan will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part.

No award may be granted under the 2014 Plan after July 29, 2024. Our board of directors may amend, suspend or terminate the 2014 Plan at any time, except that stockholder approval will be required to comply with applicable law or stock market requirements.

2014 Employee Stock Purchase Plan

Our 2014 ESPP, which became effective immediately prior to the closing of our initial public offering, was adopted by our board of directors and approved by our stockholders in June 2014. The 2014 ESPP is administered by our board of directors or by a committee appointed by our board of directors. As of March 31, 2015, the 2014 ESPP provides participating employees with the opportunity to purchase an aggregate of 227,007 shares of our common stock.

The number of shares of our common stock reserved for issuance under the 2014 ESPP will automatically increase on the first day of each fiscal year, ending on December 31, 2024, in an amount equal to the least of (1) 207,402 shares of our common stock, (2) 0.5% of the total number of shares of our common stock outstanding on the first day of the applicable fiscal year and (3) an amount determined by our board of directors. On December 23, 2014, the board of directors increased the number of shares authorized for issuance under the 2014 ESPP by an additional 25,000 shares, effective as of January 1, 2015.

All of our employees and employees of any of our designated subsidiaries, as defined in the 2014 ESPP, are eligible to participate in the 2014 ESPP, provided that:

- such person is customarily employed by us or a designated subsidiary for more than 20 hours a week and for more than five months in a calendar year;
- such person has been employed by us or by a designated subsidiary for at least six months prior to enrolling in the 2014 ESPP; and
- such person was our employee or an employee of a designated subsidiary on the first day of the applicable offering period under the 2014 ESPP.

No employee may purchase shares of our common stock under the 2014 ESPP and any of our other employee stock purchase plans in excess of $25,000 of the fair market value of our common stock (as of the date of the option grant) in any calendar year. In addition, no employee may purchase shares of our common stock under the 2014 ESPP that would result in the employee owning 5% or more of the total combined voting power or value of our stock.

Our first offering period commenced October 1, 2014, and closed on December 31, 2014, at which time 5,395 shares of common stock were issued. We plan to have offering periods two times annually, each six months in duration, to purchase stock under the 2014 ESPP. Payroll deductions will be made and held for the purchase of our common stock at the end of each offering period. Our board of directors may, at its discretion, choose a different period of not more than 12 months for offerings.

On the commencement date of each offering period, each eligible employee may authorize up to a maximum of 15% of his or her compensation to be deducted by us during the offering period. Each employee who continues to be a participant in the 2014 ESPP on the last business day of the offering period will be deemed to have exercised an option to purchase from us the number of whole shares of our common stock that his or her accumulated payroll deductions on such date will pay for, not in excess of the maximum numbers set forth above. Under the terms of the 2014 ESPP, the purchase price shall be determined by our board of directors for each offering period and will be at least 85% of the applicable closing price of our common stock. If our board of directors does not make a determination of the purchase price, the purchase price will be 85% of the lesser of the closing price of our common stock on the first business day of the offering period or on the last business day of the offering period.

An employee may for any reason withdraw from participation in an offering prior to the end of an offering period and permanently draw out the balance accumulated in the employee’s account. If an employee elects to discontinue his or her payroll deductions during an offering period but does not elect to withdraw his or her funds, funds previously deducted will be applied to the purchase of common stock at the end of the offering period. If a participating employee’s employment ends before the last business day of an offering period, no additional payroll deductions will be made and the balance in the employee’s account will be paid to the employee.

We are required to make equitable adjustments to the number and class of securities available under the 2014 ESPP, the share limitations under the 2014 ESPP and the purchase price for an offering period under the 2014 ESPP to reflect stock splits, reverse stock splits, stock dividends, recapitalizations, combinations of shares, reclassifications of shares, spin-offs and other similar changes in capitalization or events or any dividends or distributions to holders of our common stock other than ordinary cash dividends.

In connection with a merger or other reorganization event (as defined in the 2014 ESPP), our board of directors or a committee of our board of directors may take any one or more of the following actions as to outstanding options to purchase shares of our common stock under the 2014 ESPP on such terms as our board or committee determines:

- provide that options shall be assumed, or substantially equivalent options shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);
- upon written notice to employees, provide that all outstanding options will be terminated immediately prior to the consummation of such reorganization event and that all such outstanding options will become exercisable to the extent of accumulated payroll deductions as of a date specified by our board or committee in such notice, which date shall not be less than ten days preceding the effective date of the reorganization event;
- upon written notice to employees, provide that all outstanding options will be cancelled as of a date prior to the effective date of the reorganization event and that all accumulated payroll deductions will be returned to participating employees on such date;
- in the event of a reorganization event under the terms of which holders of our common stock will receive upon consummation thereof a cash payment for each share surrendered in the reorganization event, change the last day of the offering period to be the date of the consummation of the reorganization event and make or provide for a cash payment to each employee equal to (1) the cash payment for each share surrendered in the reorganization event times the number of shares of our common stock that the employee’s accumulated payroll deductions as of immediately prior to the reorganization event could purchase at the applicable purchase price, where the acquisition price is treated as the fair market value of our common stock on the last day of the applicable offering period for purposes of determining the purchase price and where the number of shares that could be purchased is subject to the applicable limitations under the 2014 ESPP, minus (2) the result of multiplying such number of shares by the purchase price; and/or
- provide that, in connection with our liquidation or dissolution, options shall convert into the right to receive liquidation proceeds (net of the purchase price thereof).

Our board of directors may at any time, and from time to time, amend or suspend the 2014 ESPP or any portion thereof. We will obtain stockholder approval for any amendment if such approval is required by Section 423 of the Code. Further, our board of directors may not make any amendment that would cause the 2014 ESPP to fail to comply with Section 423 of the Code. The 2014 ESPP may be terminated at any time by our board of directors. Upon termination, we will refund all amounts in the accounts of participating employees.

401(k) Plan

We maintain a defined contribution employee retirement plan for our employees. Our 401(k) plan is intended to qualify as a tax-qualified plan under Section 401 of the Code, so that contributions to our 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan. Our 401(k) plan provides that each participant may contribute up to 90% of his or her pre-tax compensation, up to a statutory limit, which is $18,000 for 2015. Participants who are at least 50 years old can also make “catch-up” contributions, which in 2015 may be up to an additional $6,000 above the statutory limit. Under our 401(k) plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan’s trustee, subject to participants’ ability to give investment directions by following certain procedures. We do not currently make discretionary contributions or matching contributions to our 401(k) plan.

Limitation of Liability and Indemnification

Our certificate of incorporation limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law, or the DGCL, and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of the director’s duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the DGCL is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the DGCL.

In addition, our certificate of incorporation provides that we must indemnify our directors and officers and we must advance expenses, including attorneys’ fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

We maintain a general liability insurance policy that covers specified liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we have entered into indemnification agreements with our directors and executive officers. These indemnification agreements may require us, among other things, to indemnify each such director or officer for some expenses, including attorneys’ fees, judgments, fines and settlement amounts incurred by him in any action or proceeding arising out of his or her service as one of our directors or officers.

Some of our non-employee directors may, through their relationships with their employers, be insured or indemnified against specified liabilities incurred in their capacities as members of our board of directors.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, or the Securities Act, may be permitted to directors, executive officers or persons controlling us, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Director Compensation

The following table sets forth a summary of the compensation earned by our directors for the year ended December 31, 2014, with the exception of Dr. Sawhney. During 2014, we did not provide any additional compensation to Amarpreet Sawhney, Ph.D., our President and Chief Executive Officer, for his service as a director. Dr. Sawhney's compensation as an executive officer is set forth above under "Executive Compensation—Summary Compensation Table."

Name	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)(2)	Total ($)
Jaswinder Chadha	19,313	221,317(3)	240,630
Alan Crane	—	108,971(4)(5)	108,971
James Garvey	22,313	108,971(4)	131,284
Richard Lindstrom, M.D.	19,250	221,317(3)	240,567
Bruce Peacock	24,500	120,982(6)	145,482
Charles Warden	23,188	108,971(4)	132,159

(1) Fees earned or paid in cash consist of:

- for Mr. Chadha, $4,000 for serving as a member of our board under his previous director services agreement and a prorated portion of $35,000 for serving as a member of our board following our initial public offering;
- for Mr. Garvey, a prorated portion of $35,000 for serving as a member of our board, $8,000 for serving as the chairman of our nominating and corporate governance committee and $8,000 for serving as a member of our audit committee following our initial public offering;
- for Dr. Lindstrom, a prorated portion of $35,000 for serving as a member of our board, $5,000 for serving as a member of our compensation committee and $4,000 for serving as a member of our nominating and corporate governance committee, in each case following our initial public offering;
- for Mr. Peacock, a prorated portion of $35,000 for serving as a member of our board, $16,000 for serving as the chairman of our audit committee and $5,000 for serving as a member of our compensation committee, in each case following our initial public offering; and
- for Mr. Warden, a prorated portion of $35,000 for serving as a member of our board, $10,000 for serving as the chairman of our compensation committee and $8,000 for serving as a member of our audit committee, in each case following our initial public offering.

(2) The amounts reported in the "Option Awards" column reflect the aggregate fair value of share-based compensation awarded during the year computed in accordance with the provisions of ASC Topic 718. See Note 11 to our audited financial statements included elsewhere in this prospectus, regarding assumptions underlying the valuation of equity awards.

(3) Consists of (i) the option to purchase 18,939 shares of common stock vesting over four years, with 25% of the shares underlying the option vesting on April 11, 2015 and 2.0833% of the shares vesting monthly thereafter and (ii) the option to purchase 11,363 shares of common stock which began to vest with respect to 1/36th of the shares on the one month anniversary of the closing of our initial public offering and vests with respect to an additional 1/36th of the shares on each monthly anniversary thereafter.

(4) Consists of the option to purchase 11,363 shares of common stock which began to vest with respect to 1/36th of the shares on the one month anniversary of the closing of our initial public offering and vests with respect to an additional 1/36th of the shares on each monthly anniversary thereafter.

(5) Mr. Crane resigned from the Board upon our initial public offering. As a result, his option expired prior to vesting.

(6) Consists of the option to purchase 11,363 shares of common stock which began to vest with respect to 1/36th of the shares on the one month anniversary of Mr. Peacock's election to our board of directors and vests with respect to an additional 1/36th of the shares on each monthly anniversary thereafter.

Prior to 2014, we did not pay cash compensation to any non-employee director for his or her service as a director, with the exception of Jaswinder Chadha and Richard Lindstrom, M.D., who each entered into director services agreements with us. Under the terms of his director services agreement, we agreed to grant Mr. Chadha a stock option award for 9,469 shares of our common stock and to pay him a $2,000 per-meeting attendance fee for his service as a director. In 2013, Mr. Chadha received a stock option with a fair value equal to $16,195 and cash compensation of $4,000. Under the terms of his director services agreement, we agreed to grant Dr. Lindstrom a one-time stock option award of 9,469 shares and to pay him a $5,000 per-meeting attendance fee for his service as a director. We granted Dr. Lindstrom his stock option award in 2012. In 2013, Dr. Lindstrom received cash compensation of $15,000 for his service as a director.

In April 2014, Mr. Chadha and Dr. Lindstrom were each granted an option to purchase 18,939 shares of our common stock for services previously rendered. In April 2014, all of our existing non-employee directors other than Mr. Peacock were each granted an option to purchase 11,363 shares of our common stock. In connection with his election to our board of directors, Mr. Peacock received an option to purchase 11,363 shares of our common stock in August 2014.

Director Compensation Arrangements

Since the closing of our initial public offering in July 2014, our non-employee directors are compensated for their services on our board of directors as follows:

- each new non-employee director will receive an initial grant of an option under our 2014 Plan to purchase 11,363 shares of common stock upon his or her initial election to our board of directors;
- each non-employee director who has served on our board of directors for at least six months will receive an annual grant of an option under our 2014 Plan to purchase 5,681 shares of common stock on the date of the first meeting of our board of directors held after each annual meeting of our stockholders;
- each non-employee director will receive an annual cash fee of $35,000;
- each non-employee director who is a member of the audit committee will receive an additional annual cash fee of $8,000 ($16,000 for the audit committee chairman);
- each non-employee director who is a member of the compensation committee will receive an additional annual cash fee of $5,000 ($10,000 for the compensation committee chairman); and
- each non-employee director who is a member of the nominating and corporate governance committee will receive an additional annual cash fee of $4,000 ($8,000 for the nominating and corporate governance committee chairman).

The stock options granted to our non-employee directors will have an exercise price equal to the fair market value of our common stock on the date of grant and will expire ten years after the date of grant. The initial stock options granted to our future newly elected non-employee directors will, subject to the director's continued service on our board, vest with respect to one-third of the shares on each of the first, second, and third anniversaries of the grant date. The annual stock options granted to our non-employee directors will, subject to the director's continued service on our board, vest with respect to 100% of the shares on the first anniversary of the grant date.

Each annual cash fee will be payable in arrears in four equal quarterly installments on the last day of each quarter. The amount of each payment will be prorated for any portion of a quarter that a director is not serving on our board. In addition, no fee was payable in respect of any period prior to the effective date of the registration statement from our initial public offering, and the first payment after the effective date was prorated therefor.

Each non-employee director will also be entitled to reimbursement for reasonable travel and other expenses incurred in connection with attending meetings of the board of directors and any committee on which he or she serves or otherwise in direct service of our company.

TRANSACTIONS WITH RELATED PERSONS

Since January 1, 2012, we have engaged in the following transactions with our directors, executive officers and holders of more than 5% of our voting securities, and affiliates of our directors, executive officers and holders of more than 5% of our voting securities. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Incept License Agreement

Since January 2012, we have been party to an amended and restated license agreement with Incept, LLC, or Incept, an intellectual property holding company. Dr. Sawhney, our President and Chief Executive Officer, is a general partner of Incept and has a 50% ownership stake in Incept. Farhad Khosravi, who served as a member of our board of directors until June 2013 and is a 5% stockholder in our company, is also a general partner of Incept and has a 50% ownership stake in Incept. Pursuant to the terms of the license agreement, we hold an exclusive, worldwide, perpetual, irrevocable license under specified patents and technology owned or controlled by Incept to make, have made, use, offer for sale, sell, sublicense, have sublicensed, offer for sublicense and import, products delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to all human ophthalmic diseases or conditions. This license covers all of the patent rights and a significant portion of the technology for ReSure Sealant and our hydrogel platform technology product candidates. We will also be obligated to pay Incept a royalty equal to a low single-digit percentage of net sales made by us or our affiliates. Any sublicensee of ours also will be obligated to pay Incept a royalty equal to a low single-digit percentage of net sales made by it and will be bound by the terms of the agreement to the same extent as we are. As of the date of this prospectus, we have paid $13,827 in royalties to Incept pursuant to the license agreement.

In addition, on February 12, 2014, we issued to Incept 189,393 shares of our common stock, valued at $1,665,000, in connection with the expansion of the scope of the license to include back-of-the-eye technology held by Incept. As stockholders who each own 50% of Incept, Dr. Sawhney and Mr. Khosravi each could be deemed to have an aggregate interest of approximately $0.8 million in these transactions.

Augmenix Lease and Consulting Services

Since 2012, we have had an ongoing business relationship with Augmenix, Inc., or Augmenix. Until April 2014, Dr. Sawhney was the Chief Executive Officer, Mr. Fortune was the Chief Operating Officer and Mr. Ankerud was the Executive Vice President, Clinical, Regulatory and Quality, of both Ocular Therapeutix and Augmenix. Augmenix paid us approximately $366,000 in 2012, approximately $232,000 in 2013, and approximately $82,000 in 2014 for consulting services we provided to Augmenix. Additionally, Augmenix invoiced us approximately $27,000 in 2014 for legal fees. As a stockholder who owns approximately 26% of Augmenix, Dr. Sawhney could be deemed to have an aggregate interest of approximately $177,000 in these transactions.

Khosravi Stock Grant

In February 2014, we issued to Mr. Khosravi 79,545 shares of our common stock, valued at $699,300 in exchange for consulting services rendered.

Series D Preferred Stock Financing

In November 2012, we issued and sold an aggregate of 9,670,730 shares of our series D preferred stock at a price per share of $2.46 for an aggregate purchase price of $23.8 million. As part of that financing, we sold 9,552,730 shares for an aggregate purchase price of $23.5 million to five of our 5% stockholders. The following table sets forth the aggregate number of shares of our series D preferred stock that we issued and sold to our 5% stockholders and their affiliates in these transactions and the aggregate purchase price for such shares:

	Shares of Series D Preferred Stock	Purchase Price
CHV II LP(1)	2,439,024	$5,999,999
Entities affiliated with Versant Ventures(2)	2,235,772	5,499,999
Entities affiliated with SV Life Sciences(3)	2,032,520	4,999,999
Sparta Group MA LLC Series 12(4)	1,626,016	3,999,999
Entities affiliated with Polaris Ventures(5)	1,219,512	3,000,000

(1) Ascension Ventures II, LLC is the general partner of CHV II, L.P. Ascension Ventures II, LLC is governed by a Board of Managers, which has authority to invest and vote for the shares held by CHV II, L.P. Signatory and voting authority has been delegated to Matthew I. Hermann, Senior Managing Director of Ascension Ventures II, LLC. Decisions regarding liquidation of investment positions have been delegated by the Board to Anthony J. Speranzo, Executive Vice President and Chief Financial Officer, Ascension, and Matthew I. Hermann, Senior Managing Director, Ascension Ventures II, LLC, acting jointly. Each of the individuals and entities listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for each of the individuals and entities listed above is Ascension Ventures, 101 South Hanley Road, Suite 200, Clayton, MO 63105.

(2) Consists of 2,222,648 shares held by Versant Venture Capital III, L.P. and 13,124 shares held by Versant Side Fund III, L.P. Versant Ventures III, LLC is the general partner of Versant Venture Capital III, L.P. and Versant Side Fund III, L.P. The managing members of Versant Ventures III, LLC are Brian G. Atwood, Bradley J. Bolzon, Samuel D. Colella, Ross A. Jaffe, William J. Link, Barbara N. Lubash, Donald B. Milder, Robin L. Praeger, Rebecca B. Robertson and Charles M. Warden. Each of these individuals listed above exercises shared voting and investment power over the shares held of record by Versant Venture Capital III, L.P. and Versant Side Fund III, L.P. Mr. Warden is a member of our board of directors. Each of the individuals listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for each of the individuals and entities listed above is One Sansome Street, Suite 3630, San Francisco, California 94104.

(3) Consists of 1,976,408 shares held by SV Life Sciences Fund IV, L.P. and 56,112 shares held by SV Life Sciences Fund IV Strategic Partners, L.P. SV Life Sciences Fund IV (GP), LP is the general partner of SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners, L.P. The general partner of SV Life Sciences Fund IV (GP), LP is SVLSF IV, LLC. The members of the investment committee of SVLSF IV, LLC are Kate Bingham, James Garvey, Eugene D. Hill, III, David Milne and Michael Ross. SVLSF IV, LLC and each of these individuals may be deemed to share voting, dispositive and investment power over the shares held of record by SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners L.P. Mr. Garvey is a member of our board of directors. Each of the individuals and entities listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for each of the individuals and entities listed above is One Boston Place, Suite 3900, Boston, MA 02108.

(4) Gururaj Deshpande and Jaishree Deshpande are the Managers of Sparta Group MA LLC Series 12 and exercise voting and investment power over the shares held of record by Sparta Group MA LLC Series 12. Each of the individuals and entities listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for each of the individuals and entities listed above is 92 Montvale Avenue, Suite 2500, Stoneham MA 02180.

(5) Consists of 1,176,749 shares held by Polaris Venture Partners V, L.P., 22,935 shares held by Polaris Venture Partners Entrepreneurs' Fund V, L.P., 8,061 shares held by Polaris Venture Partners Founders'

Fund V, L.P. and 11,767 shares held by Polaris Venture Partners Special Founders' Fund V, L.P., collectively the Polaris Funds. Polaris Venture Management Co. V, LLC is the general partner of the Polaris Funds. The managing members of Polaris Venture Management Co. V, LLC are Terrance G. McGuire and Jonathan A. Flint. Polaris Venture Management Co. V, LLC and each of these individuals exercises voting and investment power over the shares held of record by the Polaris Funds. Mr. Crane, a Partner and Entrepreneur of Polaris Venture Partners, an affiliate of the Polaris Funds, was a member of our board of directors prior to completion of our initial public offering. Each of the individuals and entities listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for each of the individuals and entities listed above is Polaris Venture Partners, 1000 Winter Street, Suite 3350, Waltham, MA 02451.

Series D-1 Preferred Stock Financing

In May 2013, we issued and sold an aggregate of 2,833,334 shares of our series D-1 preferred stock at a price per share of $3.00 for an aggregate purchase price of $8.5 million to two of our 5% stockholders. The following table sets forth the aggregate number of shares of our series D-1 preferred stock that we issued and sold to our 5% stockholders and their affiliates in these transactions and the aggregate purchase price for such shares:

	Shares of Series D-1 Preferred Stock	Purchase Price
Baxter Healthcare Corporation(1)	2,166,667	$ 6,500,001
CHV II LP(2)	666,667	2,000,001

(1) The shares are owned directly by Baxter Healthcare Corporation, which is a direct, wholly-owned subsidiary of Baxter International Inc., an NYSE-listed company, and as such Baxter International Inc. is an indirect beneficial owner of the shares. The address for both entities is One Baxter Parkway, Deerfield, IL, 60015.

(2) Ascension Ventures II, LLC is the general partner of CHV II, L.P. Ascension Ventures II, LLC is governed by a Board of Managers, which has authority to invest and vote for the shares held by CHV II, L.P. Signatory and voting authority has been delegated to Matthew I. Hermann, Senior Managing Director of Ascension Ventures II, LLC. Decisions regarding liquidation of investment positions have been delegated by the Board to Anthony J. Speranzo, Executive Vice President and Chief Financial Officer, Ascension, and Matthew I. Hermann, Senior Managing Director, Ascension Ventures II, LLC, acting jointly. Each of the individuals and entities listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for each of the individuals and entities listed above is Ascension Ventures, 101 South Hanley Road, Suite 200, Clayton, MO 63105.

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Initial Public Offering

In our initial public offering, certain of our officers and 5% stockholders and their affiliated entities purchased an aggregate of 707,149 shares of our common stock. Each of those purchases was made through the underwriters at the initial public offering price of $13.00 per share. The following table sets forth the aggregate number of shares of our common stock that these 5% stockholders purchased in our initial public offering.

	Shares of Common Stock Purchased	Aggregate Purchase Price
Entities affiliated with SV Life Sciences(1)	238,460	$ 3,099,980
CHV II L.P.(2)	153,846	1,999,998
Farhad Khosravi(3)	76,922	999,986
Sparta Group MA LLC Series 12(4)	92,307	1,199,991
Baxter Healthcare Corporation(5)	67,692	879,996
Amarpreet Sawhney, Ph.D.(6)	76,922	999,986
Eric Ankerud	1,000	13,000

(1) Consists of 231,877 shares purchased by SV Life Sciences Fund IV, L.P. and 6,583 shares purchased by SV Life Sciences Fund IV Strategic Partners, L.P. SV Life Sciences Fund IV (GP), LP is the general partner of SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners, L.P. The general partner of SV Life Sciences Fund IV (GP), LP is SVLSF IV, LLC. The members of the investment committee of SVLSF IV, LLC are Kate Bingham, James Garvey, Eugene D. Hill, III, David Milne and Michael Ross. SVLSF IV, LLC and each of these individuals may be deemed to share voting, dispositive and investment power over the shares held of record by SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners L.P. Mr. Garvey is a member of our board of directors. Each of the individuals and entities listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein.

(2) Ascension Ventures II, LLC is the general partner of CHV II, L.P. Ascension Ventures II, LLC is governed by a Board of Managers, which has authority to invest and vote for the shares held by CHV II, L.P. Signatory and voting authority has been delegated to Matthew I. Hermann, Senior Managing Director of Ascension Ventures II, LLC. Decisions regarding liquidation of investment positions have been delegated by the Board to Anthony J. Speranzo, Executive Vice President and Chief Financial Officer, Ascension, and Matthew I. Hermann, Senior Managing Director, Ascension Ventures II, LLC, acting jointly. Each of the individuals and entities listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein.

(3) Consists of shares purchased by the Farhad Khosravi & Flora Shirzad Khosravi Trust u/a/d 10/19/2004.

(4) Gururaj Deshpande and Jaishree Deshpande are the Managers of Sparta Group MA LLC Series 12 and exercise voting and investment power over the shares held of record by Sparta Group MA LLC Series 12. Each of the individuals listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein.

(5) Baxter Healthcare Corporation is a direct, wholly-owned subsidiary of Baxter International Inc., an NYSE-listed company, and as such Baxter International Inc. is an indirect beneficial owner of the shares.

(6) Consists of shares purchased by the Sangam Trust. Dr. Sawhney or his immediate family members are beneficiaries of the Sangam Trust.

Registration Rights

We are a party to an investor rights agreement with certain holders of our common stock, including our 5% stockholders and their affiliates and entities affiliated with some of our directors. This investors' rights agreement provides certain of these holders the right to demand that we file a registration statement or to request that their shares be covered by a registration statement that we are otherwise filing.

See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Indemnification Agreements

Our certificate of incorporation provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with all of our directors and executive officers.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which our company is a participant, the amount involved exceeds $120,000 and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a “related person,” has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a “related person transaction,” the related person must report the proposed related person transaction to our chief financial officer. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chairman of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the audit committee after full disclosure of the related person’s interest in the transaction. As appropriate for the circumstances, the audit committee will review and consider:

- the related person’s interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person’s interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

Our audit committee may approve or ratify the transaction only if it determines that, under all of the circumstances, the transaction is in our best interests. Our audit committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC’s related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person’s position as an executive officer of another entity, whether or not the person is also a director of the entity, that is a participant in the transaction where the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction and the amount involved in the transaction is less than the greater of $200,000 or 5% of the annual gross revenues of the company receiving payment under the transaction; and

- a transaction that is specifically contemplated by provisions of our certificate of incorporation or by-laws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by our compensation committee in the manner specified in the compensation committee's charter.

We did not have a written policy regarding the review and approval of related person transactions prior to our initial public offering. Nevertheless, with respect to such transactions, it had been the practice of our board of directors to consider the nature of and business reasons for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of, or not contrary to, our best interests. In addition, all related person transactions required prior approval, or later ratification, by our board of directors.

PRINCIPAL AND SELLING STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of May 31, 2015 by:

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

The percentages in the column entitled "Shares Beneficially Owned Before Offering" is based on 21,502,479 shares of our common stock outstanding as of May 31, 2015. The percentages in the column entitled "Shares Beneficially Owned After Offering" is based on 24,702,479 shares of our common stock to be outstanding after this offering, including the 3,200,000 shares of our common stock that we are selling and the 800,000 shares of our common stock that the selling stockholders are selling in this offering. The percentages in the column entitled "Shares Beneficially Owned After Offering Assuming Underwriters Exercise Option in Full" give further effect to the sale by the selling stockholders and assumes the exercise in full by the underwriters of their option to purchase an additional 600,000 shares of our common stock from the selling stockholders. The information set forth in the columns entitled "Shares Beneficially Owned After Offering" and "Shares Beneficially Owned After Offering Assuming Underwriters Exercise Option in Full" does not give effect to the issuance of any additional shares issuable upon exercise of outstanding options or warrants as of May 31, 2015.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock subject to options and warrants that are currently exercisable or exercisable within 60 days after May 31, 2015 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of each beneficial owner is c/o Ocular Therapeutix, Inc., 34 Crosby Drive, Suite 105, Bedford, Massachusetts 01730.

The information in the table below with respect to each selling stockholder has been obtained from that selling stockholder. When we refer to the "selling stockholders" in this prospectus, we mean those persons listed in the table below as offering shares, as well as the pledgees, donees, assignees, transferees, successors and others who may hold any of the selling stockholders' interests.

Name of Beneficial Owner	Shares Beneficially Owned Before Offering		Number of Shares Offered	Shares Beneficially Owned After Offering		Shares Beneficially Owned After Offering Assuming Underwriters Exercise Option in Full	
	Number	%		Number	%	Number	%
Directors and Named Executive Officers:							
Amarpreet Sawhney, Ph.D.(1)	2,893,212	13.3%	—	2,893,212	11.6%	2,893,212	11.3%
James Fortune(2)	241,739	1.1%	—	241,739	*	241,739	*
Bradford Smith(3)	46,764	*	—	46,764	*	46,764	*
Jaswinder Chadha(4)	146,031	*	—	146,031	*	146,031	*
James Garvey(5)	2,590,341	12.0%	373,000	2,217,341	9.0%	1,937,341	7.7%
Richard Lindstrom, M.D.(6)	60,523	*	—	60,523	*	60,523	*
Bruce Peacock(7)	3,787	*	—	3,787	*	3,787	*
Charles Warden(8)	2,967,118	13.8%	427,000	2,540,118	10.3%	2,220,118	8.8%
All current executive officers and directors as a group (9 persons)(9)	8,932,725	40.6%	800,000	8,132,725	32.3%	7,532,725	29.2%
5% Stockholders:							
Entities affiliated with SV Life Sciences(10)	2,585,607	12.0%	373,000	2,212,607	9.0%	1,932,607	7.6%
Entities affiliated with Polaris Ventures(11)	1,413,485	6.6%	—	1,413,485	5.7%	1,413,485	5.6%
Entities affiliated with Versant Ventures(12)	2,962,384	13.8%	427,000	2,535,384	10.3%	2,215,384	8.8%
CHV II LP(13)	2,100,138	9.8%	—	2,100,138	8.5%	2,100,138	8.3%
Farhad Khosravi(14)	1,112,422	5.2%	—	1,112,422	4.5%	1,112,422	4.4%
Wellington Management Group(15)	1,296,690	6.0%	—	1,296,690	5.3%	1,296,690	5.1%

* Less than one percent

(1) Consists of (i) 538,733 shares of common stock held by Dr. Sawhney directly; (ii) 226,669 shares of common stock issuable upon the exercise of options exercisable within 60 days after May 31, 2015; (iii) 379,419 shares of common stock held by the SAFIGS Trust; (iv) 71,969 shares of common stock held by the Sawhney Family Dynasty Trust; (v) 471,784 shares of common stock held by the Sangam Trust; (vi) 38,420 shares of common stock held by the Navdeep Chadha 2007 Delaware Trust; (vii) 130,448 shares of common stock held by the Jaswinder Chadha 2007 Delaware Trust; (viii) 189,393 shares of common stock held by the Amarpreet S. Sawhney 2014 GRAT; and (ix) 846,377 shares of common stock held by Incept, LLC. Dr. Sawhney has voting and investment power as a trustee of the Navdeep Chadha 2007 Delaware Trust and the Jaswinder Chadha 2007 Delaware Trust. Dr. Sawhney has voting and investment power as a general partner of Incept, LLC. Dr. Sawhney or his immediate family members are beneficiaries of the SAFIGS Trust, the Sawhney Family Dynasty Trust, the Sangam Trust and the Amarpreet S. Sawhney 2014 GRAT. Dr. Sawhney expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for Dr. Sawhney and for each of the entities listed above is Ocular Therapeutix, Inc., 34 Crosby Drive, Suite 105, Bedford, MA 01730.

(2) Consists of (i) 119,901 shares of common stock and (ii) 121,838 shares of common stock issuable upon the exercise of options exercisable within 60 days after May 31, 2015.

(3) Consists of shares of common stock issuable upon the exercise of options exercisable within 60 days after May 31, 2015.

(4) Consists of (i) 130,448 shares of common stock held by the Jaswinder Chadha 2007 Delaware Trust and (ii) 15,583 shares of common stock issuable upon the exercise of options exercisable within 60 days after May 31, 2015.

(5) Consists of (i) 4,734 shares of common stock issuable upon the exercise of options exercisable within 60 days after May 31, 2015 held by Mr. Garvey directly; (ii) 2,514,226 shares of common stock held by SV Life Sciences Fund IV, L.P.; and (iii) 71,381 shares of common stock held by SV Life Sciences Fund IV Strategic Partners, L.P. SV Life Sciences Fund IV (GP), LP is the general partner of SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners, L.P. The general partner of SV Life Sciences Fund IV (GP), LP is SVLSF IV, LLC. The members of the investment committee of SVLSF IV, LLC are Kate Bingham, James Garvey, Eugene D. Hill, III, David Milne and Michael Ross. SVLSF IV, LLC and each of these individuals may be deemed to share voting, dispositive and investment power over the shares held of record by SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners L.P. Mr. Garvey is a member of our board of directors. Each of the individuals and entities listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for each of the individuals and entities listed above is One Boston Place, Suite 3900, Boston, MA 02108. The number of shares offered reflects 362,703 shares of common stock that will be sold by SV Life Science Fund IV, L.P. and 10,297 shares of common stock that will be sold by SV Life Sciences Fund IV Strategic Partners, L.P.

(6) Consists of (i) 43,559 shares of common stock and (ii) 16,964 shares of common stock issuable upon the exercise of options exercisable within 60 days after May 31, 2015.

(7) Consists of shares of common stock issuable upon the exercise of options exercisable within 60 days after May 31, 2015.

(8) Consists of (i) 4,734 shares of common stock issuable upon the exercise of options exercisable within 60 days after May 31, 2015 held by Mr. Warden directly; (ii) 2,944,993 shares of common stock held by Versant Venture Capital III, L.P.; and (iii) 17,391 shares of common stock held by Versant Side Fund III, L.P. Versant Ventures III, LLC is the general partner of Versant Venture Capital III, L.P. and Versant Side Fund III, L.P. The managing members of Versant Ventures III, LLC are Brian G. Atwood, Bradley J. Bolzon, Samuel D. Colella, Ross A. Jaffe, William J. Link, Barbara N. Lubash, Donald B. Milder, Robin L. Praeger, Rebecca B. Robertson and Charles M. Warden. Each of these individuals listed above exercises shared voting and investment power over the shares held of record by Versant Venture Capital III, L.P. and Versant Side Fund III, L.P. Mr. Warden is a member of our board of directors. Each of the individuals listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for each of the individuals and entities listed above is One Sansome Street, Suite 3630, San Francisco, California 94104. The number of shares offered reflects 424,494 shares of common stock that will be sold by Versant Venture Capital III, L.P. and 2,506 shares of common stock that will be sold by Versant Side Fund III, L.P.

(9) Consists of (i) 8,456,783 shares of common stock and (ii) 475,942 shares of common stock underlying options that are exercisable as of May 31, 2015 or will become exercisable within 60 days after such date. Dr. Sawhney's interest as trustee and Mr. Chadha's interest as beneficiary of 130,448 shares of common stock held by the Jaswinder Chadha 2007 Delaware Trust are reflected in Dr. Sawhney's and Mr. Chadha's totals above. They are counted only once in this total.

(10) Consists of 2,514,226 shares of common stock held by SV Life Sciences Fund IV, L.P. and 71,381 shares of common stock held by SV Life Sciences Fund IV Strategic Partners, L.P. SV Life Sciences Fund IV (GP), LP is the general partner of SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners, L.P. The general partner of SV Life Sciences Fund IV (GP), LP is SVLSF IV, LLC. The members of the investment committee of SVLSF IV, LLC are Kate Bingham, James Garvey, Eugene D. Hill, III, David Milne and Michael Ross. SVLSF IV, LLC and each of these individuals may be deemed to share voting, dispositive and investment power over the shares held of record by SV Life Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners L.P. Mr. Garvey is a member of our board of directors. Each of the individuals and entities listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for each of the individuals and entities listed above is One Boston Place, Suite 3900, Boston, MA 02108. The number of

shares offered reflects 362,703 shares of common stock that will be sold by SV Life Science Fund IV, L.P. and 10,297 shares of common stock that will be sold by SV Life Sciences Fund IV Strategic Partners, L.P.

(11) Consists of 1,363,914 shares of common stock held by Polaris Venture Partners V, L.P., 26,585 shares of common stock held by Polaris Venture Partners Entrepreneurs' Fund V, L.P., 9,345 shares of common stock held by Polaris Venture Partners Founders' Fund V, L.P. and 13,641 shares of common stock held by Polaris Venture Partners Special Founders' Fund V, L.P., collectively the Polaris Funds. Polaris Venture Management Co. V, LLC is the general partner of the Polaris Funds. The managing members of Polaris Venture Management Co. V, LLC are Terrance G. McGuire and Jonathan A. Flint. Polaris Venture Management Co. V, LLC and each of these individuals exercises voting and investment power over the shares held of record by the Polaris Funds. Each of the individuals and entities listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for each of the individuals and entities listed above is Polaris Venture Partners, 1000 Winter Street, Suite 3350, Waltham, MA 02451.

(12) Consists of 2,944,993 shares of common stock held by Versant Venture Capital III, L.P. and 17,391 shares of common stock held by Versant Side Fund III, L.P. Versant Ventures III, LLC is the general partner of Versant Venture Capital III, L.P. and Versant Side Fund III, L.P. The managing members of Versant Ventures III, LLC are Brian G. Atwood, Bradley J. Bolzon, Samuel D. Colella, Ross A. Jaffe, William J. Link, Barbara N. Lubash, Donald B. Milder, Robin L. Praeger, Rebecca B. Robertson and Charles M. Warden. Each of these individuals listed above exercises shared voting and investment power over the shares held of record by Versant Venture Capital III, L.P. and Versant Side Fund III, L.P. Mr. Warden is a member of our board of directors. Each of the individuals listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for each of the individuals and entities listed above is One Sansome Street, Suite 3630, San Francisco, California 94104. The number of shares offered reflects 424,494 shares of common stock that will be sold by Versant Venture Capital III, L.P. and 2,506 shares of common stock that will be sold by Versant Side Fund III, L.P.

(13) Based on information provided in a Schedule 13G filed on February 10, 2015. Ascension Ventures II, LLC is the general partner of CHV II, L.P. Ascension Ventures II, LLC is governed by a Board of Managers, which has authority to invest and vote for the shares held by CHV II, L.P. Signatory and voting authority has been delegated to Matthew I. Hermann, Senior Managing Director of Ascension Ventures II, LLC. Decisions regarding liquidation of investment positions have been delegated by the Board to Anthony J. Speranzo, Executive Vice President and Chief Financial Officer, Ascension, and Matthew I. Hermann, Senior Managing Director, Ascension Ventures II, LLC, acting jointly. Each of the individuals and entities listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address for each of the individuals and entities listed above is Ascension Ventures, 101 South Hanley Road, Suite 200, Clayton, MO 63105.

(14) Consists of (i) 256,576 shares of common stock held by Mr. Khosravi directly, (ii) 9,469 shares of common stock held by the Farhad Khosravi & Flora Shirzad Khosravi Trust u/a/d 10/19/2004, and (iii) 846,377 shares of common stock held by Incept, LLC.

(15) Based on information provided in a Schedule 13G filed on February 12, 2015. These securities are owned of record by clients of one or more investment advisers directly or indirectly owned by Wellington Management Group LLP, formerly known as Wellington Management Company, LLP, which was an investment adviser to these clients as of December 31, 2014. Those clients have the right to receive, or the power to direct the receipt of, dividends from, or the proceeds from the sale of, such securities. No such client is known to have such right or power with respect to more than five percent of this class of securities.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our certificate of incorporation and bylaws are summaries and are qualified by reference to our certificate of incorporation and our bylaws. We have filed copies of these documents with the SEC as exhibits to our registration statement of which this prospectus forms a part.

Our authorized capital stock consists of 100,000,000 shares of our common stock, par value $0.0001 per share, and 5,000,000 shares of our preferred stock, par value $0.0001 per share, all of which preferred stock is undesignated.

As of May 31, 2015, we had issued and outstanding 21,502,479 shares of our common stock held by 48 stockholders of record (not including beneficial owners whose shares are held in street name).

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Each election of directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any of our outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval, subject to any limitations imposed by applicable NASDAQ rules. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. As of the date of this prospectus, we have no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Warrants

As of May 31, 2015, we had outstanding warrants to purchase up to an aggregate of 18,939 shares of our common stock at a weighted average exercise price of $7.92 per share. These warrants provide for adjustments in the event of specified mergers, reorganizations, reclassifications, stock dividends, stock splits or other changes in our corporate structure.

Options

As of May 31, 2015, options to purchase an aggregate of 2,076,952 shares of our common stock, at a weighted average exercise price of $12.54 per share, were outstanding.

Delaware Anti-Takeover Law and Certain Charter and Bylaw provisions

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a “business combination” with any “interested stockholder” for three years following the date that the person became an interested stockholder, unless either the interested stockholder attained such status with the approval of our board of directors, the business combination is approved by our board of directors and stockholders in a prescribed manner or the interested stockholder acquired at least 85% of our outstanding voting stock in the transaction in which it became an interested stockholder. A “business combination” includes, among other things, a merger or consolidation involving us and the “interested stockholder” and the sale of more than 10% of our assets. In general, an “interested stockholder” is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person. The restrictions contained in Section 203 are not applicable to any of our existing stockholders that owned 15% or more of our outstanding voting stock upon the closing of our initial public offering.

Staggered Board; Removal of Directors

Our certificate of incorporation and our bylaws divide our board of directors into three classes with staggered three-year terms. In addition, our certificate of incorporation and our bylaws provide that directors may be removed only for cause and only by the affirmative vote of the holders of 75% of our shares of capital stock present in person or by proxy and entitled to vote. Under our certificate of incorporation and bylaws, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. Furthermore, our certificate of incorporation provides that the authorized number of directors may be changed only by the resolution of our board of directors. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors, change the authorized number of directors and fill vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Stockholder Action; Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our certificate of incorporation and our bylaws provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our certificate of incorporation and our bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by the chairman of our board of directors, our chief executive officer or our board of directors. In addition, our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors, or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder’s intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions also could discourage a third party from making a tender offer for our common stock because even if the third party acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholders meeting and not by written consent.

Super-Majority Voting

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our bylaws may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described above.

Registration Rights

We entered into a fourth amended and restated investors' rights agreement dated June 30, 2013, as amended, or the investor rights agreement, with holders of our preferred stock prior to the closing of our initial public offering. Following this offering, holders of a total of 5,089,131 shares of our common stock outstanding or issuable upon exercise of the warrants will have the right to require us to register these shares under the Securities Act under specified circumstances. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. If not otherwise exercised, the rights under the investor rights agreement described below will expire five years after the closing of our initial public offering, which occurred on July 30, 2014.

Demand and Form S-3 Registration Rights

Subject to specified limitations set forth in the investor rights agreement, at any time, the holders of at least 50% of the then outstanding shares having rights under the investor rights agreement, or the registrable securities, may demand that we register registrable securities then outstanding under the Securities Act for purposes of a public offering having an aggregate offering price to the public of not less than $10 million. We are not obligated to file a registration statement pursuant to this provision on more than two occasions.

In addition, subject to specified limitations set forth in the investor rights agreement, at any time after we become eligible to file a registration statement on Form S-3, holders of the registrable securities then outstanding may request that we register their registrable securities on Form S-3 for purposes of a public offering for which the reasonably anticipated aggregate offering price to the public would exceed $1 million.

In connection with this offering, the holders of registrable securities waived the demand registration rights under the investor rights agreement for a period that ends 90 days after the closing of this offering.

Incidental Registration Rights

If we propose to register for our own account any of our securities under the Securities Act, the holders of registrable securities will be entitled to notice of the registration and, subject to specified exceptions, have the right to require us to use our best efforts to register all or a portion of the registrable securities then held by them in that registration. Under our outstanding warrants, each of the holders of the warrants is also entitled to notice of the registration at the time that we provide notice of the registration to the holders of registrable securities. The holders of registrable securities waived these incidental registration rights in connection with this offering.

In the event that any registration in which the holders of registrable securities participate pursuant to our investor rights agreement is an underwritten public offering or if any warrant holder participates in such an offering pursuant to the warrants, we have agreed to enter into an underwriting agreement containing customary representations and warranties and covenants, including without limitation customary provisions with respect to indemnification of the underwriters of such offering.

In the event that any registration in which the holders of registrable securities participate pursuant to our investor rights agreement is an underwritten offering or if any warrant holder participates pursuant to the warrants, we will use our best efforts to include the requested securities to be included, but such inclusions may be limited by market conditions to the extent set forth in the investor rights agreement.

Expenses

Pursuant to the investor rights agreement, we are required to pay all registration expenses, including all registration and filing fees, exchange listing fees, printing expenses, fees and expenses of one counsel selected by the selling stockholders to represent the selling stockholders, state Blue Sky fees and expenses, and the expense of any special audits incident to or required by any such registration, but excluding underwriting discounts, selling commissions and the fees and expenses of the selling stockholders own counsel (other than the counsel selected to represent all selling stockholders). We are not required to pay registration expenses if the registration request under the investor rights agreement is withdrawn at the request of holders initiating such registration request, unless the withdrawal is related to information concerning the business or financial condition of us after the initiation of such registration request.

The investor rights agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the registration statement attributable to us or any violation or alleged violation whether by action or inaction by us under the Securities Act, the Exchange Act, any state securities or Blue Sky law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities or Blue Sky law in connection with such registration statement or the qualification or compliance of the offering, and they are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

NASDAQ Global Market

Our common stock is listed on The NASDAQ Global Market under the symbol “OCUL.”

SHARES ELIGIBLE FOR FUTURE SALE

Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the anticipation of these sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of equity securities.

Upon the closing of this offering, we will have outstanding 24,702,479 shares of our common stock, after giving effect to the issuance by us of 3,200,000 shares of our common stock in this offering, assuming no exercise of options or warrants outstanding as of May 31, 2015.

Of the shares to be outstanding immediately after the closing of this offering, we expect that 17,320,253 shares, including the shares to be sold in this offering, including both the shares sold by us and the shares sold by the selling stockholders, will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining 7,382,226 shares of our common stock will be "restricted securities" under Rule 144 or are otherwise beneficially owned by our affiliates. These shares may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144 or 701 under the Securities Act.

After the offering, certain of our employees, including our executive officers and directors, may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Securities Exchange Act of 1934. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

Rule 144

In general, under Rule 144, any person who is not our affiliate and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell those shares without restriction, subject to the availability of current public information about us. In addition, under Rule 144, any person who is not our affiliate and has not been our affiliate at any time during the preceding three months and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

A person who is our affiliate or who was our affiliate at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 247,024 shares immediately after this offering; and
- the average weekly trading volume in our common stock on The NASDAQ Global Market during the four calendar weeks preceding the date of filing of a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Upon waiver or expiration of the 90-day lock-up period described below, approximately 7,294,058 additional shares of our common stock will be eligible for sale under Rule 144. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

Rule 701

In general, under Rule 701 of the Securities Act, any of our employees, consultants or advisors, other than our affiliates, who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement is eligible to resell those shares in reliance on Rule 144, but without compliance with the various restrictions, including the availability of public information about us, holding period and volume limitations, contained in Rule 144.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act. We filed a registration statement on Form S-1 under the Securities Act to register shares in connection with our initial public offering in July 2014, and in August 2014, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and other awards issuable pursuant to the 2006 Plan, the 2014 Plan, and the 2014 ESPP.

Lock-up Agreements

We, each of our directors and executive officers and the selling stockholders, have agreed that, without the prior written consent of Morgan Stanley & Co. LLC and Cowen and Company, LLC on behalf of the underwriters, we and they will not, subject to limited exceptions, during the period ending 90 days after the date of this prospectus:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock;
- file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock.

The lock-up restrictions and specified exceptions are described in more detail under “Underwriting.”

Registration Rights

Subject to the lock-up agreements described above, upon the closing of this offering, the holders of an aggregate of 5,870,192 shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or, along with holders of an additional 18,939 shares of our common stock issuable upon the exercise of warrants, to include their shares in registration statements that we may file for ourselves or other stockholders. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. See “Description of Capital Stock—Registration Rights” for additional information regarding these registration rights.

Stock Options, Warrants, and Form S-8 Registration Statement

As of May 31, 2015, we had outstanding options to purchase an aggregate of 2,076,952 shares of our common stock, of which options to purchase 831,369 shares were vested. In August 2014, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and reserved for future options and other awards under the 2006 Plan, the 2014 Plan, and the 2014 ESPP. See “Executive Compensation—Equity Incentive Plans” for additional information regarding these plans. Accordingly, shares of our common stock registered under the registration statement on Form S-8 are available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements applicable to these shares.

As of May 31, 2015, we had outstanding warrants to purchase 18,939 shares of our common stock at an exercise price of $7.92 per share. The warrants and the common stock issuable upon the exercise of the warrants have not been registered under the Securities Act, and any resale of any of those securities must be made pursuant to a registration statement or an available exemption from registration.

MATERIAL U.S. TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following is a general discussion of material U.S. federal income and estate tax considerations relating to ownership and disposition of our common stock by a non-U.S. holder. For purposes of this discussion, the term "non-U.S. holder" means a beneficial owner (other than a partnership or other pass-through entity) of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States or of any political subdivision of the United States;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or if the trust has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

This discussion does not address the tax treatment of partnerships or persons who hold their common stock through partnerships or other entities that are pass-through entities for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. In addition, the Internal Revenue Service, or the IRS, could challenge one or more of the tax consequences described in this prospectus.

We assume in this discussion that each non-U.S. holder holds shares of our common stock as a capital asset (generally, property held for investment) for U.S. federal income tax purposes. This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of U.S. state, local or non-U.S. taxes, the alternative minimum tax, or the Medicare tax on net investment income. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- pension plans;
- controlled foreign corporations;
- passive foreign investment companies;
- non-U.S. governments
- persons that have a functional currency other than the U.S. dollar;
- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment or who have elected to mark securities to market; and
- certain U.S. expatriates.

THIS SUMMARY IS FOR GENERAL INFORMATION ONLY AND IS NOT, AND IS NOT INTENDED TO BE, LEGAL OR TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE U.S. FEDERAL, STATE, LOCAL, ESTATE AND NON-U.S. INCOME AND OTHER TAX CONSIDERATIONS OF ACQUIRING, HOLDING AND DISPOSING OF OUR COMMON STOCK.

Distributions

As discussed under "Dividend Policy" above, we do not currently expect to make distributions in respect of our common stock. If we make distributions in respect of our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, subject to the tax treatment described in this section. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of capital, up to the holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock." Any such distributions will also be subject to the discussion below under the heading "FATCA."

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States, and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements (generally including provision of a valid IRS Form W-8ECI (or applicable successor form) certifying that the dividends are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States). However, such U.S. effectively connected income, net of specified deductions and credits, is taxed in the hands of the non-U.S. holder at the same graduated U.S. federal income tax rates as would apply if such holder were a U.S. person (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is classified as a corporation for U.S. federal income tax purposes may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Each non-U.S. holder is urged to consult its own tax advisor about the specific methods for satisfying these requirements.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock

Subject to the discussion below under the heading "FATCA," a non-U.S. holder generally will not be subject to U.S. federal income tax or withholding tax on gain recognized on a disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the regular graduated rates as would apply if it were a U.S. person, and, if the non-U.S. holder is a foreign corporation, an additional branch profits tax at a rate of 30%, (or a lower rate as may be specified by an applicable income tax treaty), may also apply;

- the non-U.S. holder is a non-resident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the non-U.S. holder recognized in the taxable year of the disposition, if any; or

- we are or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation" unless our common stock is regularly traded on an established securities market and the non-U.S. holder held no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes. If we are a U.S. real property holding corporation and either our common stock is not regularly traded on an established securities market or a non-U.S. holder holds more than 5% of our outstanding common stock, directly or indirectly, during the applicable testing period, such non-U.S. holder's gain on the disposition of shares of our common stock generally will be taxed in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders generally will have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Generally, a holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN or W-BEN-E (or other applicable Form W-8), or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above under "Distributions," will generally be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or non-U.S., unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. person (as defined in the Code) where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

Federal Estate Tax

Common stock owned or treated as owned by an individual who is not a citizen or resident of the United States (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes and, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

FATCA

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a 30% withholding tax on dividends on, and gross proceeds from the sale or disposition of, our common stock if paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," the foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," the foreign entity identifies certain of its U.S. investors, or (iii) the foreign entity is otherwise exempt under FATCA.

Withholding under FATCA generally applies (1) to payments of dividends on our common stock made after June 30, 2014, and (2) to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2016. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of the tax. Non-U.S. holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

The preceding discussion of material U.S. federal tax considerations is for general information only. It is not legal or tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed changes in applicable laws.

UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC and Cowen and Company, LLC are acting as representatives, have severally agreed to purchase, and we and the selling stockholders have agreed to sell to them, severally, the number of shares indicated below:

Name	Number of Shares
Morgan Stanley & Co. LLC	
Cowen and Company, LLC	
RBC Capital Markets, LLC	
Nomura Securities International, Inc.	
BTIG, LLC	
Total	4,000,000

The underwriters are collectively referred to as the "underwriters" and the representatives are collectively referred to as the "representatives". The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and the selling stockholders and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' option to purchase additional shares described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers. After the public offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

The selling stockholders have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 600,000 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us and the selling stockholders. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 600,000 shares of common stock.

		Total	
	Per Share	No Exercise	Full Exercise
Public offering price	$	$	$
Underwriting discounts and commissions to be paid by:			
Us	$	$	$
The selling stockholders	$	$	$
Proceeds, before expenses, to:			
Us	$	$	$
The selling stockholders	$	$	$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately $0.7 million. We have agreed to reimburse the underwriters for expense relating to clearance of this offering with the Financial Industry Regulatory Authority up to $35,000.

Our common stock is listed on the NASDAQ Global Market under the trading symbol "OCUL".

We, the selling stockholders, and our directors and officers have agreed that, subject to specified exceptions, without the prior written consent of Morgan Stanley & Co. LLC and Cowen and Company, LLC on behalf of the underwriters, we and they will not, during the period ending 90 days after the date of this prospectus (the "restricted period"):

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock,

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of Morgan Stanley & Co. LLC and Cowen and Company, LLC on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph to do not apply to:

- the sale of shares of common stock to the underwriters;
- transfers, dispositions, or distributions of shares of common stock (or any security convertible into or exercisable or exchangeable for shares of common stock);

  (i) as a bona fide gift;

  (ii) to limited partners, members, stockholders or trust beneficiaries of each such person or to any investment fund or other entity controlled or managed by each such person;

  (iii) by will or other testamentary document or by intestacy; and

  (iv) to any trust for the direct or indirect benefit of each such person or the immediate family of each such person in a transaction not involving a disposition for value,

  provided that in the case of any transfer, disposition or distribution pursuant to the above four subclauses, each donee, transferee or distributee shall sign and deliver a lock-up letter, and with respect to (i), (ii) and (iv) above, no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock, shall be required or shall be voluntarily made during the restricted period;
- transactions by each such person other than us relating to shares of common stock or other securities acquired in this offering (other than any issuer-directed shares of common stock purchased in this offering by an officer or director of ours) or acquired in open market transactions after the completion

of this offering, provided that no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock, shall be required or shall be voluntarily made during the restricted period;

- the issuance by us of shares of common stock upon the exercise of an option granted under a stock incentive plan or stock purchase plan described in this prospectus or the exercise of warrants to purchase shares of common stock described in this prospectus and outstanding as of the date of this prospectus, provided that the underlying shares of common stock continues to be subject to the restrictions set forth above;
- the issuance by us of shares of common stock upon the exercise of an option granted under a stock incentive plan or stock purchase plan described in this prospectus pursuant to an arrangement whereby we withhold shares issuable pursuant to such option in payment of the exercise price, provided that the underlying shares of common stock continues to be subject to the restrictions set forth above and that no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock, shall be required or shall be voluntarily made during the restricted period;
- the issuance by us of any options and other equity-based awards granted under a stock incentive plan or stock purchase plan described in this prospectus, provided that the underlying shares of common stock continue to be subject to the restrictions set forth above;
- the filing by us of any registration statement on Form S-8 or a successor form thereto relating to the shares of common stock granted pursuant to or reserved for issuance under a stock incentive plan or stock purchase plan described in this prospectus;
- shares of common stock or other securities convertible into or exercisable for shares of common stock issued in connection with a joint venture, marketing or distribution arrangement, collaboration agreement, intellectual property license agreement, or any acquisition of assets or not less than a majority or controlling portion of the equity of another entity, provided that (i) the aggregate number of shares of common stock or securities convertible into or exercisable for shares of common stock issued does not exceed 5.0% of the total number of shares of common stock issued and outstanding immediately following the completion of this offering, and (ii) the recipient of any such shares of common stock and securities issued during the restricted period agrees that such shares shall be subject to the restrictions set forth above;
- transfers or dispositions of shares of common stock or any security convertible into or exercisable or exchangeable for shares of common stock to us pursuant to any contractual arrangement that provides for the repurchase of each such person’s shares of common stock or such other securities by us or in connection with the termination of each such person’s employment with us, provided that the repurchase price for any such shares or securities shall not exceed the original purchase price paid by each such person to us for such shares or securities;
- the establishment of a trading plan that satisfies the requirements of Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of each such person or us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period; and
- the sale of shares of common stock by the selling stockholders as described in this prospectus

Morgan Stanley & Co. LLC and Cowen and Company, LLC, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the option to purchase additional shares. The underwriters can close out a covered short sale by exercising the option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the option to purchase additional shares. The underwriters may also sell shares in excess of the option to purchase additional shares, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We, the selling stockholders, and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging. financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Selling Restrictions

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relevant Member State”) an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

United Kingdom

Each underwriter has represented and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 ("FSMA") received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and

(b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

Hong Kong

The shares may not be offered or sold by means of any document other than (1) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), or (2) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (3) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation, or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder.

Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any shares, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares has been or will be registered with the Securities Commission of Malaysia ("Commission") for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services License; (iii) a person who acquires the shares as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares is made by a holder of a Capital Markets Services License who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA. Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares, and debentures of that corporation, or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the

Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland. Neither this document nor any other offering or marketing material relating to the offering, the Company, or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the shares.

Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

LEGAL MATTERS

The validity of the shares of common stock offered hereby is being passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP. Ropes & Gray LLP is acting as counsel for the underwriters in connection with this offering.

EXPERTS

The financial statements as of December 31, 2014 and 2013 and for each of the three years in the period ended December 31, 2014 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract, agreement or other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract, agreement or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. In addition, the SEC maintains an Internet website, which is located at *http://www.sec.gov,* that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet website.

We are subject to the reporting and information requirements of the Exchange Act and, as a result, file, or will file, periodic reports, proxy statements and other information with the SEC. These periodic reports and other information are available for inspection and copying at the SEC's public reference room and the website of the SEC, in each case, referred to above. We also maintain a website at http://www.ocutx.com and make, or plan to make, available free of charge through this website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. The information contained on, or that can be accessed through, our website is not a part of this prospectus. The reference to our web address does not constitute incorporation by reference of the information contained in, or that can be accessed through, our website.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Ocular Therapeutix, Inc.

In our opinion, the accompanying balance sheets and the related statements of operations and comprehensive loss, of changes in redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Ocular Therapeutix, Inc. at December 31, 2014 and December 31, 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 20, 2015

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OCULAR THERAPEUTIX, INC.

BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 37,393	$ 17,505
Marketable securities	37,435	—
Accounts receivable from related party	—	19
Accounts receivable	329	250
Inventory	133	—
Prepaid expenses and other current assets	893	240
Total current assets	76,183	18,014
Property and equipment, net	1,782	904
Restricted cash	228	228
Total assets	$ 78,193	$ 19,146
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,316	$ 545
Accrued expenses	3,016	741
Deferred revenue	188	250
Notes payable, net of discount, current	1,354	1,806
Total current liabilities	5,874	3,342
Preferred stock warrants	—	254
Deferred rent, long-term	112	27
Notes payable, net of discount, long-term	13,511	651
Total liabilities	19,497	4,274
Commitments and contingencies (Note 13)		
Redeemable convertible preferred stock (Series A, B, C, D and D-1), $0.001 par value; no shares and 33,979,025 shares authorized at December 31, 2014 and 2013, respectively; no shares and 32,842,187 shares issued and outstanding at December 31, 2014 and 2013, respectively	—	74,344
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 5,000,000 and no shares authorized at December 31, 2014 and 2013, respectively; no shares issued or outstanding at December 31, 2014 and 2013	—	—
Common stock, $0.0001 par value; 100,000,000 and 45,000,000 shares authorized at December 31, 2014 and 2013, respectively; 21,333,507 and 2,676,648 shares issued and outstanding at December 31, 2014 and 2013, respectively	2	—
Additional paid-in capital	148,122	1,308
Accumulated deficit	(89,428)	(60,780)
Total stockholders' equity (deficit)	58,696	(59,472)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 78,193	$ 19,146

The accompanying notes are an integral part of these financial statements.

OCULAR THERAPEUTIX, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year Ended December 31, 2014	2013	2012
Revenue:			
Product revenue	$ 460	$ —	$ 10
Collaboration revenue	312	—	—
Total revenue	772	—	10
Operating expenses:			
Cost of product revenue	91	—	7
Research and development	18,880	10,517	11,540
Selling and marketing	1,982	625	657
General and administrative	6,913	1,761	1,477
Total operating expenses	27,866	12,903	13,681
Loss from operations	(27,094)	(12,903)	(13,671)
Other income (expense):			
Interest income	7	13	4
Interest expense	(1,119)	(441)	(377)
Other income (expense), net	(442)	14	(49)
Total other expense, net	(1,554)	(414)	(422)
Net loss and comprehensive loss	(28,648)	(13,317)	(14,093)
Accretion of redeemable convertible preferred stock to redemption value	(11)	(27)	(35)
Net loss attributable to common stockholders	$ (28,659)	$ (13,344)	$ (14,128)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.69)	$ (5.11)	$ (5.60)
Weighted average common shares outstanding, basic and diluted	10,652,865	2,609,020	2,522,564

The accompanying notes are an integral part of these financial statements.

OCULAR THERAPEUTIX, INC.

STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share data)

	Series A, B, C, D and D-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Par Value			
Balances at December 31, 2011	20,338,123	$ 42,004	2,510,978	$ —	$ 641	$ (33,370)	$ (32,729)
Issuance of Series D redeemable convertible preferred stock, net of issuance costs of $6	9,670,730	23,784	—	—	—	—	—
Issuance of common stock	—	—	41,666	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	5,409	—	3	—	3
Stock-based compensation expense	—	—	—	—	243	—	243
Accretion of redeemable convertible preferred stock to redemption value	—	35	—	—	(35)	—	(35)
Net loss	—	—	—	—	—	(14,093)	(14,093)
Balances at December 31, 2012	30,008,853	65,823	2,558,053	—	852	(47,463)	(46,611)
Issuance of Series D-1 redeemable convertible preferred stock, net of issuance costs of $6	2,833,334	8,494	—	—	—	—	—
Issuance of restricted common stock	—	—	100,378	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	18,217	—	7	—	7
Stock-based compensation expense	—	—	—	—	476	—	476
Accretion of redeemable convertible preferred stock to redemption value	—	27	—	—	(27)	—	(27)
Net loss	—	—	—	—	—	(13,317)	(13,317)
Balances at December 31, 2013	32,842,187	74,344	2,676,648	—	1,308	(60,780)	(59,472)
Issuance of common stock and restricted common stock	—	—	148,227	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	44,094	—	35	—	35
Issuance of common stock in connection with employee stock purchase plan	—	—	5,395	—	64	—	64
Issuance of common stock in payment of consultant fees	—	—	79,545	—	699	—	699
Issuance of common stock in payment of licensing fees	—	—	189,393	—	1,665	—	1,665
Accretion of redeemable convertible preferred stock to redemption value	—	11	—	—	(11)	—	(11)
Issuance of common stock upon initial public offering	—	—	5,750,000	1	69,517	—	69,518
Issuance costs	—	—	—	—	(3,113)	—	(3,113)
Conversion of preferred stock to common stock	(32,842,187)	(74,355)	12,440,205	1	74,354	—	74,355
Conversion of preferred stock warrants to common stock warrants	—	—	—	—	960	—	960
Stock-based compensation expense	—	—	—	—	2,644	—	2,644
Net loss	—	—	—	—	—	(28,648)	(28,648)
Balances at December 31, 2014	—	$ —	21,333,507	$ 2	$ 148,122	$ (89,428)	$ 58,696

The accompanying notes are an integral part of these financial statements.

OCULAR THERAPEUTIX, INC.

STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2014	2013	2012
Cash flows from operating activities:			
Net loss	$(28,648)	$(13,317)	$(14,093)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	2,644	476	243
Licensing and consultant fees paid in common stock	2,364	—	—
Non-cash interest expense	103	46	86
Depreciation and amortization expense	547	404	404
Revaluation of preferred stock warrants	380	(14)	49
Loss on extinguishment of debt	57	—	—
Loss on disposal of property and equipment	4	—	—
Purchase of premium on marketable securities	(133)	—	—
Amortization of premium on marketable securities	24	—	—
Changes in operating assets and liabilities:			
Accounts receivable from related party	19	26	77
Accounts receivable	(79)	(250)	—
Prepaid expenses and other current assets	(36)	118	(114)
Inventory	(133)	—	—
Other assets	—	—	8
Accounts payable	507	(174)	145
Accrued expenses and deferred rent	1,946	(210)	610
Deferred revenue	(62)	250	—
Net cash used in operating activities	(20,496)	(12,645)	(12,585)
Cash flows from investing activities:			
Purchases of property and equipment	(1,260)	(387)	(203)
Purchases of investments	(37,326)	—	—
Proceeds from sales or maturities of investments	—	—	4,017
Net cash provided by (used in) investing activities	(38,586)	(387)	3,814
Cash flows from financing activities:			
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	8,494	23,784
Proceeds from issuance of notes payable and preferred stock warrants	14,877	—	4,417
Proceeds from issuance of common stock	69,518	—	—
Proceeds from issuance of common stock pursuant to employee stock purchase plan	64	—	—
Proceeds from exercise of stock options	35	7	3
Payments of initial public offering costs	(3,018)	—	—
Payments of insurance costs financed by a third-party	(233)	—	—
Repayment of notes payable	(2,273)	(1,818)	(909)
Net cash provided by financing activities	78,970	6,683	27,295
Net increase (decrease) in cash and cash equivalents	19,888	(6,349)	18,524
Cash and cash equivalents at beginning of period	17,505	23,854	5,330
Cash and cash equivalents at end of period	$ 37,393	$ 17,505	$ 23,854
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 844	$ 289	$ 216
Supplemental disclosure of non-cash investing and financing activities:			
Accretion of redeemable convertible preferred stock to redemption value	$ 11	$ 27	$ 35
Conversion of redeemable convertible preferred stock to common stock	$ 74,354	$ —	$ —
Conversion of warrants for redeemable convertible preferred stock to warrants for common stock	$ 960	$ —	$ —
Additions to property and equipment included in accounts payable at balance sheet dates	$ 169	$ 136	$ —
Insurance premium financed by a third party	$ 623	$ —	$ —
Initial public offering costs included in accounts payable	$ 95	$ —	$ —

The accompanying notes are an integral part of these financial statements.

OCULAR THERAPEUTIX, INC.

NOTES TO FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

1. Nature of the Business and Basis of Presentation

Ocular Therapeutix, Inc. (the “Company”) was incorporated on September 12, 2006 under the laws of the State of Delaware. The Company is a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using its proven, proprietary hydrogel platform technology. The Company’s bioresorbable hydrogel based product candidates are designed to provide sustained delivery of therapeutic agents to the eye. Since inception, the Company’s operations have been limited to organizing and staffing the Company, acquiring rights to intellectual property, business planning, raising capital, developing its technology, identifying potential product candidates, undertaking preclinical studies and clinical trials, manufacturing initial quantities of its products and product candidates and, beginning in the first quarter of 2014, commercializing ReSure Sealant. In the first quarter of 2014, the Company began recognizing revenue from product sales of ReSure Sealant, which was approved in January 2014 by the U.S. Food and Drug Administration (“FDA”) as a product to close clear corneal incisions following cataract surgery.

The Company was previously classified as a “development stage entity” in the Accounting Standards Codification and, as such, was required to present inception-to-date information in the Company’s statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders’ deficit, and cash flows. In June 2014, the Financial Accounting Standards Board (“FASB”) issued an accounting standards update that eliminates the concept of a development stage entity from U.S. generally accepted accounting principles and removes the related incremental reporting requirements. See Note 2 below for additional information on this new standard. The Company elected to early adopt the new standard. Accordingly, in contrast to the Company’s financial statements and the notes thereto for the year ended December 31, 2013 included in Company’s Registration Statement on Form S-1 on file with the Securities and Exchange Commission (“SEC”), the financial statements contained in this report do not include inception-to-date information.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations, regulatory approval, uncertainty of market acceptance of products and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization.

As of December 31, 2014, the Company’s lead product candidates were in the development stage. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants. The Company does not expect to generate meaningful revenue from sales of any product for several years, if at all. Accordingly, the Company will need to obtain additional capital to finance its operations. If the Company is unable to raise capital when needed or on attractive terms, the Company could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to the Company. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. The Company believes that its existing cash and cash equivalents and marketable securities will enable it to fund its operating expenses, debt service obligations and capital expenditure requirements at least through the first half of 2016.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP").

On July 30, 2014 the Company completed an initial public offering ("IPO") of its common stock, which resulted in the issuance and sale of 5,000,000 shares of its common stock at a public offering price of $13.00 per share, resulting in net proceeds of approximately $57,337 after deducting underwriting discounts and other offering costs. Prior to the Company's IPO, the Company had issued Series A, Series B, Series C, Series D and Series D-1 redeemable convertible preferred stock (collectively, the "Redeemable Preferred Stock"). Upon the closing of the IPO, all outstanding shares of the Company's Redeemable Preferred Stock were automatically converted into 12,440,205 shares of the Company's common stock and all outstanding warrants for the Company's Redeemable Preferred Stock were automatically converted into warrants for the Company's common stock. In August 2014, the underwriters of the Company's IPO exercised their over-allotment option to purchase an additional 750,000 shares of common stock at the initial public offering price of $13.00 per share, less underwriting discounts, resulting in additional net proceeds of approximately $9,068 after deducting underwriting discounts.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, revenue recognition, the accrual of research and development expenses and the valuation of common stock and stock-based awards and preferred stock warrants. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of ninety days or less at date of purchase to be cash equivalents. Cash equivalents, which primarily consist of money market accounts, are stated at fair value.

Revenue Recognition

The Company recognizes revenue when the following four criteria are met in accordance with Accounting Standards Codification ("ASC") 605, *Revenue Recognition*: persuasive evidence of a sales arrangement exists; delivery of goods has occurred through transfer of title and risk and rewards of ownership; the selling price is fixed or determinable; and collectability is reasonably assured.

The Company records revenue from product sales net of applicable provisions for returns, chargebacks, discounts, wholesaler management fees, government and commercial rebates, and other applicable allowances in the same period in which the related sales are recorded, based on the underlying contract terms.

The Company analyzes multiple-element arrangements based on the guidance in ASC Topic 605-25, *Revenue Recognition—Multiple-Element Arrangements* ("ASC 605-25"). Pursuant to this guidance, the

OCULAR THERAPEUTIX, INC.

NOTES TO FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share data)

Company evaluates multiple-element arrangements to determine (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: the delivered item has value to the customer on a standalone basis and, if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the Company. In assessing whether an item has standalone value, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can use the other deliverables for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered items and whether there are other vendors that can provide the undelivered elements.

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. Then, the applicable revenue recognition criteria in ASC 605 are applied to each of the separate units of accounting in determining the appropriate period and pattern of recognition. The Company determines the selling price of a unit of accounting following the hierarchy of evidence prescribed by ASC 605-25. Accordingly, the Company determines the estimated selling price for units of accounting within each arrangement using vendor-specific objective evidence (“VSOE”) of selling price, if available; third-party evidence (“TPE”) of selling price, if VSOE is not available; or best estimate of selling price (“BESP”), if neither VSOE nor TPE is available. The Company typically uses BESP to estimate the selling price as it generally does not have VSOE or TPE of selling price for its units of accounting. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, the Company considers applicable market conditions and relevant entity-specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting.

The Company recognizes arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605 are satisfied for that particular unit of accounting. The Company will recognize as revenue arrangement consideration attributed to licenses that have standalone value relative to the other deliverables to be provided in an arrangement upon delivery. The Company will recognize as revenue arrangement consideration attributed to licenses that do not have standalone value relative to the other deliverables to be provided in an arrangement over the Company’s estimated performance period, as the arrangement would be accounted for as a single unit of accounting.

At the inception of an arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (i) the consideration is commensurate with either the Company’s performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company’s performance to achieve the milestone, (ii) the consideration relates solely to past performance, and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a

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milestone is substantive. Accordingly, pursuant to the guidance of ASC Topic 605-28, *Revenue Recognition—Milestone Method* ("ASC 605-28"), revenue from milestone payments will be recognized in its entirety upon successful accomplishment of the milestone, assuming all other revenue recognition criteria are met.

Other contingent, event-based payments received for which payment is either contingent solely upon the passage of time or the results of a collaborative partner's performance would not be considered milestones under ASC 605-28. In accordance with ASC 605-25, such payments will be recognized as revenue when all of the four basic revenue recognition criteria are met.

Whenever the Company determines that an element is delivered over a period of time, revenue is recognized using either a proportional performance model or a straight-line model over the period of performance. At each reporting period, the Company reassesses its cumulative measure of performance and makes appropriate adjustments, if necessary. The Company recognizes revenue using the proportional performance model whenever the Company can make reasonably reliable estimates of the level of effort required to complete its performance obligations under an arrangement. Revenue recognized under the proportional performance model at each reporting period is determined by multiplying the total expected payments under the contract (excluding payments contingent upon achievement of milestones) by the ratio of the level of effort incurred to date to the estimated total level of effort required to complete the performance obligations under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the proportional performance model as of each reporting period. Alternatively, if the Company cannot make reasonably reliable estimates the level of effort required to complete its performance obligations under an arrangement, then revenue under the arrangement is recognized on a straight-line basis over the period expected to complete the Company's performance obligations. If and when a contingent milestone payment is earned, the additional consideration to be received is added to the total expected payments under the contract. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined on a straight-line basis as of the period end date. If the Company cannot reasonably estimate when its performance obligation period ends, then revenue is deferred until the Company can reasonably estimate when the performance obligation period ends.

Inventory Valuation

Inventory is valued at the lower of cost or market, determined by the first-in, first-out ("FIFO") method.

Prior to approval by the FDA or other regulatory agencies of the Company's products, the Company expenses inventory costs in the period incurred as research and development expenses. After such time as the product receives approval, the Company begins to capitalize the inventory costs related to the product. Inventory costs totaling $51 were expensed during the year ended December 31, 2013 prior to obtaining FDA approval of ReSure Sealant. The Company also reviews its inventories for potential obsolescence.

The Company had inventory of $133 as of December 31, 2014, which consisted primarily of raw materials.

Restricted Cash

As of December 31, 2014 and 2013, the Company held a certificate of deposit to collateralize a credit card account with its bank of $60. This amount is included in prepaid expenses and other current assets on the Company's balance sheet. As of December 31, 2014 and 2013, the Company also held a certificate of deposit of $228, which is a security deposit for the lease of the Company's corporate headquarters. The Company has classified this as long-term restricted cash on its balance sheet.

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Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. The Company has all cash and cash equivalents and marketable securities balances at one accredited financial institution, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on a small number of third-party manufacturers to supply products for research and development activities in its preclinical and clinical programs and for sales of its ReSure Sealant product. The Company's development programs as well as revenue from future sales of ReSure Sealant could be adversely affected by a significant interruption in the supply of any of the components of these products.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents, marketable securities and its preferred stock warrant liabilities are carried at fair value determined according to the fair value hierarchy described above (see Note 3). The carrying value of accounts receivable, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these assets and liabilities. The carrying value of the Company's outstanding notes payable (see Note 7) approximates fair value (a level 2 fair value measurement), as estimated by the Company using a discounted cash flow analysis, reflecting discount rates currently available to the Company.

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Marketable Securities

The Company's marketable securities are classified as available-for-sale and are carried at fair value with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses and declines in value judged to be other than temporary are included as a component of other income (expense), net based on the specific identification method. Fair value is determined based on quoted market prices. At December 31, 2014, marketable securities by security type consisted of:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
United States treasury notes	$ 10,026	$ —	$ —	$ 10,026
Agency bonds	27,409	—	—	27,409
Total	$ 37,435	$ —	$ —	$ 37,435

At December 31, 2014, marketable securities consisted of investments that mature within one year. The Company did not have marketable securities as of December 31, 2013.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over a three- to five-year estimated useful life. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Research and Development Costs

Research and development costs are expensed as incurred. Included in research and development expenses are salaries, stock-based compensation and benefits of employees and other operational costs related to the Company's research and development activities, including external costs of outside vendors engaged to conduct preclinical studies and clinical trials, manufacturing costs of the Company's products prior to regulatory approval, and facility-related expenses.

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Research Contract Costs and Accruals

The Company has entered into various research and development contracts with research institutions and other companies both inside and outside of the United States. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are recorded as general and administrative expenses as incurred, as recoverability of such expenditures is uncertain.

Accounting for Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees and directors at the fair value on the date of the grant using the Black-Scholes option-pricing model. The fair value of the awards is recognized as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. The straight-line method of expense recognition is applied to all awards with service-only conditions.

For stock-based awards granted to consultants and non-employees, compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is re-measured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies stock-based compensation expense in its statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The Company recognizes compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate, the Company has considered its historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from the Company's estimate, the Company may be required to record adjustments to stock-based compensation expense in future periods.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on advancing its hydrogel therapeutic products specifically for ophthalmology. All tangible assets are held in the United States.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2014, 2013 and 2012, there was no difference between net loss and comprehensive loss.

Net Income (Loss) Per Share

Prior to the closing of its IPO of common stock, the Company followed the two-class method when computing net income (loss) per share, as the Company had outstanding shares that met the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities, including outstanding stock options, unvested restricted common stock, common stock warrants and warrants for the purchase of Redeemable Preferred Stock. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options, common stock warrants and unvested restricted common stock.

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The Company's Redeemable Preferred Stock outstanding prior to the IPO, contractually entitled the holders of such shares to participate in dividends but did not contractually require the holders of such shares to participate in losses of the Company. Similarly, restricted stock awards granted by the Company entitle the holder of such awards to dividends declared or paid by the board of directors, regardless of whether such awards are unvested, as if such shares were outstanding common shares at the time of the dividend. However, the unvested restricted stock awards are not entitled to share in the residual net assets (deficit) of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2014, 2013 and 2012.

Recently Issued and Adopted Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update ("ASU") 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40).* The new guidance addresses management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the effect that this guidance will have on its financial statements and footnote disclosures.

In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements*. Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. The amendments in this guidance remove all incremental financial reporting requirements for development stage entities. Among other changes, this guidance will no longer require development stage entities to present inception-to-date information about income statement line items, cash flows, and equity transactions. This guidance is effective for public companies in the first annual period beginning after December 15, 2014. The Company elected to apply this disclosure guidance to its financial statements for the year ended December 31, 2014 and as a result, no longer discloses inception-to-date information in its statements of operations and comprehensive loss, cash flows and stockholders' deficit and the related notes thereto.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, ("ASU 2014-09"). ASU 2014-09 outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. ASU 2014-09 is effective for public entities for annual reporting periods beginning after December 15, 2016 and interim periods within those periods. Early adoption is not permitted. Companies may use either a full retrospective or a modified retrospective approach to adopt ASU 2014-09. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements and footnote disclosures.

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3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2014 and 2013 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of December 31, 2014 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ —	$29,103	$ —	$29,103
Agency bonds	—	7,599	—	7,599
Marketable securities:				
United States treasury notes	—	10,026	—	10,026
Agency bonds	—	27,409	—	27,409
Total	$ —	$74,137	$ —	$74,137

	Fair Value Measurements as of December 31, 2013 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ —	$17,272	$ —	$17,272
Liabilities:				
Liability for preferred stock warrants	$ —	$ —	$ 254	$ 254

During the years ended December 31, 2014, 2013 and 2012, there were no transfers between Level 1, Level 2 and Level 3.

The warrant liability in the table above is comprised of the values of warrants for the purchase of Series A, B and D redeemable convertible preferred stock and was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The Company's valuation of the redeemable convertible preferred stock warrants utilized the Black-Scholes option-pricing model, which incorporates assumptions and estimates to value the preferred stock warrants. The Company assessed these assumptions and estimates on a quarterly basis as additional information impacting the assumptions was obtained. Changes in the fair value of the redeemable convertible preferred stock warrants were recognized in the statements of operations.

Related to the valuation of the warrants, the quantitative elements associated with the Company's Level 3 inputs impacting fair value measurement included the fair value per share of the underlying Series A, Series B and Series D redeemable convertible preferred stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield, and expected volatility of the price of the underlying preferred stock. The Company determined the fair value per share of the underlying preferred stock by taking into consideration its most recent sales of its redeemable convertible preferred stock as well as additional factors that the Company deemed relevant. The Company historically has been a private company and lacked company-specific historical and implied volatility information of its stock. Therefore, it estimated its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared dividends.

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The following table provides a rollforward of the aggregate fair values of the Company's preferred stock warrants for which fair value was determined by level 3 inputs:

Balance, January 1, 2012	$ 219
Increase in fair value	49
Balance, December 31, 2012	268
Decrease in fair value	(14)
Balance, December 31, 2013	254
Issuance of Series D-1 warrants	326
Increase in fair value	380
Conversion of preferred stock warrants to common stock warrants (see Note 8)	(960)
Balance, December 31, 2014	$ —

4. Property and Equipment, net

Property and equipment, net consisted of the following as of December 31, 2014 and 2013:

	December 31,	
	2014	**2013**
Equipment	$ 2,606	$ 1,806
Leasehold improvements	815	398
Furniture and fixtures	295	145
Software	25	25
Construction in progress	262	205
	4,003	2,579
Less: Accumulated depreciation	(2,221)	(1,675)
	$ 1,782	$ 904

Depreciation expense was $547, $404 and $404 for the years ended December 31, 2014, 2013 and 2012, respectively.

The construction in progress is related to the build-out of a clean room, which commenced in 2013.

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5. Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2014 and 2013:

	December 31, 2014	December 31, 2013
Accrued payroll and related expenses	$1,495	$464
Accrued professional fees	338	90
Accrued research and development expenses	540	82
Accrued insurance	389	—
Accrued other	254	105
	$3,016	$741

6. Feasibility Agreement

In September 2013, the Company entered into a feasibility agreement with a biopharmaceutical company. Under this agreement, the biopharmaceutical company will pay up to $500 for completing certain tasks and achieving certain milestones. In the event that the agreement is terminated in advance of the completion of the tasks/achievement of the milestones, the Company would be required to refund portions of the amounts received, based on the actual work completed/milestones achieved as of the date of termination. As of December 31, 2013, no milestones had been achieved and, accordingly, the Company did not record any revenue related to this agreement. As of December 31, 2013, the Company had accounts receivable and deferred revenue of $250 related to this agreement recorded on its balance sheet. In the fourth quarter of 2014, the Company completed the tasks related to the first milestone at which time the $250 became non-refundable and therefore the Company recorded revenue of $250. The biopharmaceutical company has indicated that they will not proceed with the second phase of the agreement. The Company does not have any further obligations in connection with this agreement.

In October 2014, the Company entered into a feasibility agreement with a biotechnology company. Under this agreement, the biotechnology company will pay up to $700, of which $250 was a non-refundable payment due upon contract execution and $450 will be due upon the achievement of certain milestones. The Company is recognizing the non-contingent revenue of $250 on a straight-line basis over the twelve-month period expected to complete the Company's performance obligations. If and when a contingent milestone payment is earned, the additional consideration to be received will be added to the total expected payments under the contract. As of December 31, 2014, the Company has recognized revenue of $63, has deferred revenue of $187 and has $250 in accounts receivable related to this agreement. In January 2015, we achieved the first milestone under the feasibility agreement triggering a payment due of $250.

7. Notes Payable

The Company entered into a credit agreement with a lending institution in 2011 (the "2011 Modification Agreement") which had a total borrowing capacity of $5,000 which was fully drawn down. Borrowings under the agreement were required to be repaid in 33 monthly installments commencing July 1, 2012 of $152, plus interest on the principal balance at a rate of the greater of (i) 4.75% above the lender's prime rate or (ii) 8% per annum. In addition to these principal payments, the Company was required to make a final payment of $225 in March 2015 (or upon earlier termination of the agreement) to the lender, which amount was being accreted to the carrying value of the debt, using the effective interest method. The effective annual interest rate of the outstanding debt under the 2011 Modification Agreement was approximately 11%.

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On April 17, 2014, the Company entered into a credit and security agreement (the “2014 Credit Facility”) and terminated the 2011 Modification Agreement. The 2014 Credit Facility provides for initial borrowings of $15,000 under a term loan (“Tranche 1 loan”) and additional borrowings of up to $5,000 under a term loan (“Tranche 2 loan”), for a maximum of $20,000. On that same date, the Company received proceeds of $15,000 through the issuance of promissory notes to the lenders under the Tranche 1 loan. Upon the completion of the IPO in July 2014, borrowings under the Tranche 2 loan became available through December 31, 2014. The Company did not draw down the $5,000 available under the Tranche 2 loan prior to its expiration, and this amount is no longer available to the Company. All promissory notes issued under the 2014 Credit Facility mature on April 1, 2018 and are collateralized by substantially all of the Company’s personal property, other than its intellectual property. There are no financial covenants associated with the 2014 Credit Facility; however, there are negative covenants restricting the Company’s activities, including limitations on dispositions, mergers or acquisitions; encumbering its intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. The obligations under the 2014 Credit Facility are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the Company’s business, operations or financial or other condition.

The Company is obligated to make monthly, interest-only payments on the Tranche 1 loan funded under the 2014 Credit Facility until September 30, 2015 and, thereafter, to pay 30 consecutive, equal monthly installments of principal from October 1, 2015 through March 1, 2018 plus interest. The Tranche 1 loan under the 2014 Credit Facility bears interest at an annual rate of 8.25%. In addition, a final payment equal to 3.75% of any amounts drawn under the 2014 Credit Facility is due upon its maturity date.

In connection with the Tranche 1 loan, the lenders received warrants to purchase 100,000 shares of the Company’s Series D-1 redeemable convertible preferred stock with an exercise price of $3.00 per share, which are exercisable until April 2021. The fair value of the warrants as of the issuance date totaling $326 was recorded as a preferred stock warrant liability (see Note 8). Of this amount, $290 was allocated to the 2014 Credit Facility and recorded as debt discount and $36 was allocated to the 2011 Modification Agreement and recorded as loss on extinguishment of debt (see below). As of December 31, 2014, the effective annual interest rate of the outstanding debt under the 2014 Credit Facility was approximately 11%.

The terms of the 2014 Credit Facility required that the existing outstanding borrowings be repaid. Accordingly, on April 17, 2014, the Company used $1,898 of proceeds from the Tranche 1 loan to repay all amounts then due under the 2011 Modification Agreement, consisting of $1,667 of principal, $6 of interest and $225 of a final payment.

The Company accounted for the termination of the 2011 Modification Agreement as an extinguishment in accordance with the guidance in ASC 470-50, Debt. The total amount of unamortized debt discount of $10 is reflected as a loss on extinguishment of debt and included in other expense within the statements of operations and comprehensive loss. Additionally, fees paid to the lenders that were allocated to the existing debt and treated as an extinguishment, inclusive of the value of warrants issued and debt issuance costs paid, totaling $47, were also reflected as a loss on extinguishment of debt included in other expense within the statements of operations and comprehensive loss.

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As of December 31, 2014, the annual repayment requirements for the 2014 Credit Facility, inclusive of the final payment of $563 due at expiration, were as follows:

Year Ending December 31,	Principal	Interest and Final Payment	Total
2015	$ 1,500	$ 1,244	$ 2,744
2016	6,000	902	6,902
2017	6,000	397	6,397
2018	1,500	583	2,083
	$15,000	$ 3,126	$18,126

8. Warrants

The Company previously had outstanding warrants for the purchase of 236,836 shares of preferred stock. Effective upon the closing of the Company’s IPO in July 2014, the Company’s outstanding preferred stock warrants became warrants for the purchase of 89,708 shares of common stock at a weighted average exercise price of $6.32 per share. Through December 31, 2014, no warrants have been exercised and warrants for the purchase of 89,708 shares of common stock remain outstanding at December 31, 2014.

9. Redeemable Convertible Preferred Stock

Prior to the Company’s IPO, the Company had issued Series A, Series B, Series C, Series D and Series D-1 redeemable convertible preferred stock (collectively, the “Redeemable Preferred Stock”). The Redeemable Preferred Stock was classified outside of stockholders’ equity (deficit) because the shares contained redemption features that were not solely within the control of the Company.

During 2012, the Company issued 9,670,730 shares of Series D redeemable convertible preferred stock at an issuance price equal to $2.46 per share and received gross proceeds of $23,790. In connection with this financing, the Company paid total issuance costs of $6.

During 2013, the Company issued 2,833,334 shares of Series D-1 redeemable convertible preferred stock at an issuance price equal to $3.00 per share and received gross proceeds of $8,500. In connection with this financing, the Company paid total issuance costs of $6.

On July 10, 2014, the Company effected a 1-for-2.64 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of Redeemable Preferred Stock. Accordingly, all share and per share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

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Redeemable Preferred Stock consisted of the following as of December 31, 2013:

	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Liquidation Preference	Carrying Value	Common Stock Issuable Upon Conversion
Series A redeemable convertible preferred stock	1,172,836	1,145,836	$ 1,146	$ 1,145	434,028
Series B redeemable convertible preferred stock	3,306,189	3,257,329	6,000	5,989	1,233,835
Series C redeemable convertible preferred stock	10,500,000	10,243,901	21,000	20,973	3,880,260
Series D redeemable convertible preferred stock	16,000,000	15,361,787	37,790	37,742	5,818,850
Series D-1 redeemable convertible preferred stock	3,000,000	2,833,334	8,500	8,495	1,073,232
	33,979,025	32,842,187	$ 74,436	$74,344	12,440,205

Upon the closing of the Company's IPO in July 2014, all outstanding shares of the Company's Redeemable Preferred Stock were converted into 12,440,205 shares of common stock.

Prior to the conversion, the rights and preferences of the Company's outstanding Redeemable Preferred Stock were as follows:

Voting Rights

The holders of Redeemable Preferred Stock were entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Each holder of Redeemable Preferred Stock was entitled to cast the number of votes equal to the number of whole shares of common stock into which such Redeemable Preferred Stock could convert on the record date for determination of stockholders entitled to vote.

Dividends

The holders of the Redeemable Preferred Stock, in order of preference, were entitled to receive, out of funds that were legally available, noncumulative dividends when and if declared by the board of directors. No dividends had been declared by the Company prior to the conversion.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company (each, a "Liquidation Event"), the redeemable convertible preferred stockholders were entitled to be paid out of the assets of the Company in the order and preference as specified in the Company's previous certificate of incorporation, as amended and restated.

Conversion

Each share of Redeemable Preferred Stock was convertible into common stock at the option of the stockholder at any time after the date of issuance and were automatically converted into shares of common stock upon the closing of the Company's IPO in July 2014 on a 2.64-for-1 basis.

Redemption Rights

At the written election of at least 60% of the holders of the Redeemable Preferred Stock, voting together as a single class on an as-converted basis, the shares of such Redeemable Preferred Stock outstanding were redeemable, at any time on or after May 31, 2018, in three equal annual installments commencing sixty days after receipt of the required vote, in an amount equal to the Original Issue Price per share of Redeemable Preferred Stock plus all declared but unpaid dividends thereon.

The carrying values of the Redeemable Preferred Stock was being accreted to their redemption values through their respective redemption dates.

10. Common Stock and Preferred Stock

On July 30, 2014 the Company completed its IPO, which resulted in the sale of 5,000,000 shares of its common stock at a public offering price of $13.00 per share. Upon closing of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock were automatically converted into 12,440,205 shares of common stock. Additionally upon closing the IPO, the Company adopted an amended and restated certificate of incorporation increasing the number of its authorized shares of its common stock to 100,000,000 shares. In conjunction with the IPO and the amended and restated certificate of incorporation, the Company is authorized to issue 5,000,000 shares of preferred stock, $0.0001 par value, all of which is undesignated.

On August 19, 2014, the Company completed the sale of an additional 750,000 shares of common stock at the initial public offering price of $13.00 per share to the underwriters of the Company's IPO pursuant to the exercise of their over-allotment option. The Company received additional net proceeds of approximately $9,068 after deducting underwriting discounts and offering costs.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders.

As of December 31, 2014 the Company had reserved 3,196,228 shares of common stock for the exercise of outstanding stock options and the number of shares remaining available for grant under the Company's 2014 Stock Option Plan and the number of shares available for issuance under the 2014 Employee Stock Purchase Plan (see Note 11), and the outstanding warrants to purchase common stock (see Note 8).

11. Stock-Based Awards

2006 Stock Option Plan

The Company's 2006 Stock Option Plan, as amended (the "2006 Plan"), provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company. The 2006 Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or their committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock options may not be greater than ten years.

Stock options granted under the 2006 Plan generally vest over four years and expire after ten years, although options have been granted with vesting terms less than four years.

On July 30, 2014, the Company's 2014 Stock Incentive Plan (the "2014 Plan") became effective and no further stock options or other awards will be made under the 2006 Plan. Shares of common stock that were available for grant under the 2006 Plan as of July 30, 2014 as well as any shares of common stock subject to awards under the 2006 Plan that expire, terminate, or are otherwise surrendered, cancelled, forfeited or repurchased without having been fully exercised or resulting in any common stock being issued will become available for issuance under the 2014 Plan, up to a specified number of shares.

2014 Stock Incentive Plan

On June 19, 2014, the Company's stockholders approved the 2014 Plan, which became effective immediately prior to the closing of the Company's IPO on July 30, 2014. The 2014 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The number of shares originally reserved for issuance under the 2014 Plan, inclusive of shares from the 2006 Plan, was 1,336,907. As of December 31, 2014, 1,292,522 shares remain available for issuance under the 2014 Plan. The number of shares of common stock that may be issued under the 2014 Plan is subject to increase on the first day of each fiscal year, beginning on January 1, 2015 and ending on December 31, 2024, equal to the least of 1,659,218 shares of the Company's common stock, 4% of the number of shares of the Company's common stock outstanding on the first day of the applicable fiscal year, and an amount determined by the Company's board of directors. On December 23, 2014, the board of directors adopted a resolution to increase the number available under the 2014 Plan by an additional 790,000 shares effective as of January 1, 2015.

The Company generally grants stock-based awards with service conditions only ("service-based" awards).

As required by the 2006 Plan and 2014 Plan, the exercise price for stock options granted is not to be less than the fair value of common shares as of the date of grant. Prior to the IPO, the value of common stock was determined by the board of directors by taking into consideration its most recently available valuation of common shares performed by management and the board of directors as well as additional factors which might have changed since the date of the most recent contemporaneous valuation through the date of grant.

2014 Employee Stock Purchase Plan

On June 19, 2014, the Company's stockholders approved the 2014 Employee Stock Purchase Plan (the "ESPP"). A total of 207,402 shares of common stock are reserved for issuance under this plan. The ESPP became effective immediately prior to the closing of the Company's IPO on July 30, 2014. In addition, the number of shares of common stock that may be issued under the ESPP will automatically increase on the first day of each fiscal year, commencing on January 1, 2015 and ending on December 31, 2024, in an amount equal to the least of 207,402 shares of the Company's common stock, 0.5% of the number of shares of the Company's common stock outstanding on the first day of the applicable fiscal year, and an amount determined by the Company's board of directors. The Company's first offering period commenced October 1, 2014 and closed on December 31, 2014 at which time 5,395 shares of common stock were issued for total proceeds of $64. As of December 31, 2014, 202,007 shares of common stock remain available for issuance. On December 23, 2014, the board of directors adopted a resolution to increase the number of authorized under the ESPP by an additional 25,000 shares effective as of January 1, 2015.

Stock Option Valuation

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to the Company's IPO in July 2014, the Company had been a private company and lacked company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to

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do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options to employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to nonemployees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

As of December 31, 2014, there were outstanding unvested service-based stock options held by nonemployees for the purchase of 9,587 shares of common stock.

The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors are as follows, presented on a weighted average basis:

	Year Ended December 31,		
	2014	2013	2012
Risk-free interest rate	2.24%	1.23%	1.51%
Expected term (in years)	5.96	5.38	6.25
Expected volatility	76.5%	74.6%	70.0%
Expected dividend yield	0%	0%	0%

The following table summarizes the Company's stock option activity:

	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2013	924,132	$ 1.69	7.0	$ 1,986
Granted	753,886	9.35		
Exercised	(44,094)	0.78		
Forfeited	(21,933)	5.56		
Outstanding as of December 31, 2014	1,611,991	$ 5.24	6.5	$ 29,464
Options vested and expected to vest as of December 31, 2014	1,603,423	$ 5.26	6.5	$ 29,279
Options exercisable as of December 31, 2014	651,303	$ 1.72	4.8	$ 14,196

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised was $323, $38 and $6 during the years ended December 31, 2014, 2013 and 2012, respectively.

The weighted average grant date fair value of stock options granted to employees and directors during the years ended December 31, 2014, 2013 and 2012 was $6.55, $1.51 and $0.87 per share, respectively.

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Restricted Common Stock

The 2006 and 2014 Plans provide for the award of restricted common stock. The Company has granted restricted common stock with time-based vesting conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder. These restrictions lapse according to the time-based vesting conditions of each award. There was no restricted common stock activity in 2013. The table below summarizes the Company's restricted stock activity in 2014:

	Shares	Weighted Average Grant Date Fair Value
Unvested restricted common stock as of December 31, 2013	—	—
Issued	123,134	$ 8.80
Vested	(94,697)	$ 8.80
Forfeited	—	—
Unvested restricted common stock as of December 31, 2014	28,437	$ 8.80

The aggregate intrinsic value of restricted stock awards is calculated as the positive difference between the prices paid, if any, of the restricted stock awards and the fair value of the Company's common stock. The aggregate intrinsic value of restricted stock awards that vested during the years ended December 31, 2014, 2013 and 2012 was $1,142, $278 and $10, respectively.

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options, vesting of restricted common stock and grants of common stock in the following expense categories of its statements of operations:

	Year Ended December 31,		
	2014	2013	2012
Research and development	$ 397	$ 70	$ 67
Selling and marketing	68	22	28
General and administrative	2,179	384	148
	$2,644	$476	$243

As of December 31, 2014, the Company had an aggregate of $4,342 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.9 years.

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12. Net Loss Per Share and Unaudited Pro Forma Net Loss Per Share

Net Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the years ended December 31, 2014, 2013 and 2012:

	Year Ended December 31,		
	2014	2013	2012
Numerator:			
Net loss	$ (28,648)	$ (13,317)	$ (14,093)
Accretion of redeemable convertible preferred stock to redemption value	(11)	(27)	(35)
Net loss attributable to common stockholders	$ (28,659)	$ (13,344)	$ (14,128)
Denominator:			
Weighted average common shares outstanding, basic and diluted	10,652,865	2,609,020	2,522,564
Net loss per share attributable to common stockholders, basic and diluted	$ (2.69)	$ (5.11)	$ (5.60)

The Company excluded the following common stock equivalents, outstanding as of December 31, 2014, 2013 and 2012, from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2014, 2013 and 2012 because they had an anti-dilutive impact due to the net loss attributable to common stockholders incurred for the periods.

	December 31,		
	2014	2013	2012
Options to purchase common stock	1,611,991	924,132	615,377
Non-vested restricted common stock	28,437	—	6,992
Warrants for the purchase of redeemable convertible preferred stock	—	51,830	51,830
Warrants for the purchase of common stock	89,708	—	—
Redeemable convertible preferred stock (as converted to common stock)	—	12,440,205	11,366,973
	1,730,136	13,416,167	12,041,172

13. Commitments and Contingencies

Leases

The Company leases office, laboratory and manufacturing space in Bedford, Massachusetts and certain office equipment under non-cancelable operating leases that expire in June 2017 and June 2018.

On April 25, 2014, the Company entered into an amendment to its lease of office, laboratory and manufacturing space in Bedford, Massachusetts. The lease amendment provides for additional office space effective as of July 2014, with a term expiring in June 2017, and also extends the term of the original lease until June 2018.

(Amounts in thousands, except share and per share data)

Future minimum lease payments for its operating leases as of December 31, 2014 are as follows:

Years Ending December 31,	
2015	$ 802
2016	820
2017	676
2018	262
Total	$2,560

During the years ended December 31, 2014, 2013 and 2012, the Company recognized $649, $448 and $436, respectively, of rental expense, related to its office, laboratory and manufacturing space and office equipment.

Intellectual Property Licenses

The Company has a license agreement with Incept, LLC (“Incept”) (see Note 16) to use and develop certain patent rights (the “Incept License”). Under the Incept License, as amended and restated, the Company was granted a worldwide, perpetual, exclusive license to develop and commercialize products that are delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to ophthalmic diseases or conditions. The Company is obligated to pay low single-digit royalties on net sales of commercial products developed using the licensed technology, commencing with the date of the first commercial sale of such products and until the expiration of the last to expire of the patents covered by the license. Any of the Company’s sublicensees also will be obligated to pay Incept a royalty equal to a low single-digit percentage of net sales made by it and will be bound by the terms of the agreement to the same extent as the Company. The Company is obligated to reimburse Incept for its share of the reasonable fees and costs incurred by Incept in connection with the prosecution of the patent applications licensed to the Company under the Incept License. Through December 31, 2014, royalties payable under this agreement related to product sales were not material.

On February 12, 2014, the Company issued to Incept 189,393 shares of its common stock in connection with the expansion of the scope of the license to include back of the eye technology held by Incept (see Note 16).

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements as of December 31, 2014.

14. Income Taxes

During the years ended December 31, 2014, 2013 and 2012, the Company recorded no income tax benefits for the net operating losses incurred in each year or interim period, due to its uncertainty of realizing a benefit from those items.

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A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2014	2013	2012
Federal statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
Federal and state research and development tax credit	(2.5)	(6.6)	(1.2)
State taxes, net of federal benefit	(4.6)	(4.8)	(5.1)
Stock-based compensation	1.6	1.3	0.3
Other	0.8	—	—
Change in deferred tax asset valuation allowance	38.7	44.1	40.0
Effective income tax rate	0.0%	0.0%	0.0%

Net deferred tax assets as of December 31, 2014 and 2013 consisted of the following:

	December 31,	
	2014	2013
Net operating loss carryforwards	$ 15,243	$ 9,204
Research and development tax credit carryforwards	2,582	2,005
Capitalized start-up costs	2,204	2,426
Capitalized research and development expenses, net	15,746	11,571
Accrued expenses and other temporary differences	1,050	570
Total gross deferred tax assets	36,825	25,776
Valuation allowance	(36,825)	(25,776)
Net deferred tax assets	$ —	$ —

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2014, 2013 and 2012 related primarily to the increase in net operating loss carryforwards, capitalized research and development expenses and research and development tax credit carryforwards and were as follows:

	Year Ended December 31,		
	2014	2013	2012
Valuation allowance as of beginning of year	$25,776	$19,815	$14,171
Decreases recorded as benefit to income tax provision	—	—	—
Increases recorded to income tax provision	11,049	5,961	5,644
Valuation allowance as of end of year	$36,825	$25,776	$19,815

As of December 31, 2014 the Company had net operating loss carryforwards for federal and state income tax purposes of $39,231 and $36,923, respectively, which begin to expire in 2026 and 2030, respectively. Included in the federal and state net operating loss carryforwards are approximately $114 of deductions related to the exercise of stock options which tax benefit will be realized when it results in the reduction of cash income tax in accordance with ASC 718. As of December 31, 2014, the Company also had available research and development tax credit carryforwards for federal and state income tax purposes of $1,784 and $1,208, respectively, which begin to expire in 2026 and 2024, respectively. Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets, including the Company's history of cumulative net losses incurred since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2014 and 2013. Management reevaluates the positive and negative evidence at each reporting period.

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2014 or 2013.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's tax years are still open under statute from 2011 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

15. 401(k) Savings Plan

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Company contributions to the plan may be made at the discretion of the board of directors. Through December 31, 2014, no contributions have been made to the plan by the Company.

16. Related Party Transactions

The Company has a license agreement with Incept to use and develop certain patent rights that it entered into in 2007. Royalties incurred and payable to Incept have not been material to date. On February 12, 2014, the Company issued 189,393 shares of its common stock to Incept in connection with the expansion of the scope of the Incept License to include back-of-the-eye technology held by Incept. The fair value of the shares of $1,665 as of the issuance date was recorded as research and development expense. Incept and certain owners of Incept participated in the Company's Series A, Series B and Series C preferred stock financing and have also been

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granted shares of common stock and redeemable convertible preferred stock of the Company. In addition, certain employees of the Company are shareholders of Incept. The Company's President and Chief Executive Officer is a general partner of Incept.

On February 12, 2014, the Company issued 79,545 shares of common stock to a former member of the Company's board of directors and current stockholder of Incept for consulting services rendered. The fair value of the shares of $699 as of the issuance date was recorded as general and administrative expense.

During the years ended December 31, 2014, 2013 and 2012, the Company invoiced Augmenix, Inc. ("Augmenix") $82, $232 and $366, respectively, for consulting and other services. During the years ended December 31, 2014, 2013 and 2012, Augmenix invoiced the Company $27, $0 and $0 for legal fees paid by Augmenix on behalf of the Company. During the years ended December 31, 2014, 2013 and 2012, Augmenix invoiced the Company $0, $14 and $0 respectively, for consulting services. Certain shareholders of Augmenix were holders of the Company's redeemable convertible preferred stock and common stock which is now entirely common stock. In addition, certain employees of the Company are shareholders of Augmenix. Through December 31, 2014, the Company's President and Chief Executive was Chairman of the board of directors of Augmenix.

17. Selected Quarterly Financial Data (Unaudited)

	Three Months Ended							
	Dec 31, 2014	Sept 30, 2014	June 30, 2014	Mar 31, 2014	Dec 31, 2013	Sept 30, 2013	June 30, 2013	Mar 31, 2013
Statements of Operations Data:								
Revenue	$ 505	$ 143	$ 97	$ 27	$ —	$ —	$ —	$ —
Loss from operations	(7,547)	(6,776)	(5,946)	(6,825)	(3,419)	(3,435)	(2,989)	(3,060)
Net loss	(7,954)	(7,294)	(6,392)	(7,008)	(3,505)	(3,522)	(3,090)	(3,200)
Net loss attributable to common stockholders	(7,954)	(7,294)	(6,397)	(7,014)	(3,510)	(3,527)	(3,099)	(3,208)
Basic and diluted net loss attributable to common stockholders per share	$ (0.37)	$ (0.48)	$ (2.10)	$ (2.45)	$ (1.32)	$ (1.34)	$ (1.19)	$ (1.26)

The fourth quarter of 2014 includes collaboration revenue of $312.

Ocular Therapeutix, Inc.

Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 12,523	$ 37,393
Marketable securities	54,900	37,435
Accounts receivable	352	329
Inventory	158	133
Prepaid expenses and other current assets	1,537	893
Total current assets	69,470	76,183
Property and equipment, net	1,799	1,782
Restricted cash	228	228
Total assets	$ 71,497	$ 78,193
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,195	$ 1,316
Accrued expenses	1,922	3,016
Deferred revenue	250	188
Notes payable, net of discount, current	2,860	1,354
Total current liabilities	7,227	5,874
Deferred rent, long-term	103	112
Notes payable, net of discount, long-term	12,094	13,511
Total liabilities	19,424	19,497
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 authorized at March 31, 2015 and December 31, 2014, no shares issued or outstanding at March 31, 2015 and December 31, 2014	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at March 31, 2015 and December 31, 2014, respectively; 21,428,571 and 21,333,507 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	2	2
Additional paid-in capital	149,077	148,122
Accumulated deficit	(97,006)	(89,428)
Total stockholders' equity	52,073	58,696
Total liabilities and stockholders' equity	$ 71,497	$ 78,193

The accompanying notes are an integral part of these financial statements.

Ocular Therapeutix, Inc.

Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Revenue:		
Product revenue	$ 238	$ 27
Collaboration revenue	188	—
Total revenue:	426	27
Operating expenses:		
Cost of product revenue	56	9
Research and development	4,719	4,958
Selling and marketing	870	310
General and administrative	1,894	1,575
Total operating expenses	7,539	6,852
Loss from operations	(7,113)	(6,825)
Other income (expense):		
Interest income	40	1
Interest expense	(505)	(43)
Other income (expense), net	—	(141)
Total other expense, net	(465)	(183)
Net loss and comprehensive loss	(7,578)	(7,008)
Accretion of redeemable convertible preferred stock to redemption value	—	(6)
Net loss attributable to common stockholders	$ (7,578)	$ (7,014)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.35)	$ (2.45)
Weighted average common shares outstanding, basic and diluted	21,362,731	2,859,752

The accompanying notes are an integral part of these financial statements.

Ocular Therapeutix, Inc.

Statements of Cash Flows
(In thousands)
(Unaudited)

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Cash flows from operating activities:		
Net loss	$ (7,578)	$ (7,008)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	921	503
Licensing and consultant fees paid in common stock	—	2,364
Non-cash interest expense	37	6
Depreciation and amortization expense	173	93
Revaluation of preferred stock warrants	—	141
Purchase of premium on marketable securities	17	—
Amortization of premium on marketable securities	18	—
Changes in operating assets and liabilities:		
Accounts receivable from related party	—	(11)
Accounts receivable	(23)	(26)
Prepaid expenses and other current assets	170	(108)
Inventory	(25)	(87)
Accounts payable	153	304
Accrued expenses and deferred rent	(804)	(196)
Deferred revenue	62	—
Net cash used in operating activities	(6,879)	(4,025)
Cash flows from investing activities:		
Purchases of property and equipment	(354)	(297)
Purchases of investments	(17,500)	—
Net cash used in investing activities	(17,854)	(297)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	34	21
Repayments of notes payable	—	(454)
Payments of insurance costs financed by a third-party	(171)	—
Net cash used in financing activities	(137)	(433)
Net decrease in cash and cash equivalents	(24,870)	(4,755)
Cash and cash equivalents at beginning of period	37,393	17,505
Cash and cash equivalents at end of period	$ 12,523	$ 12,750
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 310	$ 46
Supplemental disclosure of non-cash investing and financing activities:		
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 6
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 326
Additions to property and equipment included in accounts payable at balance sheet dates	$ 5	$ 69

The accompanying notes are an integral part of these financial statements.

Ocular Therapeutix, Inc.

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1. Nature of the Business and Basis of Presentation

Ocular Therapeutix, Inc. (the "Company") was incorporated on September 12, 2006 under the laws of the State of Delaware. The Company is a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology. The Company's bioresorbable hydrogel based product candidates are designed to provide sustained delivery of therapeutic agents to the eye. Since inception, the Company's operations have been primarily focused on organizing and staffing the Company, acquiring rights to intellectual property, business planning, raising capital, developing its technology, identifying potential product candidates, undertaking preclinical studies and clinical trials, manufacturing initial quantities of its products and product candidates and, beginning in the first quarter of 2014, commercializing ReSure Sealant. In the first quarter of 2014, the Company began recognizing revenue from sales of ReSure Sealant, which was approved in January 2014 by the U.S. Food and Drug Administration ("FDA") as a product to close clear corneal incisions following cataract surgery.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations, regulatory approval, uncertainty of market acceptance of products and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization.

As of March 31, 2015, the Company's lead product candidates were in development. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval and adequate reimbursement or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants. The Company does not expect to generate meaningful revenue from sales of any product for several years, if at all. Accordingly, the Company will need to obtain additional capital to finance its operations. If the Company is unable to raise capital when needed or on attractive terms, the Company could be forced to delay, reduce or eliminate its research and development programs or any future commercialization efforts or to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to the Company. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. The Company believes that its existing cash and cash equivalents and marketable securities will enable it to fund its operating expenses, debt service obligations and capital expenditure requirements at least through the first half of 2016.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP").

On July 30, 2014 the Company completed an initial public offering ("IPO") of its common stock, through the issuance and sale of 5,000,000 shares of its common stock at a public offering price of $13.00 per share, resulting in net proceeds of approximately $57,337 after deducting underwriting discounts and other offering costs. Upon the closing of the IPO, all outstanding shares of the Company's redeemable convertible preferred

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stock were automatically converted into 12,440,205 shares of the Company's common stock and all outstanding warrants for the Company's redeemable convertible preferred stock were automatically converted into warrants for the Company's common stock. In August 2014, the underwriters of the Company's IPO exercised their over-allotment option to purchase an additional 750,000 shares of common stock at the initial public offering price of $13.00 per share, less underwriting discounts, resulting in additional net proceeds of approximately $9,068 after deducting underwriting discounts (Note 8).

Unaudited Interim Financial Information

The balance sheet at December 31, 2014 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of March 31, 2015 and for the three months ended March 31, 2015 and 2014 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC, for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto for the year ended December 31, 2014 included in the Company's Annual Report on Form 10-K on file with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair presentation of the Company's financial position as of March 31, 2015 and results of operations and cash flows for the three months ended March 31, 2015 and 2014 have been made. The results of operations for the three months ended March 31, 2015 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2015.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, revenue recognition, the accrual of research and development expenses and the valuation of common stock and stock-based awards and preferred stock warrants. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Inventory Valuation

Inventory is valued at the lower of cost or market, determined by the first-in, first-out ("FIFO") method.

Prior to approval by the FDA or other regulatory agencies of the Company's products, the Company expenses inventory costs in the period incurred as research and development expenses. After such time as the product receives approval, the Company begins to capitalize the inventory costs related to the product. The Company also reviews its inventories for potential obsolescence.

The Company had an inventory balance of $158 and $133, respectively, as of March 31, 2015 and December 31, 2014, which consisted primarily of raw materials.

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Restricted Cash

As of March 31, 2015 and December 31, 2014, the Company held a certificate of deposit to collateralize a credit card account with its bank of $60. This amount is included in prepaid expenses and other current assets on the Company's balance sheet. As of March 31, 2015 and December 31, 2014, the Company also held a certificate of deposit of $228, which is a security deposit for the lease of the Company's corporate headquarters. The Company has classified this as long-term restricted cash on its balance sheet.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities at March 31, 2015 and December 31, 2014, were carried at fair value determined according to the fair value hierarchy described above (see Note 3). The carrying value of accounts receivable, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these assets and liabilities. The carrying value of the Company's outstanding notes payable (see Note 7) approximates fair value (a level 2 fair value measurement), using a discounted cash flow analysis, reflecting discount rates currently available by the Company.

Marketable Securities

The Company's marketable securities are classified as available-for-sale and are carried at fair value with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses and declines in value judged to be other than temporary are included as a component of other income (expense), net based on the specific identification method. Fair value is determined based on quoted market prices. At March 31, 2015, marketable securities by security type consisted of:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
United States treasury notes	$ 10,022	$ —	$ —	$ 10,022
Agency bonds	44,878	—	—	44,878
Total	$ 54,900	$ —	$ —	$ 54,900

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At December 31, 2014, marketable securities by security type consisted of:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
United States treasury notes	$ 10,026	$ —	$ —	$ 10,026
Agency bonds	27,409	—	—	27,409
Total	$ 37,435	$ —	$ —	$ 37,435

At March 31, 2015 marketable securities consisted of investments that mature within one year.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on advancing its hydrogel therapeutic products exclusively for ophthalmology. All tangible assets are held in the United States.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the three months ended March 31, 2015 and 2014, there was no difference between net loss and comprehensive loss.

Net Income (Loss) Per Share

Prior to the closing of its IPO of common stock, the Company followed the two-class method when computing net income (loss) per share, as the Company had outstanding shares that met the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities, including outstanding stock options, unvested restricted common stock, common stock warrants and warrants for the purchase of redeemable convertible preferred stock. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options and unvested restricted common stock.

Prior to the closing of the IPO, the Company's redeemable convertible preferred stock contractually entitled the holders of such shares to participate in dividends but did not contractually require the holders of such shares to participate in losses of the Company. Similarly, restricted stock awards granted by the Company entitle the holder of such awards to dividends declared or paid by the board of directors, regardless of whether such awards

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are unvested, as if such shares were outstanding common shares at the time of the dividend. However, the unvested restricted stock awards are not entitled to share in the residual net assets (deficit) of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the three months ended March 31, 2015 and 2014.

The following common stock equivalents outstanding as of March 31, 2015 and 2014 were excluded from the computation of diluted net loss per share for the three months ended March 31, 2015 and 2014, because they had an anti-dilutive impact:

	As of March 31,	
	2015	2014
Options to purchase common stock	2,151,729	1,443,781
Non-vested restricted stock	21,328	71,022
Warrants for the purchase of redeemable convertible preferred stock	—	51,830
Warrants for the purchase of common stock	18,939	—
Redeemable convertible preferred stock	—	12,440,205
Total options, warrants and redeemable convertible preferred stock exercisable or convertible into common stock and restricted stock	2,191,996	14,006,838

Recently Issued and Adopted Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update (“ASU”) 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40).* The new guidance addresses management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. Management’s evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the effect that this guidance will have on its financial statements and footnote disclosures.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, (“ASU 2014-09”). ASU 2014-09 outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. In April 2015, the FASB proposed a one year delay in the effective date of ASU 2014-09, which was originally effective for public entities for annual reporting periods beginning after December 15, 2016 and interim periods within those periods. Early adoption is not permitted. Companies may use either a full retrospective or a modified retrospective approach to adopt ASU 2014-09. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements and footnote disclosures.

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In April 2015, the FASB issued ASU No. 2015-03, *Interest—Imputation of Interest (Subtopic 835-30)*: *Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"). ASU 2015-03 requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. Prior to the issuance of the standard, debt issuance costs were required to be presented in the balance sheet as an asset. The Company is currently assessing the impact that adopting this new accounting guidance will have on its consolidated financial statements and footnote disclosures. ASU 2015-03 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2015.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2015 and December 31, 2014 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of March 31, 2015 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ —	$12,461	$ —	$12,461
Marketable securities:				
United States treasury notes	—	10,022	—	10,022
Agency bonds	—	44,878	—	44,878
Total	$ —	$67,361	$ —	$67,361

	Fair Value Measurements as of December 31, 2014 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ —	$29,103	$ —	$29,103
Agency bonds	—	7,599	—	7,599
Marketable securities:				
United States treasury notes	—	10,026	—	10,026
Agency bonds	—	27,409	—	27,409
Total	$ —	$74,137	$ —	$74,137

As of March 31, 2015 and December 31, 2014, the Company's cash equivalents that were invested in money market funds were valued based on Level 2 inputs. During the three months ended March 31, 2015, there were no transfers between Level 1 and Level 2.

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4. Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2015	December 31, 2014
Accrued compensation and related expenses	$ 615	$ 1,495
Accrued professional fees	252	338
Accrued research and development expenses	531	540
Accrued insurance	218	389
Accrued other	306	254
	$ 1,922	$ 3,016

As of March 31, 2015, the Company's accrued insurance represents premiums for the period from July 2014 through June 2015 which the Company financed with a third-party.

5. Income Taxes

The Company did not provide for any income taxes in its statement of operations for the three month periods ended March 31, 2015 or 2014. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at March 31, 2015 and December 31, 2014, it was more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized.

The Company has not recorded any amounts for unrecognized tax benefits as of March 31, 2015 or December 31, 2014. As of March 31, 2015 and December 31, 2014, the Company had no accrued interest or tax penalties recorded. The Company's income tax return reporting periods since December 31, 2011 are open to income tax audit examination by the federal and state tax authorities. In addition, because the Company has net operating loss carryforwards, the Internal Revenue Service is permitted to audit earlier years and propose adjustments up to the amount of net operating losses generated in those years.

6. Feasibility Agreements

In September 2013, the Company entered into a feasibility agreement with a biopharmaceutical company. Under this agreement, the biopharmaceutical company will pay up to $500 for completing certain tasks and achieving certain milestones. In the event that the agreement is terminated in advance of the completion of the tasks/achievement of the milestones, the Company would be required to refund portions of the amounts received, based on the actual work completed/milestones achieved as of the date of termination. In the fourth quarter of 2014, the Company completed the tasks related to the first milestone at which time the $250 became non-refundable and therefore the Company recorded revenue of $250. The biopharmaceutical company has indicated that they will not proceed with the second phase of the agreement. The Company does not have any further obligations in connection with this agreement.

In October 2014, the Company entered into a feasibility agreement with a biotechnology company. Under this agreement, the biotechnology company will pay up to $700, of which $250 was a non-refundable payment due upon contract execution and $450 will be due upon the achievement of certain milestones. The Company is recognizing the non-contingent revenue of $250 on a straight-line basis over the twelve-month period expected to complete the Company's performance obligations. If and when a contingent milestone payment is earned, the

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additional consideration to be received will be added to the total expected payments under the contract. As of March 31, 2015, the Company has recognized revenue of $250, has deferred revenue of $250 and has $250 in accounts receivable related to this agreement. In January 2015, the Company achieved the first milestone under the feasibility agreement triggering a payment due of $250. As of December 31, 2014, the Company had deferred revenue of $187 and had $250 in accounts receivable related to this agreement.

7. Notes Payable

The Company had a credit agreement with a lending institution entered into in 2011 (the “2011 Modification Agreement”) which had a total borrowing capacity of $5,000 which was fully drawn down. Borrowings under the agreement were required to be repaid in 33 monthly installments commencing July 1, 2012 of $152, plus interest on the principal balance at a rate of the greater of (i) 4.75% above the lender’s prime rate or (ii) 8% per annum. In addition to these principal payments, the Company was required to make a final payment of $225 in March 2015 (or upon earlier termination of the agreement) to the lender, which amount was being accreted to the carrying value of the debt, using the effective interest method. The effective annual interest rate of the outstanding debt under the 2011 Modification Agreement was approximately 11%.

On April 17, 2014, the Company entered into a credit and security agreement (the “2014 Credit Facility”) and terminated the 2011 Modification Agreement. The 2014 Credit Facility provides for initial borrowings of $15,000 under a term loan (“Tranche 1 loan”) and additional borrowings of up to $5,000 under a term loan (“Tranche 2 loan”), for a maximum of $20,000. On that same date, the Company received proceeds of $15,000 through the issuance of promissory notes to the lenders under the Tranche 1 loan. Upon the completion of the IPO in July 2014, borrowings under the Tranche 2 loan became available through December 31, 2014. The Company did not draw down the $5,000 available under the Tranche 2 loan prior to its expiration, and this amount is no longer available to the Company. All promissory notes issued under the 2014 Credit Facility mature on April 1, 2018 and are collateralized by substantially all of the Company’s personal property, other than its intellectual property. There are no financial covenants associated with the 2014 Credit Facility; however, there are negative covenants restricting the Company’s activities, including limitations on dispositions, mergers or acquisitions; encumbering its intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. The obligations under the 2014 Credit Facility are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the Company’s business, operations or financial or other condition.

The Company is obligated to make monthly, interest-only payments on the Tranche 1 loan funded under the 2014 Credit Facility until September 30, 2015 and, thereafter, to pay 30 consecutive, equal monthly installments of principal from October 1, 2015 through March 1, 2018 plus interest. The Tranche 1 loan under the 2014 Credit Facility bears interest at an annual rate of 8.25%. In addition, a final payment equal to 3.75% of any amounts drawn under the 2014 Credit Facility is due upon its maturity date.

In April 2014, in connection with the Tranche 1 loan, the lenders received warrants to purchase 100,000 shares of the Company’s Series D-1 redeemable convertible preferred stock with an exercise price of $3.00 per share, which are exercisable until April 2021. The fair value of the warrants as of the issuance date totaling $326 was recorded as a preferred stock warrant liability. Of this amount, $290 was allocated to the 2014 Credit Facility and recorded as debt discount and $36 was allocated to the 2011 Modification Agreement and recorded as loss on extinguishment of debt (see below). Upon the closing of our IPO in July 2014, the preferred stock warrants became exercisable for 37,878 common stock warrants at an exercise price of $7.92 and the fair value of the warrant liability became fixed as of that date and was reclassified to additional paid-in capital. As of March 31, 2015, the effective annual interest rate of the outstanding debt under the 2014 Credit Facility was approximately 11%.

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The terms of the 2014 Credit Facility required that the existing outstanding borrowings be repaid. Accordingly, on April 17, 2014, the Company used $1,898 of proceeds from the Tranche 1 loan to repay all amounts then due under the 2011 Modification Agreement, consisting of $1,667 of principal, $6 of interest and $225 of a final payment.

In the second quarter of 2014, the Company accounted for the termination of the 2011 Modification Agreement as an extinguishment in accordance with the guidance in ASC 470-50, Debt and the total amount of unamortized debt discount of $10 was reflected as a loss on extinguishment of debt and included in other expense within the statements of operations and comprehensive loss. Additionally, fees paid to the lenders that were allocated to the existing debt and treated as an extinguishment, inclusive of the value of warrants issued and debt issuance costs paid, totaling $47, was also reflected as a loss on extinguishment of debt included in other expense within the statements of operations and comprehensive loss.

As of March 31, 2015, the annual repayment requirements for the 2014 Credit Facility, inclusive of the final payment of $563 due at expiration, were as follows:

Year Ending December 31,	Principal	Interest and Final Payment	Total
2015	$ 1,500	$ 935	$ 2,435
2016	6,000	902	6,902
2017	6,000	397	6,397
2018	1,500	583	2,083
	$15,000	$ 2,817	$17,817

8. Common Stock and Preferred Stock

On April 14, 2014, the Company effected an increase in the number of authorized shares of its common stock from 45,000,000 shares to 47,500,000 shares and an increase in the number of authorized shares of its preferred stock from 33,979,025 shares to 34,229,025 shares.

On July 10, 2014, the Company effected a 1-for-2.64 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of Redeemable Convertible Preferred Stock. Accordingly, all share and per share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

On July 30, 2014 the Company completed its IPO, which resulted in the sale of 5,000,000 shares of its common stock at a public offering price of $13.00 per share. Upon closing of the IPO, all outstanding shares of the Company’s redeemable convertible preferred stock were automatically converted into 12,440,205 shares of common stock. Additionally upon closing the IPO, the Company adopted an amended and restated certificate of incorporation increasing the number of its authorized shares of its common stock to 100,000,000 shares. This amended and restated certificate of incorporation also authorizes the Company to issue 5,000,000 shares of preferred stock, $0.0001 par value, all of which is undesignated.

On August 19, 2014, the Company completed the sale of an additional 750,000 shares of common stock at the initial public offering price of $13.00 per share to the underwriters of the Company’s IPO pursuant to the exercise of their over-allotment option. The Company received additional net proceeds of approximately $9,068 after deducting underwriting discounts.

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9. Warrants

The Company's outstanding preferred stock warrants for the purchase of 236,836 shares of preferred stock were converted to warrants for the purchase of 89,708 shares of common stock at a weighted average exercise price of $6.32 per share. During the three month ended March, 31, 2015, warrants covering 70,769 shares were exercised via net share settlement and the Company issued 53,852 shares of common stock as a result of the exercise. Warrants for the purchase of 18,939 shares of common stock remain outstanding at March 31, 2015 at a weighted average exercise price of $7.92 per share.

10. Stock-Based Awards

2006 Stock Option Plan

The Company's 2006 Stock Option Plan, as amended (the "2006 Plan"), provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company. The 2006 Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or their committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock options may not be greater than ten years.

Stock options granted under the 2006 Plan generally vest over four years and expire after ten years, although options have been granted with vesting terms less than four years.

On July 30, 2014, the Company's 2014 Stock Incentive Plan (the "2014 Plan") became effective and no further stock options or other awards will be made under the 2006 Plan. Shares of common stock that were available for grant under the 2006 Plan as of July 30, 2014 as well as any shares of common stock subject to awards under the 2006 Plan that expire, terminate, or are otherwise surrendered, cancelled, forfeited or repurchased without having been fully exercised or resulting in any common stock being issued will become available for issuance under the 2014 Plan, up to a specified number of shares.

2014 Stock Incentive Plan

On June 19, 2014, the Company's stockholders approved the 2014 Plan, which became effective immediately prior to the closing of the Company's IPO on July 30, 2014. The 2014 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The number of shares originally reserved for issuance under the 2014 Plan, inclusive of shares from the 2006 Plan, was 1,336,907. On December 23, 2014, the board of directors adopted a resolution to increase the number available under the 2014 Plan by an additional 790,000 shares effective as of January 1, 2015. As of March 31, 2015, 1,501,730 shares remain available for issuance under the 2014 Plan. The number of shares of common stock that may be issued under the 2014 Plan is subject to increase on the first day of each fiscal year, beginning on January 1, 2015 and ending on December 31, 2024, equal to the least of 1,659,218 shares of the Company's common stock, 4% of the number of shares of the Company's common stock outstanding on the first day of the applicable fiscal year, and an amount determined by the Company's board of directors.

The Company generally grants stock-based awards with service conditions only ("service-based" awards).

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As required by the 2006 Plan and 2014 Plan, the exercise price for stock options granted is not to be less than the fair value of common shares as of the date of grant. Prior to the IPO, the value of common stock was determined by the board of directors by taking into consideration its most recently available valuation of common shares performed by management and the board of directors as well as additional factors which might have changed since the date of the most recent contemporaneous valuation through the date of grant.

2014 Employee Stock Purchase Plan

On June 19, 2014, the Company's stockholders approved the 2014 Employee Stock Purchase Plan (the "ESPP"). A total of 207,402 shares of common stock are reserved for issuance under this plan. The ESPP became effective immediately prior to the closing of the Company's IPO on July 30, 2014. In addition, the number of shares of common stock that may be issued under the ESPP will automatically increase on the first day of each fiscal year, commencing on January 1, 2015 and ending on December 31, 2024, in an amount equal to the least of 207,402 shares of the Company's common stock, 0.5% of the number of shares of the Company's common stock outstanding on the first day of the applicable fiscal year, and an amount determined by the Company's board of directors. The Company's first offering period commenced October 1, 2014 and closed on December 31, 2014 at which time 5,395 shares of common stock were issued for total proceeds of $64. On December 23, 2014, the board of directors adopted a resolution to increase the number of authorized under the ESPP by an additional 25,000 shares effective as of January 1, 2015. As of March 31, 2015, 227,007 shares of common stock remain available for issuance

Stock Option Valuation

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to the Company's IPO in July 2014, the Company had been a private company and lacked company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to nonemployees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors are as follows, presented on a weighted average basis:

	Three Months Ended March 31,	
	2015	2014
Risk-free interest rate	1.62%	2.29%
Expected term (in years)	6.00	6.00
Expected volatility	72.0%	77.0%
Expected dividend yield	0%	0%

As of March 31, 2015, there were outstanding unvested service-based stock options held by nonemployees for the purchase of 7,931 shares of common stock.

Ocular Therapeutix, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and restricted common stock in the following expense categories of its statements of operations:

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Research and development	$ 302	$ 30
Selling and marketing	63	4
General and administrative	556	469
	$ 921	$ 503

As of March 31, 2015, the Company had an aggregate of $14,065 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.5 years.

11. Commitments and Contingencies

Leases

The Company leases office, laboratory and manufacturing space in Bedford, Massachusetts and certain office equipment under non-cancelable operating leases that expire in June 2017 and June 2018.

Future minimum lease payments for its operating leases as of March 31, 2015 are as follows:

Years Ending December 31,	
2015	$ 604
2016	820
2017	676
2018	262
Total	$2,362

During the three months ended March 31, 2015 and 2014, the Company recognized $195 and $111, respectively, of rental expense, related to its office, laboratory and manufacturing space and office equipment.

Intellectual Property Licenses

The Company has a license agreement with Incept, LLC (“Incept”) (Note 12) to use and develop certain patent rights (the “Incept License”). Under the Incept License, as amended and restated, the Company was granted a worldwide, perpetual, exclusive license to develop and commercialize products that are delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to ophthalmic diseases or conditions. The Company is obligated to pay low single-digit royalties on net sales of commercial products developed using the licensed technology, commencing with the date of the first commercial sale of such products and until the expiration of the last to expire of the patents covered by the license. Any of the Company’s sublicensees also will be obligated to pay Incept a royalty equal to a low single-digit percentage of net sales made by it and will be bound by the terms of the agreement to the same extent as the Company. The Company is obligated to reimburse Incept for its share of the reasonable fees and costs incurred by Incept in connection with the prosecution of the patent applications licensed to the Company under the Incept License. Through March 31, 2015, royalties payable under this agreement related to product sales were not material.

On February 12, 2014, the Company issued to Incept 189,393 shares of its common stock in connection with the expansion of the scope of the license to include back-of-the-eye technology held by Incept (Note 12).

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements as of December 31, 2014 or March 31, 2015.

Purchase Commitments

Purchase commitments represent non-cancelable contractual commitments associated with certain clinical trial activities within our clinical research organization.

Manufacturing Commitments

These contracts generally provide for termination on notice, and therefore are cancelable contracts but are contracts that we are likely to continue, regardless of the fact that they were cancellable.

12. Related Party Transactions

The Company has a license agreement with Incept to use and develop certain patent rights that it entered into in 2007. Royalties incurred and payable to Incept have not been material to date. On February 12, 2014, the Company issued 189,393 shares of its common stock to Incept in connection with the expansion of the scope of the Incept License to include back-of-the-eye technology held by Incept. In the three months ended March 31, 2014, the fair value of the shares of $1,665 as of the issuance date was recorded as research and development expense. Incept and certain owners of Incept participated in the Company's Series A, Series B and Series C preferred stock financing and have also been granted shares of common stock and redeemable convertible preferred stock of the Company. In addition, certain employees of the Company are shareholders of Incept. The Company's President and Chief Executive Officer is a general partner of Incept.

On February 12, 2014, the Company issued 79,545 shares of common stock to a former member of the Company's board of directors and current stockholder of Incept for consulting services rendered. In the three months ended March 31, 2014, the fair value of the shares of $699 as of the issuance date was recorded as general and administrative expense.

Ocular Therapeutix, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

During the three months ended March 31, 2015, the Company invoiced Augmenix, Inc. ("Augmenix") $5 for consulting and other services. During the three months ended March 31, 2014, the Company invoiced Augmenix $67 for consulting and other services. Certain shareholders of Augmenix were holders of the Company's redeemable convertible preferred stock and common stock which is now entirely common stock. In addition, certain employees of the Company are shareholders of Augmenix. The Company's President and Chief Executive Officer was also the Chief Executive Officer of Augmenix up until April 2014. Through March 31, 2015, the Company's President and Chief Executive was the Chairman of the board of directors of Augmenix.

Ocular Therapeutix

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by the Registrant. All amounts are estimates except the Securities and Exchange Commission, or SEC, registration fee and the Financial Industry Regulatory Authority, Inc., filing fee.

	Amount
Securities and Exchange Commission registration fee	$ 12,845
Financial Industry Regulatory Authority, Inc. filing fee	18,500
Accountant's fees and expenses	155,000
Legal fees and expenses	350,000
Blue sky fees and expenses	5,000
Transfer agent's fees and expenses	5,000
Printing and engraving expenses	85,000
Miscellaneous	68,655
Total expenses	$ 700,000

Item 14. Indemnification of Directors and Officers.

Section 102 of the Delaware General Corporation Law, or the DGCL, permits a corporation to eliminate the personal liability of its directors or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides that no director shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnification for such expenses which the Court of Chancery or such other court shall deem proper.

Our certificate of incorporation provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of us), by reason of the fact that he or she is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an

Indemnitee), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful.

Our certificate of incorporation also provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee or, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred by him or her or on his or her behalf in connection therewith. If we do not assume the defense, expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into indemnification agreements with all of our directors and executive officers. In general, these agreements provide that we will indemnify the director or officer to the fullest extent permitted by law for claims arising in his or her capacity as a director or officer of our company or in connection with their service at our request for another corporation or entity. The indemnification agreements also provide for procedures that will apply in the event that a director or officer makes a claim for indemnification and establish certain presumptions that are favorable to the director or officer.

We maintain a general liability insurance policy that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

The underwriting agreement we will enter into in connection with the offering of common stock being registered hereby provides that the underwriters will indemnify, under certain conditions, our directors and officers (as well as certain other persons) against certain liabilities arising in connection with such offering.

Insofar as the forgoing provisions permit indemnification of directors, executive officers, or persons controlling us for liability arising under the Securities Act of 1933, as amended, or the Securities Act, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of our common stock, shares of our preferred stock, warrants to purchase shares of our preferred stock, and stock options granted, by us within the past three years that were not registered under the Securities Act. Also included is the consideration, if any, received by us for such shares and options and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

(a) Issuances of Securities

In November 2012, we issued and sold 9,670,730 shares of our series D preferred stock to 14 investors at a price per share of $2.46 for an aggregate purchase price of $23.8 million.

In May 2013, we issued and sold 2,833,334 shares of our series D-1 preferred stock to two investors at a price per share of $3.00 for an aggregate purchase price of $8.5 million.

Between April 2012 and March 2015, we issued and sold 604,662 shares of our common stock to three investors at a weighted average price per share of $6.65 for an aggregate purchase price of $4.0 million.

No underwriters were involved in the foregoing issuances of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and Regulation D thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers of shares of our preferred stock described above represented to us in connection with their purchase that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

(b) Stock Option Grants

From June 1, 2012 to August 19, 2014, we granted options to purchase an aggregate of 1,064,064 shares of common stock, with exercise prices ranging from $1.21 to $9.67 per share, to our employees, directors, advisors and consultants. From June 1, 2012 to August 19, 2014, options to purchase 58,680 shares of our common stock had been exercised for aggregate consideration of $32,362 and options to purchase 49,634 shares had been forfeited.

The stock options and the common stock issuable upon the exercise of such options as described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with the Registrant's employees, directors, advisors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act, or pursuant to Section 4(a)(2) under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All recipients either received adequate information about the Registrant or had access, through employment or other relationships, to such information.

(c) Issuance of Warrants

In connection with a credit facility, we issued to the lenders in April 2014 warrants to purchase up to 100,000 shares of our series D-1 preferred stock, at an exercise price of $3.00 per share.

The issuance of these warrants was made in reliance on the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. The investor represented that it was an accredited investor and was acquiring the warrants for its own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the warrants for an indefinite period of time and appropriate legends were affixed to the instruments representing such warrants issued in such transactions. Such recipients either received adequate information about us or had, through their relationships with us, access to such information.

All of the foregoing securities described in sections (a), (b) and (c) of Item 15 are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

Item 16. Exhibits and Financial Statement Schedules.

The exhibits to the registration statement are listed in the Exhibit Index attached hereto and incorporated by reference herein.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Amendment No. 1 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Bedford, Commonwealth of Massachusetts, on this 2nd day of June, 2015.

OCULAR THERAPEUTIX, INC.

By: /s/ Amarpreet Sawhney, Ph.D.
Amarpreet Sawhney, Ph.D.
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 1 to the Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
/s/ Amarpreet Sawhney, Ph.D. Amarpreet Sawhney, Ph.D.	Director, President and Chief Executive Officer (Principal Executive Officer)	June 2, 2015
/s/ W. Bradford Smith W. Bradford Smith	Chief Financial Officer (Principal Financial and Accounting Officer)	June 2, 2015
* Jaswinder Chadha	Director	June 2, 2015
* James Garvey	Director	June 2, 2015
* Richard L. Lindstrom, M.D.	Director	June 2, 2015
* Bruce A. Peacock	Director	June 2, 2015
* Charles Warden	Director	June 2, 2015

*By: /s/ Amarpreet Sawhney, Ph.D.
Amarpreet Sawhney, Ph.D.
Attorney-In-Fact

EXHIBIT INDEX

Exhibit Number	Description of Exhibit	Incorporated by Reference Form	File Number	Date of Filing	Exhibit Number	Filed Herewith
1.1	Form of Underwriting Agreement				1.1	Yes
3.1	Restated Certificate of Incorporation	8-K	001-36554	7/30/2014	3.1	
3.2	Amended and Restated By-laws of the Registrant	8-K	001-36554	7/30/2014	3.2	
4.1	Specimen Stock Certificate evidencing the shares of common stock	S-1/A	333-196932	7/11/2014	4.1	
4.2	Fourth Amended and Restated Investors' Rights Agreement of the Registrant	S-1	333-196932	6/20/2014	4.2	
5.1	Opinion of Wilmer Cutler Pickering Hale and Dorr LLP				5.1	Yes
10.1	2006 Stock Incentive Plan, as amended	S-1	333-196932	6/20/2014	10.1	
10.2	Form of Stock Option Agreement under the 2006 Stock Incentive Plan	S-1	333-196932	6/20/2014	10.2	
10.3	Form of Restricted Stock Agreement under the 2006 Stock Incentive Plan	S-1	333-196932	6/20/2014	10.2	
10.4	2014 Stock Incentive Plan	S-1/A	333-196932	7/11/2014	10.4	
10.5	Form of Incentive Stock Option Agreement under 2014 Stock Incentive Plan	S-1/A	333-196932	7/11/2014	10.5	
10.6	Form of Non-statutory Stock Option Agreement under 2014 Stock Incentive Plan	S-1/A	333-196932	7/11/2014	10.6	
10.7	Form of Restricted Stock Agreement under the 2014 Stock Incentive Plan	S-1/A	333-196932	7/11/2014	10.7	
10.8†	Amended And Restated License Agreement, dated January 27, 2012, between the Registrant and Incept LLC	S-1	333-196932	6/20/2014	10.8	
10.9	Lease Agreement dated September 2, 2009, by and between Registrant and RAR2-Crosby Corporate Center QRS, Inc., as amended	S-1	333-196932	6/20/2014	10.9	
10.10	2014 Employee Stock Purchase Plan	S-1/A	333-196932	7/11/2014	10.10	
10.11	Credit and Security Agreement, by and among MidCap Financial SBIC, LP, Silicon Valley Bank, and the Registrant	S-1	333-196932	6/20/2014	10.11	
10.12	Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers	S-1	333-196932	6/20/2014	10.12	
10.13	Amended and Restated Employment Agreement, dated June 24, 2014, by and between the Registrant and Amarpreet S. Sawhney, Ph.D.	S-1/A	333-196932	7/11/2014	10.13	

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Exhibit Number	Description of Exhibit	Incorporated by Reference Form	File Number	Date of Filing	Exhibit Number	Filed Herewith
10.14	Employment Agreement, dated June 24, 2014, by and between the Registrant and Bradford Smith	S-1/A	333-196932	7/11/2014	10.14	
10.15	Employment Agreement, dated June 19, 2014, by and between the Registrant and James Fortune	S-1/A	333-196932	7/11/2014	10.15	
10.16	Employment Agreement, dated July 3, 2014, by and between the Registrant and Eric Ankerud	S-1/A	333-196932	7/11/2014	10.16	
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm				23.1	Yes
23.2	Consent of Wilmer Cutler Pickering Hale and Dorr LLP (included in Exhibit 5.1)				23.2	Yes
24.1	Power of Attorney (included on signature page)	S-1	333-204344	5/20/2015	24.1	
101.INS	XBRL Instance Document	S-1	333-204344	5/20/2015	101.INS	
101.SCH	XBRL Taxonomy Extension Schema Document	S-1	333-204344	5/20/2015	101.SCH	
101.CAL	XBRL Taxonomy Calculation Linkbase Document	S-1	333-204344	5/20/2015	101.CAL	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	S-1	333-204344	5/20/2015	101.DEF	
101.LAB	XBRL Taxonomy Label Linkbase Document	S-1	333-204344	5/20/2015	101.LAB	
101.PRE	XBRL Taxonomy Presentation Linkbase Document	S-1	333-204344	5/20/2015	101.PRE	

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

Exhibit 1.1

[●] Shares

OCULAR THERAPEUTIX, INC.

COMMON STOCK, $0.0001 PAR VALUE PER SHARE

UNDERWRITING AGREEMENT

[●], 2015

[●], 2015

Morgan Stanley & Co. LLC
Cowen and Company, LLC
As Representatives of the several
Underwriters listed in Schedule I to
the Underwriting Agreement

c/o Morgan Stanley & Co. LLC
1585 Broadway
New York, New York 10036

c/o Cowen and Company, LLC
599 Lexington Avenue, 27th Floor
New York, New York 10022

Ladies and Gentlemen:

Ocular Therapeutix, Inc., a Delaware corporation (the "**Company**"), proposes to issue and sell to the several Underwriters named in Schedule I hereto (the "**Underwriters**"), for whom you are acting as representatives (the "**Representatives**"), and certain shareholders of the Company (the "**Selling Shareholders**") named in Schedule II hereto severally propose to sell to the several Underwriters, an aggregate of [●] shares of the common stock, $0.0001 par value per share, of the Company (the "**Firm Shares**"), of which [●] shares are to be issued and sold by the Company and [●] shares are to be sold by the Selling Shareholders, each Selling Shareholder selling the amount set forth opposite such Selling Shareholder's name in Schedule II hereto.

The Selling Shareholders also propose to sell to the several Underwriters not more than an additional [●] shares of the Company's common stock, $0.0001 par value per share (the "**Additional Shares**"), if and to the extent that you, as representatives of the several Underwriters participating in the offering, shall have determined to exercise, on behalf of the Underwriters, the right to purchase such shares of common stock granted to the Underwriters in Section 3 hereof. The Firm Shares and the Additional Shares are hereinafter collectively referred to as the "**Shares**." The shares of common stock, $0.0001 par value per share, of the Company to be outstanding after giving effect to the sales contemplated hereby are hereinafter referred to as the "**Common Stock**." The Company and the Selling Shareholders are hereinafter sometimes collectively referred to as the "**Sellers**."

The Company has filed with the Securities and Exchange Commission (the "**Commission**") a registration statement, including a prospectus, relating to the Shares. The registration statement, as amended at the time it becomes effective, including the information (if any) deemed to be part of the registration statement at the time of effectiveness pursuant to Rule 430A under the Securities Act of 1933, as amended (the

"**Securities Act**"), is hereinafter referred to as the "**Registration Statement**"; the prospectus in the form first used to confirm sales of Shares (or in the form first made available to the Underwriters by the Company to meet requests of purchasers pursuant to Rule 173 under the Securities Act) is hereinafter referred to as the "**Prospectus**." If the Company has filed an abbreviated registration statement to register additional shares of Common Stock pursuant to Rule 462(b) under the Securities Act (the "**Rule 462 Registration Statement**"), then any reference herein to the term "**Registration Statement**" shall be deemed to include such Rule 462 Registration Statement.

For purposes of this Agreement, "**free writing prospectus**" has the meaning set forth in Rule 405 under the Securities Act, "**Time of Sale Prospectus**" means the preliminary prospectus together with the documents and pricing information set forth in Schedule IV hereto, and "**broadly available road show**" means a "bona fide electronic road show" as defined in Rule 433(h)(5) under the Securities Act that has been made available without restriction to any person. As used herein, the terms "Registration Statement," "preliminary prospectus," "Time of Sale Prospectus" and "Prospectus" shall include the documents, if any, incorporated by reference therein as of the date hereof.

1. *Representations and Warranties of the Company*. The Company represents and warrants to and agrees with each of the Underwriters that:

(a) The Registration Statement has become effective; no stop order suspending the effectiveness of the Registration Statement is in effect, and no proceedings for such purpose are pending before or, to the knowledge of the Company, threatened by the Commission.

(b) (i) The Registration Statement, when it became effective, did not contain and, as amended or supplemented, if applicable, will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) the Registration Statement and the Prospectus comply and, as amended or supplemented, if applicable, will comply in all material respects with the Securities Act and the applicable rules and regulations of the Commission thereunder, (iii) the Time of Sale Prospectus does not, and at the time of each sale of the Shares in connection with the offering when the Prospectus is not yet available to prospective purchasers and at the Closing Date (as defined in Section 5), the Time of Sale Prospectus, as then amended or supplemented by the Company, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, (iv) each broadly available road show, if any, when considered together with the Time of Sale Prospectus, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading and (v) the Prospectus does not contain and, as amended or supplemented, if applicable, will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, except that the representations and warranties set forth in this paragraph do not apply to statements or omissions in the

Registration Statement, the Time of Sale Prospectus, any broadly available road show or the Prospectus based upon information relating to any Underwriter furnished to the Company in writing by such Underwriter through you expressly for use therein.

(c) The Company is not an "ineligible issuer" in connection with the offering pursuant to Rules 164, 405 and 433 under the Securities Act. Any free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder. Each free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder. Except for the free writing prospectuses, if any, identified in Schedule IV hereto, and electronic road shows, if any, each furnished to you before first use, the Company has not prepared, used or referred to, and will not, without your prior consent, prepare, use or refer to, any free writing prospectus.

(d) The Company has been duly incorporated, is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation, has the corporate power and authority to own its property and to conduct its business as described in the Time of Sale Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing would not have a material adverse effect on the Company.

(e) The Company has no subsidiaries.

(f) This Agreement has been duly authorized, executed and delivered by the Company.

(g) The authorized capital stock of the Company conforms as to legal matters to the description thereof contained in each of the Time of Sale Prospectus and the Prospectus.

(h) The shares of Common Stock (including the Shares to be sold by the Selling Shareholders) outstanding prior to the issuance of the Shares to be sold by the Company have been duly authorized and are validly issued, fully paid and non-assessable.

(i) The Shares to be sold by the Company have been duly authorized and, when issued and delivered in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable, and the issuance of such Shares will not be subject to any preemptive or similar rights that have not been validly waived.

(j) The execution and delivery by the Company of, and the performance by the Company of its obligations under, this Agreement will not contravene any provision of applicable law or the certificate of incorporation or by-laws of the Company or any agreement or other instrument binding upon the Company that is material to the Company, or any judgment, order or decree of any governmental body, agency or court having jurisdiction over the Company, and no consent, approval, authorization or order of, or qualification with, any governmental body or agency is required for the performance by the Company of its obligations under this Agreement, except such as have already been obtained or made or as may be required by the securities or Blue Sky laws of the various states in connection with the offer and sale of the Shares.

(k) There has not occurred any material adverse change, or any development that would reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business or operations of the Company from that set forth in the Time of Sale Prospectus.

(l) There are no legal or governmental proceedings pending or, to the Company's knowledge, threatened to which the Company is a party or to which any of the properties of the Company is subject (i) other than proceedings accurately described in all material respects in the Time of Sale Prospectus and proceedings that would not have a material adverse effect on the Company or on the power or ability of the Company to perform its obligations under this Agreement or to consummate the transactions contemplated by the Time of Sale Prospectus or (ii) that are required to be described in the Registration Statement or the Prospectus and are not so described; and there are no statutes, regulations, contracts or other documents that are required to be described in the Registration Statement or the Prospectus or to be filed as exhibits to the Registration Statement that are not described or filed as required.

(m) Each preliminary prospectus filed as part of the registration statement as originally filed or as part of any amendment thereto, or filed pursuant to Rule 424 under the Securities Act, complied when so filed in all material respects with the Securities Act and the applicable rules and regulations of the Commission thereunder.

(n) The Company is not, and after giving effect to the offering and sale of the Shares to be sold by the Company and the application of the proceeds thereof as described in the Prospectus will not be, required to register as an "investment company" as such term is defined in the Investment Company Act of 1940, as amended.

(o) The Company (i) is in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("**Environmental Laws**"), (ii) has received all permits, licenses or other approvals required of it under applicable Environmental Laws to conduct its business and (iii) is in compliance with all terms and conditions of any such permit, license or approval, except where such noncompliance with Environmental Laws, failure to receive required permits, licenses or other approvals or failure to comply with the terms and conditions of such permits, licenses or approvals would not, singly or in the aggregate, have a material adverse effect on the Company.

(p) There are no costs or liabilities associated with Environmental Laws (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties) which would, singly or in the aggregate, have a material adverse effect on the Company.

(q) Except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, there are no contracts, agreements or understandings between the Company and any person granting such person the right to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company or to require the Company to include such securities with the Shares registered pursuant to the Registration Statement, other than rights that have been validly waived.

(r) Neither the Company nor any of its directors or officers, nor, to the Company's knowledge, any of its affiliates, employees or any agent or representative of the Company or of any of its affiliates, has taken or will take any action in furtherance of an offer, payment, promise to pay, or authorization or approval of the payment or giving of money, property, gifts or anything else of value, directly or indirectly, to any "government official" (including any officer or employee of a government or government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office) to influence official action or secure an improper advantage; and the Company and, to the Company's knowledge, its affiliates have conducted their businesses in compliance with applicable anti-corruption laws and have instituted and maintain and will continue to maintain policies and procedures designed to promote and achieve compliance with such laws and with the representation and warranty contained herein.

(s) The operations of the Company are and have been conducted at all times in material compliance with all applicable financial recordkeeping and reporting requirements, including those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of jurisdictions where the Company conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Anti-Money Laundering Laws**"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Anti-Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

(t) (i) Neither the Company nor any of its directors or officers, nor, to the Company's knowledge, any of its employees or any agent, affiliate or representative of the Company, is an individual or entity ("**Person**") that is, or is owned or controlled by a Person that is:

(A) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control ("**OFAC**"), the United Nations Security Council ("**UNSC**"), the European Union ("**EU**"), Her Majesty's Treasury ("**HMT**"), or other relevant sanctions authority (collectively, "**Sanctions**"), nor

(B) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Cuba, Iran, North Korea, Sudan and Syria).

(ii) The Company will not, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any joint venture partner or other Person:

(A) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

(B) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).

(iii) For the past five years, the Company has not knowingly engaged in, is not now knowingly engaged in, and will not engage in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(u) Subsequent to the respective dates as of which information is given in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, (i) the Company has not incurred any material liability or obligation, direct or contingent, nor entered into any material transaction; (ii) the Company has not purchased any of its outstanding capital stock (except in connection with the departure of an employee or consultant and pursuant to the terms of an existing agreement between such person and the Company of which the Underwriters have been advised in writing), nor declared, paid or otherwise made any dividend or distribution of any kind on its capital stock other than ordinary and customary dividends; and (iii) there has not been any material change in the capital stock, short-term debt or long-term debt of the Company, except in each case as described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, respectively.

(v) The Company does not own any real property. The Company has good title to all personal property owned by it which is material to the business of the Company, free and clear of all liens, encumbrances and defects except such as are described in the Time of Sale Prospectus or such as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company; and any real property and buildings held under lease by the Company are held by it under valid, subsisting and enforceable leases with such exceptions as are not material and do not materially interfere with the use made and proposed to be made of such property and buildings by the Company, in each case except as described in the Time of Sale Prospectus.

(w) The Company owns or has valid, binding and enforceable licenses under the patents, patent applications, inventions, copyrights, know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures), trademarks, service marks, trade names and other intellectual property necessary for the conduct of the business of the Company in all material respects as currently conducted and as proposed to be conducted, in the manner described in the Registration Statement, the Time of Sale Prospectus and the Prospectus (collectively, the "**Intellectual Property**"), except as enforceability of any such licenses may be limited by bankruptcy and other similar laws affecting the rights of creditors generally and general principles of equity; to the knowledge of the Company, the patents, trademarks, and copyrights, if any, included within the Intellectual Property are valid, enforceable, and subsisting; other than as disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, (A) the Company is not obligated to pay a material royalty, grant a license to, or provide other material consideration to any third party in connection with the Intellectual Property, (B) the Company has not received any notice of any claim of infringement, misappropriation or conflict with any asserted rights of others with respect to any of the Company's drug candidates, drug products, processes or Intellectual Property, (C) to the knowledge of the Company, neither the sale nor use of any of the discoveries, inventions, drug candidates, drug products or processes of the Company referred to in the Registration Statement, the Time of Sale Prospectus or the Prospectus do or will infringe, misappropriate or violate any right or valid issued patent claim of any third party in any material respect, and (D) to the knowledge of the Company, no third party has any ownership right in or to any Intellectual Property that is owned by the Company, other than any co-owner of any patent constituting Intellectual Property who is listed on the records of the U.S. Patent and Trademark Office and any co-owner of any patent application constituting Intellectual Property who is named in such patent application, and, to the knowledge of the Company, no third party has any ownership right in or to any Intellectual Property in any field of use that is exclusively licensed to the Company, other than any licensor to the Company of such Intellectual Property. The Company's Amended and Restated License Agreement with Incept LLC, dated January 27, 2012 (as amended, the "**Incept License**"), is valid, subsisting and enforceable on its terms, except as enforceability may be limited by bankruptcy and other similar laws affecting the rights of creditors generally and general principles of equity, and to the Company's knowledge neither party to the Incept License has breached any obligation thereof.

(x) No material labor dispute with the employees of the Company exists, except as described in the Time of Sale Prospectus, or, to the knowledge of the Company, is imminent; and the Company is not aware of any existing, threatened or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers or contractors that could have a material adverse effect on the Company.

(y) The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the business in which it is engaged; the Company has not been refused any insurance coverage sought or applied for; and the Company does not have any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a material adverse effect on the Company, except as described in the Time of Sale Prospectus.

(z) The Company possesses all certificates, authorizations and permits issued by the appropriate federal, state or foreign regulatory authorities necessary to conduct its business, and the Company has not received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would have a material adverse effect on the Company, taken as a whole, except as described in the Time of Sale Prospectus.

(aa) The Company has established a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v) the interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement is accurate. Except as described in the Time of Sale Prospectus, since the end of the Company's most recent audited fiscal year, there has been (i) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (ii) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(bb) Except as described in the Time of Sale Prospectus, the Company has not sold, issued or distributed any shares of Common Stock during the six-month period preceding the date hereof, including any sales pursuant to Rule 144A under, or Regulation D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, qualified stock option plans or other employee compensation plans or pursuant to outstanding options, rights or warrants.

(cc) The statistical and market-related data contained in the Time of Sale Prospectus are based on or derived from sources which the Company reasonably and in good faith believes are reliable and accurate, and such data agree with the sources from which they were derived.

(dd) The Company has filed all federal, state, local and foreign tax returns required to be filed through the date of this Agreement or has requested extensions thereof (except where the failure to file would not, individually or in the aggregate, have a material adverse effect) and has paid all taxes required to be paid thereon (except for cases in which the failure to file or pay would not have a material adverse effect, or, except as currently being contested in good faith and for which reserves required by U.S. GAAP have been created in the financial statements of the Company), and no tax deficiency has been determined adversely to the Company which has had (nor does the Company have any notice or knowledge of any tax deficiency which could reasonably be expected to be determined adversely to the Company and which could reasonably be expected to have) a material adverse effect.

(ee) The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(ff) From the time of initial filing of the Registration Statement with the Commission (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "**Emerging Growth Company**"). "**Testing-the-Waters Communication**" means any oral or written communication with potential investors with regard to the offering contemplated by the Registration Statement undertaken in reliance on Section 5(d) of the Securities Act.

(gg) The Company (i) has not alone engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (ii) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule V hereto. "**Written Testing-the-Waters Communication**" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.

(hh) The Company has not been advised, and has no reason to believe, that it is not conducting business in compliance with all applicable laws, rules and regulations of the jurisdictions in which it is conducting business, except where failure to be so in compliance would not have a material adverse effect on the Company. The Company: (i) is and at all times has been in material compliance with all statutes, rules or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product under development, manufactured or distributed by the Company ("**Applicable Laws**"); (ii) has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the U.S. Food and Drug Administration (the "**FDA**") or any other federal, state, local or foreign governmental or regulatory authority alleging or asserting material noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws ("**Authorizations**") except for FDA Forms 483 that have been resolved as of the date hereof; (iii) possesses all material Authorizations and such Authorizations are valid and in full force and effect and the Company is not in material violation of any term of any such Authorizations; (iv) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the FDA or any other federal, state, local or foreign governmental or regulatory authority or third party alleging that any product operation or activity is in material violation of any Applicable Laws or Authorizations and has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (v) has not received notice that the FDA or any other federal, state, local or foreign governmental or regulatory authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Authorizations and has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority is considering such action; (vi) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were corrected or supplemented by a subsequent submission); and (vii) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company's knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

(ii) The studies, tests and preclinical and clinical trials conducted by or on behalf of the Company that are described in the Registration Statement, the Time of Sale Prospectus and the Prospectus were and, if still pending, are being conducted, and in the case of those conducted on behalf of the Company, to the Company's knowledge, in all material respects in accordance with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all Applicable Laws and Authorizations, including, without limitation, the Federal Food, Drug and Cosmetic Act and the rules and regulations promulgated thereunder (collectively, "**FFDCA**"); the descriptions of the results of such studies, tests and trials contained in the Registration Statement and the Prospectus are accurate and complete in all material respects and fairly present the data derived from such studies, tests and trials; the Company is not aware of any studies, tests or trials, the results of which the Company believes materially contradict the study, test, or trial results described or referred to in the Registration Statement and the Prospectus when viewed in the context in which such results are described and the clinical state of development; and, except as disclosed in the

Registration Statement, the Time of Sale Prospectus and the Prospectus, the Company has not received any notices or correspondence from the FDA or any other federal, state, local or foreign governmental or regulatory authority requiring the termination, suspension or material modification of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company.

(jj) As of the time of each sale of the Shares in connection with the offering when the Prospectus is not yet available to prospective purchasers, none of (A) the Time of Sale Prospectus, and (B) any free writing prospectus, when considered together with the Time of Sale Prospectus, and (C) any individual Written Testing-the-Waters Communication, when considered together with the Time of Sale Prospectus, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided* that the Company makes no representation and warranty with respect to any statements or omissions made in each such Written Testing-the-Waters Communication in reliance upon and in conformity with the written information furnished to the Company in writing by the Representatives expressly for use in such Written Testing-the-Waters Communication.

2. *Representations and Warranties of the Selling Shareholders*. Each Selling Shareholder represents and warrants to and agrees with each of the Underwriters that:

(a) This Agreement has been duly authorized, executed and delivered by or on behalf of such Selling Shareholder.

(b) The execution and delivery by such Selling Shareholder of, and the performance by such Selling Shareholder of its obligations under, this Agreement, the Custody Agreement signed by such Selling Shareholder and Comuptershare Inc., as Custodian, relating to the deposit of the Shares to be sold by such Selling Shareholder (the "**Custody Agreement**"), and the Power of Attorney appointing certain individuals as such Selling Shareholder's attorneys-in-fact to the extent set forth therein, relating to the transactions contemplated hereby and by the Registration Statement (the "**Power of Attorney**"), will not contravene any provision of applicable law, or the certificate of incorporation or by-laws of such Selling Shareholder (if such Selling Shareholder is a corporation), or any agreement or other instrument binding upon such Selling Shareholder or any judgment, order or decree of any governmental body, agency or court having jurisdiction over such Selling Shareholder, and no consent, approval, authorization or order of, or qualification with, any governmental body or agency is required for the performance by such Selling Shareholder of its obligations under this Agreement or the Custody Agreement or Power of Attorney of such Selling Shareholder, except such as may be required by the securities or Blue Sky laws of the various states in connection with the offer and sale of the Shares.

(c) Such Selling Shareholder has, and on the Closing Date will have, valid title to, or a valid "security entitlement" within the meaning of Section 8-501 of the New York Uniform Commercial Code in respect of, the Shares to be sold by such Selling

Shareholder free and clear of all security interests, claims, liens, equities or other encumbrances and the legal right and power, and all authorization and approval required by law, to enter into this Agreement, the Custody Agreement and the Power of Attorney and to sell, transfer and deliver the Shares to be sold by such Selling Shareholder or a security entitlement in respect of such Shares.

(d) Each of the Custody Agreement and the Power of Attorney has been duly authorized, executed and delivered by such Selling Shareholder, and is a valid and binding agreement of such Selling Shareholder enforceable against such Selling Shareholder in accordance with its terms.

(e) Upon payment for the Shares to be sold by such Selling Shareholder pursuant to this Agreement, delivery of such Shares, as directed by the Underwriters, to Cede & Co. ("**Cede**") or such other nominee as may be designated by the Depository Trust Company ("**DTC**"), registration of such Shares in the name of Cede or such other nominee and the crediting of such Shares on the books of DTC to securities accounts of the Underwriters (assuming that neither DTC nor any such Underwriter has notice of any adverse claim (within the meaning of Section 8-105 of the New York Uniform Commercial Code (the "**UCC**")) to such Shares), (A) DTC shall be a "protected purchaser" of such Shares within the meaning of Section 8-303 of the UCC, (B) under Section 8-501 of the UCC, the Underwriters will acquire a valid security entitlement in respect of such Shares and (C) no action based on any "adverse claim," within the meaning of Section 8-102 of the UCC, to such Shares may be asserted against the Underwriters with respect to such security entitlement; for purposes of this representation, such Selling Shareholder may assume that when such payment, delivery and crediting occur, (x) such Shares will have been registered in the name of Cede or another nominee designated by DTC, in each case on the Company's share registry in accordance with its certificate of incorporation, bylaws and applicable law, (y) DTC will be registered as a "clearing corporation" within the meaning of Section 8-102 of the UCC and (z) appropriate entries to the accounts of the several Underwriters on the records of DTC will have been made pursuant to the UCC.

(f) Such Selling Shareholder has no reason to believe that the representations and warranties of the Company contained in Section 1 are not true and correct, is familiar with the Registration Statement, the Time of Sale Prospectus and the Prospectus and has no knowledge of any material fact, condition or information not disclosed in the Time of Sale Prospectus or the Prospectus that has had, or may have, a material adverse effect on the Company. Such Selling Shareholder is not prompted by any information concerning the Company which is not set forth in the Time of Sale Prospectus to sell its Shares pursuant to this Agreement.

(g) (i) The Registration Statement, when it became effective, did not contain and, as amended or supplemented, if applicable, will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) the Registration Statement and the Prospectus comply and, as amended or supplemented, if applicable, will comply in all material respects with the Securities Act and the applicable rules and regulations of the

Commission thereunder, (iii) the Time of Sale Prospectus does not, and at the time of each sale of the Shares in connection with the offering when the Prospectus is not yet available to prospective purchasers and at the Closing Date (as defined in Section 5), the Time of Sale Prospectus, as then amended or supplemented by the Company, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, (iv) each broadly available road show, if any, when considered together with the Time of Sale Prospectus, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading and (v) the Prospectus does not contain and, as amended or supplemented, if applicable, will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, provided that the representations and warranties set forth in this paragraph 2(f) are limited to statements or omissions made in reliance upon information relating to such Selling Shareholder furnished to the Company in writing by such Selling Shareholder expressly for use in the Registration Statement, the Time of Sale Prospectus, the Prospectus or any amendments or supplements thereto.

3. *Agreements to Sell and Purchase*. Each Seller, severally and not jointly, hereby agrees to sell to the several Underwriters, and each Underwriter, upon the basis of the representations and warranties herein contained, but subject to the conditions hereinafter stated, agrees, severally and not jointly, to purchase from such Seller the respective number of Firm Shares set forth in Schedules I and II, respectively, opposite such Seller's name at $[●] a share (the "**Purchase Price**").

On the basis of the representations and warranties contained in this Agreement, and subject to its terms and conditions, the Underwriters shall have the right to purchase, severally and not jointly, up to [●] Additional Shares at the Purchase Price, and each Selling Shareholder agrees to sell to the Underwriters at the Purchase Price up to that number of Additional Shares (subject to adjustments to eliminate fractional shares as may be determined by you) as set forth in Schedule III hereto opposite the name of such Selling Shareholder, provided, however, that the amount paid by the Underwriters for any Additional Shares shall be reduced by an amount per share equal to any dividends declared by the Company and payable on the Firm Shares but not payable on such Additional Shares. Any such election to purchase Additional Shares shall be made in proportion to the maximum number of Additional Shares to be sold by each Selling Shareholder as set forth in Schedule III hereto. You may exercise this right on behalf of the Underwriters in whole or from time to time in part by giving written notice not later than 30 days after the date of this Agreement. Any exercise notice shall specify the number of Additional Shares to be purchased by the Underwriters and the date on which such shares are to be purchased. Each purchase date must be at least one business day after the written notice is given and may not be earlier than the closing date for the Firm Shares nor later than ten business days after the date of such notice. On each day, if any, that Additional Shares are to be purchased (an "**Option Closing Date**"), each Underwriter agrees, severally and not jointly, to purchase the number of Additional Shares (subject to such adjustments to eliminate fractional shares as you may determine) that bears the same proportion to the total number of Additional Shares to be purchased on such Option Closing Date as the number of Firm Shares set forth in Schedule I hereto opposite the name of such Underwriter bears to the total number of Firm Shares.

4. *Terms of Public Offering*. The Sellers are advised by you that the Underwriters propose to make a public offering of their respective portions of the Shares as soon after the Registration Statement and this Agreement have become effective as in your judgment is advisable. The Sellers are further advised by you that the Shares are to be offered to the public initially at $ a share (the "**Public Offering Price**") and to certain dealers selected by you at a price that represents a concession not in excess of $ a share under the Public Offering Price, and that any Underwriter may allow, and such dealers may reallow, a concession, not in excess of $ a share, to any Underwriter or to certain other dealers.

5. *Payment and Delivery*. Payment for the Firm Shares to be sold by each Seller shall be made to such Seller in Federal or other funds immediately available in New York City against delivery of such Firm Shares for the respective accounts of the several Underwriters at 10:00 a.m., New York City time, on , 2015, or at such other time on the same or such other date, not later than , 2015, as shall be designated in writing by you. The time and date of such payment are hereinafter referred to as the "**Closing Date**."

Payment for any Additional Shares shall be made to the Selling Shareholders in Federal or other funds immediately available in New York City against delivery of such Additional Shares for the respective accounts of the several Underwriters at 10:00 a.m., New York City time, on the date specified in the corresponding notice described in Section 3 or at such other time on the same or on such other date, in any event not later than , 2015, as shall be designated in writing by you.

The Firm Shares and Additional Shares shall be registered in such names and in such denominations as you shall request in writing not later than one full business day prior to the Closing Date or the applicable Option Closing Date, as the case may be. The Firm Shares and Additional Shares shall be delivered to you on the Closing Date or an Option Closing Date, as the case may be, for the respective accounts of the several Underwriters. The Purchase Price payable by the Underwriters shall be reduced by (i) any transfer taxes payable in connection with the transfer of the Shares to the Underwriters duly paid, against payment of the Purchase Price therefor and (ii) any withholding required by law.

6. *Conditions to Agreements to Sell and Purchase*. The obligations of the Sellers to sell the Shares to the Underwriters and the several obligations of the Underwriters to purchase and pay for the Shares on the Closing Date are subject to the condition that the Registration Statement shall have become effective not later than [   ] (New York City time) on the date hereof.

The several obligations of the Underwriters are subject to the following further conditions:

(a) Subsequent to the execution and delivery of this Agreement and prior to the Closing Date:

(i) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any of the securities of the Company by any "nationally recognized statistical rating organization," as such term is defined in Section 3(a)(62) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"); and

(ii) there shall not have occurred any change, or any development involving a prospective change, in the condition, financial or otherwise, or in the earnings, business or operations of the Company, from that set forth in the Time of Sale Prospectus that, in your judgment, is material and adverse and that makes it, in your judgment, impracticable to market the Shares on the terms and in the manner contemplated in the Time of Sale Prospectus.

(b) The Underwriters shall have received on the Closing Date a certificate, dated the Closing Date and signed by an executive officer of the Company, to the effect set forth in Section 6(a)(i) above and to the effect that the representations and warranties of the Company contained in this Agreement are true and correct as of the Closing Date and that the Company has complied with all of the agreements and satisfied all of the conditions on its part to be performed or satisfied hereunder on or before the Closing Date.

The officer signing and delivering such certificate may rely upon the best of his or her knowledge as to proceedings threatened.

(c) The Underwriters shall have received on the Closing Date a certificate of an attorney-in-fact on behalf of each Selling Shareholder, dated the Closing Date, to the effect that the representations and warranties of the Selling Shareholder contained in this Agreement are true and correct as of the Closing Date and that the Selling Shareholder has complied with all of the agreements and satisfied all of the conditions on its part to be performed or satisfied hereunder on or before the Closing Date.

(d) The Underwriters shall have received on the Closing Date an opinion of Wilmer Cutler Pickering Hale and Dorr LLP, outside counsel for the Company, dated the Closing Date, substantially in the form attached hereto as Exhibit B.

(e) The Underwriters shall have received on the Closing Date an opinion of BRL Law Group LLC, counsel for the Selling Shareholders, dated the Closing Date, substantially in the form attached hereto as Exhibit C.

(f) The Underwriters shall have received on the Closing Date an opinion of Dardi & Herbert, PLLC, intellectual property counsel for the Company, dated the Closing Date, substantially in the form attached hereto as Exhibit D.

(g) The Underwriters shall have received on the Closing Date an opinion of Ropes & Gray LLP, counsel for the Underwriters, dated the Closing Date, in form and substance reasonably acceptable to the Representatives.

The opinion of Wilmer Cutler Pickering Hale and Dorr LLP described in Section 6(d) above, the opinion of BRL Law Group LLC described in section 6(e) above, and the opinion of Dardi & Herbert, PLLC described in Section 6(f) above shall be rendered to the Underwriters at the request of the Company and shall so state therein.

(h) The Underwriters shall have received, on each of the date hereof and the Closing Date, a letter dated the date hereof or the Closing Date, as the case may be, in form and substance satisfactory to the Underwriters, from PricewaterhouseCoopers LLP, independent public accountants, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus and the Prospectus; *provided* that the letter delivered on the Closing Date shall use a "cut-off date" not earlier than the date hereof.

(i) The "lock-up" agreements, each substantially in the form of Exhibit A hereto, between you and the Selling Shareholders, certain other shareholders and officers and directors of the Company relating to sales and certain other dispositions of shares of Common Stock or certain other securities, delivered to you on or before the date hereof, shall be in full force and effect on the Closing Date.

(j) The several obligations of the Underwriters to purchase Additional Shares hereunder are subject to the delivery to you on the applicable Option Closing Date of the following:

(i) a certificate, dated the Option Closing Date and signed by an executive officer of the Company, confirming that the certificate delivered on the Closing Date pursuant to Section 6(b) hereof remains true and correct as of such Option Closing Date;

(ii) a certificate, dated the Option Closing Date and signed by an attorney-in-fact on behalf of each Selling Shareholder, confirming that the certificate delivered by the Selling Shareholder on the Closing Date pursuant to Section 6(c) hereof remains true and correct as of such Option Closing Date;

(iii) an opinion of Wilmer Cutler Pickering Hale and Dorr LLP, outside counsel for the Company, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 6(d) hereof;

(iv) an opinion of BRL Law Group LLC, outside counsel for the Selling Shareholders, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 6(e) hereof;

(v) an opinion of Dardi & Herbert PLLC, intellectual property counsel for the Company, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 6(f) hereof;

(vi) an opinion of Ropes & Gray LLP, counsel for the Underwriters, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 6(g) hereof;

(vii) a letter dated the Option Closing Date, in form and substance satisfactory to the Underwriters, from PricewaterhouseCoopers LLP, independent public accountants, substantially in the same form and substance as the letter furnished to the Underwriters pursuant to Section 6(h) hereof; *provided* that the letter delivered on the Option Closing Date shall use a “cut-off date” not earlier than three business days prior to such Option Closing Date; and

(viii) such other documents as you may reasonably request with respect to the good standing of the Company, the due authorization and issuance of the Additional Shares to be sold on such Option Closing Date and other matters related to the sale of such Additional Shares.

7. *Covenants of the Company*. The Company covenants with each Underwriter as follows:

(a) To furnish to you, without charge, four conformed copies of the Registration Statement (including exhibits thereto) and for delivery to each other Underwriter a conformed copy of the Registration Statement (without exhibits thereto) and to furnish to you in New York City, without charge, prior to 10:00 a.m. New York City time on the second business day succeeding the date of this Agreement and during the period mentioned in Section 7(e) or 7(f) below, as many copies of the Time of Sale Prospectus, the Prospectus and any supplements and amendments thereto or to the Registration Statement as you may reasonably request.

(b) Before amending or supplementing the Registration Statement, the Time of Sale Prospectus or the Prospectus, to furnish to you a copy of each such proposed amendment or supplement and not to file any such proposed amendment or supplement to which you reasonably object, and to file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(c) To furnish to you a copy of each proposed free writing prospectus to be prepared by or on behalf of, used by, or referred to by the Company and not to use or refer to any proposed free writing prospectus to which you reasonably object.

(d) Not to take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Underwriter that the Underwriter otherwise would not have been required to file thereunder.

(e) If the Time of Sale Prospectus is being used to solicit offers to buy the Shares at a time when the Prospectus is not yet available to prospective purchasers and any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Time of Sale Prospectus in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, or if any event shall occur or condition exist as a result of which the Time of Sale Prospectus conflicts with the information contained in the Registration Statement then on file, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Time of Sale Prospectus to comply with applicable law, forthwith to prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, either amendments or supplements to the Time of Sale Prospectus so that the statements in the Time of Sale Prospectus as so amended or supplemented will not, in the light of the circumstances when the Time of Sale Prospectus is delivered to a prospective purchaser, be misleading or so that the Time of Sale Prospectus, as amended or supplemented, will no longer conflict with the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law.

(f) If, during such period after the first date of the public offering of the Shares as in the opinion of counsel for the Underwriters the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is required by law to be delivered in connection with sales by an Underwriter or dealer, any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus in order to make the statements therein, in the light of the circumstances when the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is delivered to a purchaser, not misleading, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Prospectus to comply with applicable law, forthwith to prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to the dealers (whose names and addresses you will furnish to the Company) to which Shares may have been sold by you on behalf of the Underwriters and to any other dealers upon request, either amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not, in the light of the circumstances when the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is delivered to a purchaser, be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law.

(g) To endeavor to qualify the Shares for offer and sale under the securities or Blue Sky laws of such jurisdictions as you shall reasonably request; provided that in connection therewith the Company shall not be required to qualify as a foreign corporation or to file a general consent to service of process in any jurisdiction.

(h) To make generally available to the Company's security holders and to you as soon as practicable an earnings statement covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.

(i) If any Seller is not a U.S. person for U.S. federal income tax purposes, the Company will deliver to each Underwriter (or its agent), on or before the Closing Date, (i) a certificate with respect to the Company's status as a "United States real property holding corporation," dated not more than thirty (30) days prior to the Closing Date, as described in Treasury Regulations Sections 1.897-2(h) and 1.1445-2(c)(3), and (ii) proof of delivery to the IRS of the required notice, as described in Treasury Regulations 1.897-2(h)(2).

(j) The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (a) completion of the distribution of the Shares within the meaning of the Securities Act and (b) completion of the Restricted Period referred to in this Section 6.

(k) If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

The Company also covenants with each Underwriter that, without the prior written consent of each of the Representatives on behalf of the Underwriters, it will not, during the period ending 90 days after the date of the Prospectus (the "**Restricted Period**"), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of Common

Stock or any securities convertible into or exercisable or exchangeable for Common Stock or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise, or (3) file any registration statement with the Commission relating to the offering of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock.

The restrictions contained in the preceding paragraph shall not apply to (a) the Shares to be sold hereunder, (b) the issuance by the Company of shares of Common Stock upon the exercise of an option or warrant or the conversion of a security described in the Prospectus and outstanding on the date hereof, *provided*, that the Company shall cause each recipient of any such issuance to execute and deliver to the Representatives an agreement substantially in the form of Exhibit A hereto if such recipient has not already delivered one, (c) any options and other equity-based awards granted under a stock incentive plan or stock purchase plan described in the Prospectus (and the issuance by the Company of shares of Common Stock upon the exercise thereof), *provided*, that the Company shall cause each recipient of any such grant to execute and deliver to the Representatives an agreement substantially in the form of Exhibit A hereto if such recipient has not already delivered one, (d) the filing by the Company of any registration statement on Form S-8 or a successor form thereto relating to the shares of Common Stock granted pursuant to or reserved for issuance under a stock incentive plan or stock purchase plan described in the Prospectus or (e) shares of Common Stock or other securities convertible into or exercisable for shares of Common Stock issued in connection with a joint venture, marketing or distribution arrangement, collaboration agreement, intellectual property license agreement, or any acquisition of assets or not less than a majority or controlling portion of the equity of another entity, provided that (x) the aggregate number of shares of Common Stock or securities convertible into or exercisable for shares of Common Stock issued pursuant to this clause (e) shall not exceed 5.0% of the total number of shares of Common Stock issued and outstanding immediately following the completion of the transactions contemplated by this agreement, and (y) the recipient of any such shares of Common Stock and securities issued pursuant to this clause (e) during the Restricted Period shall execute and deliver to the Representatives an agreement substantially in the form of Exhibit A hereto prior to such issuance.

8. *Covenants of the Selling Shareholders*. Each Selling Shareholder, severally and not jointly, covenants with each Underwriter as follows:

(a) Each Selling Shareholder will deliver to each Underwriter (or its agent), prior to or at the Closing Date, a properly completed and executed Internal Revenue Service ("**IRS**") Form W-9 or an IRS Form W-8, as appropriate, together with all required attachments to such form.

9. *Expenses*. Whether or not the transactions contemplated in this Agreement are consummated or this Agreement is terminated, the Sellers agree to pay or

cause to be paid all expenses incident to the performance of their obligations under this Agreement, including: (i) the fees, disbursements and expenses of the Company's counsel, the Company's accountants and one counsel for the Selling Shareholders in connection with the registration and delivery of the Shares under the Securities Act and all other fees or expenses in connection with the preparation and filing of the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, the Prospectus, any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company and amendments and supplements to any of the foregoing, including all printing costs associated therewith, and the mailing and delivering of copies thereof to the Underwriters and dealers, in the quantities hereinabove specified, (ii) all costs and expenses related to the transfer and delivery of the Shares to the Underwriters, including any transfer or other taxes payable thereon, (iii) the cost of printing or producing any Blue Sky or Legal Investment memorandum in connection with the offer and sale of the Shares under state securities laws and all reasonable expenses in connection with the qualification of the Shares for offer and sale under state securities laws as provided in Section 7(g) hereof, including filing fees and the reasonable fees and disbursements of counsel for the Underwriters in connection with such qualification and in connection with the Blue Sky or Legal Investment memorandum, (iv) all filing fees and expenses incurred in connection with the review and qualification of the offering of the Shares by the Financial Industry Regulatory Authority (including the reasonable fees and disbursements of counsel to the Underwriters in an amount not to exceed $35,000), (v) all fees and expenses in connection with the preparation and filing of the registration statement on Form 8-A relating to the Common Stock and all costs and expenses incident to listing the Shares on the NASDAQ Global Market, (vi) the cost of printing certificates representing the Shares, (vii) the costs and charges of any transfer agent, registrar or depositary, (viii) the costs and expenses of the Company relating to investor presentations on any "road show" as defined in Rule 433(h) under the Securities Act undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives and officers of the Company and any such consultants, and one half of the cost of any aircraft chartered in connection with the road show, (ix) the document production charges and expenses associated with printing this Agreement and (x) all other costs and expenses incident to the performance of the obligations of the Company hereunder for which provision is not otherwise made in this Section. It is understood, however, that except as provided in this Section, Section 11 entitled "Indemnity and Contribution" and the last paragraph of Section 13 below, the Underwriters will pay all of their costs and expenses, including fees and disbursements of their counsel, stock transfer taxes payable on resale of any of the Shares by them and any advertising expenses connected with any offers they may make.

The provisions of this Section shall not supersede or otherwise affect any agreement that the Sellers may otherwise have for the allocation of such expenses among themselves.

10. *Covenants of the Underwriters*. Each Underwriter severally covenants with the Company not to take any action that would result in the Company being required to file with the Commission under Rule 433(d) a free writing prospectus prepared by or on behalf of such Underwriter that otherwise would not be required to be filed by the Company thereunder, but for the action of the Underwriter.

11. *Indemnity and Contribution*. (a) The Company agrees to indemnify and hold harmless each Underwriter, each person, if any, who controls any Underwriter within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act, and each affiliate of any Underwriter within the meaning of Rule 405 under the Securities Act from and against any and all losses, claims, damages and liabilities (including, without limitation, any legal or other expenses reasonably incurred in connection with defending or investigating any such action or claim) caused by any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or any amendment thereof, any preliminary prospectus, the Time of Sale Prospectus or any amendment or supplement thereto, any issuer free writing prospectus as defined in Rule 433(h) under the Securities Act, any Company information that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act, any road show as defined in Rule 433(h) under the Securities Act, or the Prospectus or any amendment or supplement thereto, or any Written Testing-the-Waters Communication or caused by any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, except insofar as such losses, claims, damages or liabilities are caused by any such untrue statement or omission or alleged untrue statement or omission based upon information relating to any Underwriter furnished to the Company in writing by such Underwriter through you expressly for use therein.

(b) Each Selling Shareholder agrees, severally and not jointly, to indemnify and hold harmless each Underwriter, each person, if any, who controls any Underwriter within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act, and each affiliate of any Underwriter within the meaning of Rule 405 under the Securities Act, from and against any and all losses, claims, damages and liabilities (including, without limitation, any legal or other expenses reasonably incurred in connection with defending or investigating any such action or claim) caused by any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or any amendment thereof, any preliminary prospectus, the Time of Sale Prospectus or any amendment or supplement thereto, any issuer free writing prospectus as defined in Rule 433(h) under the Securities Act, any Company information that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act, any road show as defined in Rule 433(h) under the Securities Act, or the Prospectus or any amendment or supplement thereto, or any Written Testing-the-Waters Communication or caused by any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, but only with reference to information relating to such Selling Shareholder furnished in writing by or on behalf of such Selling Shareholder expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any issuer free writing prospectus, road show or the Prospectus or any amendment or supplement thereto.

(c) Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, the Selling Shareholders, the directors of the Company, the officers of the Company who sign the Registration Statement and each person, if any, who controls the Company or a Selling Shareholder within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act to the same extent as the foregoing indemnity from the Company to such Underwriter, but only with reference to information relating to such Underwriter furnished to the Company in writing by such Underwriter through you expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any issuer free writing prospectus, a road show, or the Prospectus or any amendment or supplement thereto.

(d) In case any proceeding (including any governmental investigation) shall be instituted involving any person in respect of which indemnity may be sought pursuant to Section 11(a), 11(b) or 11(c), such person (the "**indemnified party**") shall promptly notify the person against whom such indemnity may be sought (the "**indemnifying party**") in writing and the indemnifying party, upon request of the indemnified party, shall retain counsel reasonably satisfactory to the indemnified party to represent the indemnified party and any others the indemnifying party may designate in such proceeding and shall pay the reasonably incurred fees and disbursements of such counsel related to such proceeding. In any such proceeding, any indemnified party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the indemnifying party and the indemnified party shall have mutually agreed to the retention of such counsel or (ii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them. It is understood that the indemnifying party shall not, in respect of the legal expenses of any indemnified party in connection with any proceeding or related proceedings in the same jurisdiction, be liable for (i) the reasonably incurred fees and expenses of more than one separate firm (in addition to any local counsel) for the Underwriters and all persons, if any, who control any Underwriter within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act or who are affiliates of any Underwriter within the meaning of Rule 405 under the Securities Act, (ii) the reasonably incurred fees and expenses of more than one separate firm (in addition to any local counsel) for the Company, its directors, its officers who sign the Registration Statement and each person, if any, who controls the Company within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act and (iii) the reasonably incurred fees and expenses of more than one separate firm (in addition to any local counsel) for all Selling Shareholders and all persons, if any, who control any Selling Shareholder within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act, and that all such fees and expenses shall be reimbursed as they are incurred. In the case of any such separate firm for the Underwriters and such control persons and affiliates of any Underwriters, such firm shall be designated in writing by the Representatives. In the case of any such separate firm for the Company, and such directors, officers and control persons of the Company, such firm shall be designated in writing by the Company. In the case of any such separate firm for the Selling Shareholders and such control persons of any Selling Shareholders, such firm shall be designated in a writing signed by the persons named as attorneys-in-fact for the Selling Shareholders under the Powers of Attorney representing a majority of the Shares proposed to be sold or sold by the Selling Shareholders. The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any loss or liability by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by the second and third sentences of this paragraph, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into (A) more than 60 days after receipt by the indemnifying party of such request and (B) more than 30 days after receipt by such indemnifying party of the proposed terms of such settlement and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement of any pending or threatened proceeding in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party, unless such settlement includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such proceeding.

(e) To the extent the indemnification provided for in Section 11(a), 11(b) or 11(c) is unavailable to an indemnified party or insufficient in respect of any losses, claims, damages or liabilities referred to therein, then each indemnifying party under such paragraph, in lieu of indemnifying such indemnified party thereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities (i) in such proportion as is appropriate to reflect the relative benefits received by the indemnifying party or parties on the one hand and the indemnified party or parties on the other hand from the offering of the Shares or (ii) if the allocation provided by clause 11(d)(i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause 11(d)(i) above but also the relative fault of the indemnifying party or parties on the one hand and of the indemnified party or parties on the other hand in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Sellers on the one hand and the Underwriters on the other hand in connection with the offering of the Shares shall be deemed to be in the same respective proportions as the net proceeds from the offering of the Shares (before deducting expenses) received by each Seller and the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover of the Prospectus, bear to the aggregate Public Offering Price of the Shares. The relative fault of the Sellers on the one hand and the Underwriters on the other hand shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Sellers or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The Underwriters' respective obligations to contribute pursuant to this Section 11 are several in proportion to the respective number of Shares they have purchased hereunder, and not joint.

(f) The Sellers and the Underwriters agree that it would not be just or equitable if contribution pursuant to this Section 11 were determined by *pro rata* allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take account of the equitable considerations referred to in Section 11(d). The amount paid or payable by an indemnified party as a result of the losses, claims, damages and liabilities referred to in Section 11(d) shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 11, no Underwriter shall be required to contribute any amount in excess of the amount by which the total price at which the Shares underwritten by it and distributed to the public were offered to the public exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The remedies provided for in this Section 11 are not exclusive and shall not limit any rights or remedies which may otherwise be available to any indemnified party at law or in equity.

(g) The indemnity and contribution provisions contained in this Section 11 and the representations, warranties and other statements of the Company and the Selling Shareholders contained in this Agreement shall remain operative and in full force and effect regardless of (i) any termination of this Agreement, (ii) any investigation made by or on behalf of any Underwriter, any person controlling any Underwriter or any affiliate of any Underwriter, or by or on behalf of any Selling Shareholder or any person controlling any Selling Shareholder, or the Company, its officers or directors or any person controlling the Company and (iii) acceptance of and payment for any of the Shares.

12. *Termination*. The Underwriters may terminate this Agreement by notice given by you to the Sellers, if after the execution and delivery of this Agreement and prior to the Closing Date (i) trading generally shall have been suspended or materially limited on, or by, as the case may be, any of the New York Stock Exchange, the NYSE MKT, the NASDAQ Global Market, the Chicago Board of Options Exchange, the Chicago Mercantile Exchange or the Chicago Board of Trade, (ii) trading of any securities of the Company shall have been suspended on any exchange or in any over-the-counter market, (iii) a material disruption in securities settlement, payment or clearance services in the United States shall have occurred, (iv) any moratorium on commercial banking activities shall have been declared by Federal or New York State

authorities or (v) there shall have occurred any outbreak or escalation of hostilities, or any change in financial markets or any calamity or crisis that, in your judgment, is material and adverse and which, singly or together with any other event specified in this clause (v), makes it, in your judgment, impracticable or inadvisable to proceed with the offer, sale or delivery of the Shares on the terms and in the manner contemplated in the Time of Sale Prospectus or the Prospectus.

13. *Effectiveness; Defaulting Underwriters*. This Agreement shall become effective upon the execution and delivery hereof by the parties hereto.

If, on the Closing Date or an Option Closing Date, as the case may be, any one or more of the Underwriters shall fail or refuse to purchase Shares that it has or they have agreed to purchase hereunder on such date, and the aggregate number of Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase is not more than one-tenth of the aggregate number of the Shares to be purchased on such date, the other Underwriters shall be obligated severally in the proportions that the number of Firm Shares set forth opposite their respective names in Schedule I bears to the aggregate number of Firm Shares set forth opposite the names of all such non-defaulting Underwriters, or in such other proportions as you may specify, to purchase the Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase on such date; *provided* that in no event shall the number of Shares that any Underwriter has agreed to purchase pursuant to this Agreement be increased pursuant to this Section 13 by an amount in excess of one-ninth of such number of Shares without the written consent of such Underwriter. If, on the Closing Date, any Underwriter or Underwriters shall fail or refuse to purchase Firm Shares and the aggregate number of Firm Shares with respect to which such default occurs is more than one-tenth of the aggregate number of Firm Shares to be purchased on such date, and arrangements satisfactory to you, the Company and the Selling Shareholders for the purchase of such Firm Shares are not made within 36 hours after such default, this Agreement shall terminate without liability on the part of any non-defaulting Underwriter, the Company or the Selling Shareholders. In any such case either you or the Company shall have the right to postpone the Closing Date, but in no event for longer than seven days, in order that the required changes, if any, in the Registration Statement, in the Time of Sale Prospectus, in the Prospectus or in any other documents or arrangements may be effected. If, on an Option Closing Date, any Underwriter or Underwriters shall fail or refuse to purchase Additional Shares and the aggregate number of Additional Shares with respect to which such default occurs is more than one-tenth of the aggregate number of Additional Shares to be purchased on such Option Closing Date, the non-defaulting Underwriters shall have the option to (i) terminate their obligation hereunder to purchase the Additional Shares to be sold on such Option Closing Date or (ii) purchase not less than the number of Additional Shares that such non-defaulting Underwriters would have been obligated to purchase in the absence of such default. Any action taken under this paragraph shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

If this Agreement shall be terminated by the Underwriters, or any of them, because of any failure or refusal on the part of any Seller to comply with the terms or to fulfill any of the conditions of this Agreement, or if for any reason any Seller shall be unable to perform its obligations under this Agreement, the Company will reimburse the Underwriters or such Underwriters as have so terminated this Agreement with respect to themselves, severally, for all out-of-pocket expenses (including the fees and disbursements of their counsel) reasonably incurred by such Underwriters in connection with this Agreement or the offering contemplated hereunder.

14. *Entire Agreement*. (a) This Agreement, together with any contemporaneous written agreements and any prior written agreements (to the extent not superseded by this Agreement) that relate to the offering of the Shares, represents the entire agreement between the Company and the Selling Shareholders, on the one hand, and the Underwriters, on the other, with respect to the preparation of any preliminary prospectus, the Time of Sale Prospectus, the Prospectus, the conduct of the offering, and the purchase and sale of the Shares.

(b) The Company and the Selling Shareholders acknowledge that in connection with the offering of the Shares: (i) the Underwriters have acted at arms length, are not agents of, and owe no fiduciary duties to, the Company, the Selling Shareholders, or any other person, (ii) the Underwriters owe the Company and the Selling Shareholders only those duties and obligations set forth in this Agreement and prior written agreements (to the extent not superseded by this Agreement), if any, and (iii) the Underwriters may have interests that differ from those of the Company and the Selling Shareholders. The Company and the Selling Shareholders waive to the full extent permitted by applicable law any claims it may have against the Underwriters arising from an alleged breach of fiduciary duty in connection with the offering of the Shares.

15. *Counterparts*. This Agreement may be signed in two or more counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

16. *Applicable Law*. This Agreement and any claim, controversy or dispute relating to or arising out of this Agreement shall be governed by and construed in accordance with the internal laws of the State of New York.

17. *Headings*. The headings of the sections of this Agreement have been inserted for convenience of reference only and shall not be deemed a part of this Agreement.

18. *Information Furnished by the Underwriters*. The parties hereto acknowledge and agree that the only information provided by any Underwriter to the Company through the Representatives in writing expressly for use in the Registration Statement, the Time of Sale Prospectus, any broadly available road show or the Prospectus shall be the statements contained in the Prospectus in the (i) last paragraph of text on the cover page concerning the delivery of the Shares by the Underwriters, (ii) table following the first paragraph under the caption “Underwriting,” and (iii) third paragraph under the caption “Underwriting.”

19. *Notices*. All communications hereunder shall be in writing and effective only upon receipt and if to the Underwriters shall be delivered, mailed or sent to the Representatives c/o Morgan Stanley & Co. LLC, 1585 Broadway, New York, New York 10036, Attention: Equity Syndicate Desk, with a copy to the Legal Department, c/o Cowen and Company, LLC, 599 Lexington Avenue, 27th Floor, New York, New York 10022, and, in each case, with a copy (which copy shall not constitute notice) to Ropes & Gray LLP, Prudential Tower, 800 Boylston Street, Boston, Massachusetts 02199, Attention: Patrick O'Brien, if to the Company shall be delivered, mailed or sent to Ocular Therapeutix, Inc. 36 Crosby Drive, Suite 101, Bedford, MA 01730, Attention: Chief Financial Officer, and if to the Selling Shareholders shall be delivered, mailed or sent to [address].

Very truly yours,

Ocular Therapeutix, Inc.

By: ______________________________
Name:
Title:

[Signature Page to Underwriting Agreement]

Versant Venture Capital III, L.P.
Versant Side Fund III, L.P.

as Selling Stockholders named in Schedule II hereto

By: Versant Ventures III, LLC
Its: General Partner

By: ______________________________
Name: Charles Warden
Title: Managing Director

[Signature Page to Underwriting Agreement]

SV Life Sciences Fund IV, L.P.

as a Selling Stockholder named in Schedule II hereto

By: SV Life Sciences Fund IV (GP), L.P.
Its: Sole General Partner

By: SVLSF IV, LLC
Its: Sole General Partner

By: ______________________________
Name:
Title:

[Signature Page to Underwriting Agreement]

SV Life Sciences Fund IV Strategic Partners, L.P.

as a Selling Stockholder named in Schedule II hereto

By: SV Life Sciences Fund IV (GP), L.P.
Its: Sole General Partner

By: SVLSF IV, LLC
Its: Sole General Partner

By: ______________________________
Name:
Title:

[Signature Page to Underwriting Agreement]

Accepted as of the date hereof

Morgan Stanley & Co. LLC
Cowen and Company, LLC

Acting severally on behalf of themselves and the several
Underwriters named in Schedule I hereto.

By: Morgan Stanley & Co. LLC

By: ______________________________
Name:
Title:

By: Cowen and Company, LLC

By: ______________________________
Name:
Title:

[Signature Page to Underwriting Agreement]

SCHEDULE I

Underwriter	Number of Firm Shares To Be Purchased
Morgan Stanley & Co. LLC	[●]
Cowen and Company, LLC	[●]
RBC Capital Markets, LLC	[●]
Nomura Securities International, Inc.	[●]
BTIG, LLC	[●]
Total:	

SCHEDULE II

Selling Shareholder	**Number of Firm Shares To Be Sold**
[NAMES OF SELLING SHAREHOLDERS]	
Total:	

SCHEDULE III

Selling Shareholder	Number of Additional Shares To Be Sold
[NAMES OF SELLING SHAREHOLDERS]	
Total:	

SCHEDULE IV

Time of Sale Prospectus

1. Preliminary prospectus issued [●], 2015
2. The information set forth on the pricing term sheet attached hereto as Exhibit E
3. [●]

SCHEDULE V

Written Testing-the-Waters Communications

1. [ ]

EXHIBIT A

FORM OF LOCK-UP LETTER

, 2015

Morgan Stanley & Co. LLC
Cowen and Company, LLC
As the Representatives of the several
underwriters named in Schedule I to
the Underwriting Agreement

c/o Morgan Stanley & Co. LLC
1585 Broadway
New York, NY 10036

c/o Cowen and Company, LLC
599 Lexington Avenue, 27th Floor
New York, NY 10022

Ladies and Gentlemen:

The undersigned understands that Morgan Stanley & Co. LLC ("**Morgan Stanley**") and Cowen and Company, LLC ("**Cowen**"), as representatives of the several Underwriters (as defined below) (each of Morgan Stanley and Cowen is a "**Representative**" and together, the "**Representatives**") propose to enter into an Underwriting Agreement (the "**Underwriting Agreement**") with Ocular Therapeutix, Inc., a Delaware corporation (the "**Company**") and certain selling shareholders (the "**Selling Shareholders**") to be named in the Underwriting Agreement, providing for the public offering (the "**Public Offering**") by the several Underwriters, including the Representatives (the "**Underwriters**"), of shares of the Common Stock, $0.0001 par value per share, of the Company (the "**Common Stock**").

To induce the Underwriters that may participate in the Public Offering to continue their efforts in connection with the Public Offering, the undersigned hereby agrees that, without the prior written consent of each of Morgan Stanley and Cowen on behalf of the Underwriters, it will not, during the period commencing on the date hereof and ending 90 days after the date of the final prospectus (the "**Restricted Period**") relating to the Public Offering (the "**Prospectus**"), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock beneficially owned (as such term is used in Rule 13d-3 of the

Securities Exchange Act of 1934, as amended (the "**Exchange Act**")), by the undersigned or any other securities so owned convertible into or exercisable or exchangeable for Common Stock or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise. The foregoing sentence shall not apply to (a) transfers or dispositions of shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock as a bona fide gift, (b) transfers or distributions of shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock to limited partners, members, stockholders or trust beneficiaries of the undersigned or to any investment fund or other entity controlled or managed by the undersigned, (c) transfers or dispositions of shares of Common Stock or any security convertible into Common Stock by will or other testamentary document or by intestacy, (d) transfers or dispositions of shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned in a transaction not involving a disposition for value, (e) transfers or dispositions of Common Stock acquired in the Public Offering (other than any issuer-directed shares of Common stock purchased in the Public Offering by an officer or director of the Company) or acquired in open market transactions after the completion of the Public Offering, (f) the exercise of options to purchase shares of Common Stock granted under a stock incentive plan or stock purchase plan described in the Prospectus or the exercise of warrants to purchase shares of Common Stock (or any security convertible into or exercisable or exchangeable for Common Stock) described in the Prospectus and outstanding as of the date of the Prospectus, provided that the underlying Common Stock continues to be subject to the restrictions set forth above, (g) the exercise of options to purchase shares of Common Stock granted under a stock incentive plan or stock purchase plan described in the Prospectus pursuant to an arrangement whereby the Company withholds shares issuable pursuant to such option in payment of the exercise price, provided that the underlying Common Stock continues to be subject to the restrictions set forth above, (h) transfers or dispositions of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock to the Company pursuant to any contractual arrangement in effect on the date of this Letter Agreement that provides for the repurchase of the undersigned's Common Stock or such other securities by the Company or in connection with the termination of the undersigned's employment with the Company, provided that the repurchase price for any such shares or securities shall not exceed the original purchase price (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization) paid by the undersigned to the Company for such shares or securities; *provided further* that (i) in the case of any transfer or distribution pursuant to clause (a), (b), (c) or (d) each donee, transferee or distributee shall sign and deliver a lock-up letter substantially in the form of this letter and (ii) in the case of any transfer or distribution pursuant to clauses (a), (b), (d), (e) and (g), no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of Common Stock, shall be required or shall be voluntarily made during the Restricted Period, (i) the establishment of a trading plan that satisfies the requirements of Rule 10b5-1 under the

Exchange Act for the transfer of shares of Common Stock, *provided* that (i) such plan does not provide for the transfer of Common Stock during the Restricted Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Common Stock may be made under such plan during the Restricted Period, or (j) the sale of Common Stock by the Selling Shareholders in the Public Offering pursuant to the terms of the Underwriting Agreement. In addition, the undersigned agrees that, without the prior written consent of each of Morgan Stanley and Cowen on behalf of the Underwriters, it will not, during the Restricted Period, make any demand for or exercise any right with respect to, the registration of any shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock. The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the undersigned's shares of Common Stock except in compliance with the foregoing restrictions.

The undersigned understands that the Company and the Underwriters are relying upon this agreement in proceeding toward consummation of the Public Offering. The undersigned further understands that this agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representatives, successors and assigns.

Whether or not the Public Offering actually occurs depends on a number of factors, including market conditions. Any Public Offering will only be made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Underwriters.

The undersigned understands that, (i) if either Morgan Stanley and Cowen, on the one hand, or the Company, on the other hand, informs the other in writing, prior to the execution of the Underwriting Agreement, that it has determined not to proceed with the Public Offering, (ii) if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the securities to be sold thereunder, (iii) if the registration statement related to the Public Offering has been withdrawn prior to the execution of the Underwriting Agreement or (iv) the Underwriting Agreement is not executed on or before August 31, 2015, the undersigned shall be automatically released from all obligations under this agreement.

Very truly yours,

____
(Name)

____
(Address)

EXHIBIT B

Form of Legal Opinion of Company Counsel

EXHIBIT C

Form of Legal Opinion of Selling Shareholders Counsel

EXHIBIT D

Form of Legal Opinion of Intellectual Property Counsel

Exhibit E

Pricing Term Sheet

Ocular Therapeutix, Inc.
[●] Common Shares

Issuer:	Ocular Therapeutix, Inc.
Symbol:	OCUL
Size (Pre-Greenshoe):	$[●]
Total Firm Shares Offered by Issuer:	[●] common shares
Total Firm Shares Offered by Selling Shareholders:	[●] common shares
Greenshoe Shares Offered by Selling Shareholders:	[●] common shares
Price to Public:	$[●]
Trade Date:	[●], 2015
Closing Date:	[●], 2015
CUSIP No:	67576A100
Underwriters:	Morgan Stanley & Co. LLC Cowen and Company, LLC RBC Capital Markets, LLC Nomura Securities International, Inc. BTIG, LLC

The issuer has filed a registration statement (including a preliminary prospectus) with the Securities and Exchange Commission (the "SEC") for the offering to which this communication relates, which was declared effective by the SEC on [●], 2015. Before you invest, you should read the preliminary prospectus in that registration statement for more complete information about the issuer and this offering. You may get these documents for free by visiting EDGAR on the SEC web site at www.sec.gov.

This communication shall not constitute an offer to sell or the solicitation of any offer to buy, nor shall there be any sale of the securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities law of any such jurisdiction.

Exhibit 5.1

WILMERHALE

+1 212 230 8800 (t)
+1 212 230 8888 (f)
wilmerhale.com

June 2, 2015

Ocular Therapeutix, Inc.
34 Crosby Drive, Suite 105
Bedford, Massachusetts 01730

Re: Ocular Therapeutix, Inc. – Registration Statement on Form S-1

Ladies and Gentlemen:

This opinion is furnished to you in connection with a Registration Statement on Form S-1 (File No. 333-204344) (the "**Registration Statement**") filed with the Securities and Exchange Commission (the "**Commission**") under the Securities Act of 1933, as amended (the "**Securities Act**"), for the registration of an aggregate of 4,600,000 shares of Common Stock, $0.0001 par value per share (the "**Shares**"), of Ocular Therapeutix, Inc., a Delaware corporation (the "**Company**"), of which up to 3,200,000 of the Shares will be issued and sold by the Company and the remaining 1,400,000 of the Shares will be sold by certain stockholders of the Company (the "**Selling Stockholders**"), including up to 600,000 Shares that may be sold upon the exercise of an over-allotment option.

The Shares are to be sold by the Company and the Selling Stockholders pursuant to an underwriting agreement (the "**Underwriting Agreement**") to be entered into by and among the Company, the Selling Stockholders and Morgan Stanley & Co. LLC and Cowen and Company, LLC, as representatives of the several underwriters named in the Underwriting Agreement, the form of which has been filed as Exhibit 1.1 to the Registration Statement.

We are acting as counsel for the Company in connection with the issue and sale by the Company and the sale by the Selling Stockholders of the Shares. We have examined signed copies of the Registration Statement as filed with the Commission. We have also examined and relied upon the Underwriting Agreement, minutes of meetings and actions of the stockholders and the Board of Directors of the Company as provided to us by the Company, stock record books of the Company as provided to us by the Company, the Certificate of Incorporation and By-Laws of the Company, each as restated and/or amended to date, and such other documents as we have deemed necessary for purposes of rendering the opinions hereinafter set forth.

In our examination of the foregoing documents, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as copies, the authenticity of the originals of such latter documents and the legal competence of all signatories to such documents.

Our opinion in clause (ii) below, insofar as it relates to the Shares to be sold by the Selling Stockholders being fully paid, is based solely on a certificate of the Chief Financial Officer of the Company confirming the Company's receipt of the consideration called for by the applicable resolutions authorizing the issuance of such shares.

We express no opinion herein as to the laws of any state or jurisdiction other than the state laws of the State of New York, the General Corporation Law of the State of Delaware and the federal laws of the United States of America.

Based upon and subject to the foregoing, we are of the opinion that (i) the Shares to be issued and sold by the Company have been duly authorized for issuance and, when such Shares are issued and paid for in accordance with the terms and conditions of the Underwriting Agreement, such Shares will be validly issued, fully paid and nonassessable and (ii) the Shares to be sold by the Selling Stockholders have been duly authorized and are validly issued, fully paid and nonassessable.

Please note that we are opining only as to the matters expressly set forth herein, and no opinion should be inferred as to any other matters. This opinion is based upon currently existing statutes, rules, regulations and judicial decisions, and we disclaim any obligation to advise you of any change in any of these sources of law or subsequent legal or factual developments which might affect any matters or opinions set forth herein.

We hereby consent to the filing of this opinion with the Commission as an exhibit to the Registration Statement in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act and to the use of our name therein and in the related Prospectus under the caption "Legal Matters." In giving such consent, we do not hereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission.

Very truly yours,

WILMER CUTLER PICKERING
HALE AND DORR LLP

By: /s/ Brian A. Johnson
Brian A. Johnson, a Partner

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Amendment No. 1 to the Registration Statement on Form S-1 of Ocular Therapeutix, Inc. of our report dated March 20, 2015 relating to the financial statements of Ocular Therapeutix, Inc., which appears in such Registration Statement. We also consent to the reference to us under the heading “Experts” in such Registration Statement.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
June 2, 2015