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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 29, 2016

OCULAR THERAPEUTIX, INC.
(Exact Name of Company as Specified in Charter)

Delaware	**001-36554**	**20-5560161**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

34 Crosby Drive, Suite 105
Bedford, MA 01730
(Address of Principal Executive Offices) (Zip Code)

Company's telephone number, including area code: (781) 357-4000

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry into a Material Definitive Agreement.

On November 29, 2016, Ocular Therapeutix, Inc., a Delaware corporation (the "Company"), entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as agent ("Cantor Fitzgerald"), pursuant to which the Company may offer and sell shares of its common stock, $0.0001 par value per share, having an aggregate offering price of up to $40,000,000 (the "Shares") from time to time through Cantor Fitzgerald (the "Offering"). The Company has also filed a prospectus supplement with the Securities and Exchange Commission (the "SEC") in connection with the Offering (the "Prospectus Supplement") under the Company's existing shelf Registration Statement on Form S-3 (File No. 333-210777), which became effective on April 28, 2016 (the "Registration Statement").

Upon delivery of a placement notice and subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald may sell the Shares by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on or through The NASDAQ Global Market ("NASDAQ"), on any other existing trading market for the Company's common stock, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, or by any other method permitted by law, including privately negotiated transactions, subject, in the case of privately negotiated transactions, to the prior written consent of the Company.

The Company or Cantor Fitzgerald may suspend or terminate the offering of Shares upon notice to the other party, subject to certain conditions. Cantor Fitzgerald will act as sales agent on a commercially reasonable efforts basis consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of NASDAQ.

The Company has agreed to pay Cantor Fitzgerald commissions for its services of acting as agent of up to 3.0% of the gross proceeds from the sale of the Shares pursuant to the Sales Agreement. The Company has also agreed to provide Cantor Fitzgerald with customary indemnification and contribution rights.

A copy of the Sales Agreement is attached as Exhibit 1.1 hereto and is incorporated herein by reference. The foregoing description of the material terms of the Sales Agreement does not purport to be complete and is qualified in its entirety by reference to such exhibit.

Wilmer Cutler Pickering Hale and Dorr LLP, counsel to the Company, has issued a legal opinion relating to the Shares. A copy of such legal opinion, including the consent included therein, is attached as Exhibit 5.1 hereto.

The Shares will be sold pursuant to the Registration Statement, and offerings of the Shares will be made only by means of the Prospectus Supplement. This Current Report on Form 8-K shall not constitute an offer to sell or solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities law of such state or jurisdiction.

Item 8.01 Other Events

The Company is filing the additional disclosure attached to this Current Report on Form 8-K as Exhibit 99.1 to provide an update to its business operations, clinical trials and regulatory submissions as described in its periodic reports filed with the SEC pursuant to the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including its Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 10, 2016 (the "Annual Report"), and its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2016, filed with the SEC on November 9, 2016 (the "Q3 Quarterly Report"). The Company is filing the risk factors attached to this Current Report on Form 8-K as Exhibit 99.2 to update and supersede the risk factors contained in its periodic reports filed with the SEC pursuant to the Exchange Act, including those under the heading "Item 1A. Risk Factors" in the Annual Report and the Q3 Quarterly Report.

Item 9.01. Financial Statements and Exhibits.

(d) The Exhibits to this Current Report on Form 8-K are listed in the Exhibit Index attached hereto.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OCULAR THERAPEUTIX, INC.

Date: November 29, 2016

By: /s/ W. Bradford Smith
W. Bradford Smith
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
1.1	Controlled Equity Offering[SM] Sales Agreement, dated November 29, 2016, by and between Ocular Therapeutix, Inc. and Cantor Fitzgerald & Co.
5.1	Opinion of Wilmer Cutler Pickering Hale and Dorr LLP, dated November 29, 2016.
23.1	Consent of Wilmer Cutler Pickering Hale and Dorr LLP (contained in Exhibit 5.1 above).
99.1	Update Regarding Business Operations, Clinical Trials and Regulatory Submissions
99.2	Risk Factors

Exhibit 1.1

OCULAR THERAPEUTIX, INC.
Shares of Common Stock
(par value $0.0001 per share)

Controlled Equity Offering℠

Sales Agreement

November 29, 2016

Cantor Fitzgerald & Co.
499 Park Avenue
New York, NY 10022

Ladies and Gentlemen:

Ocular Therapeutix, Inc., a Delaware corporation (the "**Company**"), confirms its agreement (this "**Agreement**") with Cantor Fitzgerald & Co. (the "**Agent**"), as follows:

1. Issuance and Sale of Shares. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through the Agent, shares of common stock (the "**Placement Shares**") of the Company, par value $0.0001 per share (the "**Common Stock**"), up to an aggregate offering price of $40,000,000; *provided*, *however*, that in no event shall the Company issue or sell through the Agent such number or dollar amount of Placement Shares that would (a) exceed the number or dollar amount of shares of Common Stock registered on the effective Registration Statement (as defined below) pursuant to which the offering is being made, (b) exceed the number of authorized but unissued shares of Common Stock, or (c) exceed the number or dollar amount of shares of Common Stock for which the Company has filed a Prospectus Supplement (as defined below) (the lesser of (a), (b), and (c), the "**Maximum Amount**"). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitations set forth in this Section 1 on the amount of Placement Shares issued and sold under this Agreement shall be the sole responsibility of the Company and that the Agent shall have no obligation in connection with such compliance. The offer and sale of Placement Shares through the Agent will be effected pursuant to the Registration Statement (as defined below) filed by the Company and declared effective by the Securities and Exchange Commission (the "**Commission**") on April 28, 2016, although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement to issue Common Stock.

The Company has filed, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the "**Securities Act**"), with the Commission a registration statement on Form S-3 (File No. 333-210777), including a base prospectus, relating to certain securities, including the Placement Shares, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the "**Exchange Act**"). The Company has prepared a prospectus supplement to the base prospectus included as part of the registration statement, which prospectus supplement relates to the Placement Shares to be issued

from time to time by the Company (the "**Prospectus Supplement**"). The Company will furnish to the Agent, for use by the Agent, copies of the prospectus included as part of such registration statement, as supplemented by the Prospectus Supplement, relating to the Placement Shares to be issued from time to time by the Company. The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable (which shall be a Prospectus Supplement), with respect to the Placement Shares. Except where the context otherwise requires, such registration statement(s), including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) or deemed to be a part of such registration statement pursuant to Rule 430B, is herein called the "**Registration Statement**." The base prospectus or base prospectuses, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented, if necessary, by the Prospectus Supplement, in the form in which such prospectus or prospectuses and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b), together with the then issued Issuer Free Writing Prospectus(es) (as defined below), is herein called the "**Prospectus**."

Any reference herein to the Registration Statement, any Prospectus Supplement, Prospectus or any Issuer Free Writing Prospectus shall be deemed to refer to and include the documents, if any, incorporated by reference therein. Any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement, any Prospectus Supplement, the Prospectus or any Issuer Free Writing Prospectus shall be deemed to refer to and include the filing of any document under the Exchange Act on or after the most-recent effective date of the Registration Statement, or the date of the Prospectus Supplement, Prospectus or such Issuer Free Writing Prospectus, as the case may be, and incorporated therein by reference. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include the most recent copy filed with the Commission pursuant to its Electronic Data Gathering Analysis and Retrieval system or any successor thereto (collectively, "**EDGAR**").

2. Placements. Each time that the Company wishes to issue and sell Placement Shares hereunder (each, a "**Placement**"), it will notify the Agent by email notice (or other method mutually agreed to by the parties) of the number of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one Trading Day (as defined below) and any minimum price below which sales may not be made (a "**Placement Notice**"), the form of which is attached hereto as Schedule 1. The Placement Notice shall originate from any of the individuals from the Company set forth on Schedule 2 (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from the Agent set forth on Schedule 2, as such Schedule 2 may be amended from time to time. The Placement Notice shall be effective upon receipt by the Agent unless and until (i) the Agent declines to accept the terms contained therein for any reason, in its sole discretion, within two (2) Trading Day from the time such Placement Notice was received (ii) the entire amount of the Placement Shares thereunder have been sold, (iii) the Company suspends or terminates the Placement Notice or (iv) this Agreement has been terminated under the provisions of Section 12. The amount of any discount, commission or other compensation to be paid by the Company to

Agent in connection with the sale of the Placement Shares shall be calculated as an amount up to 3.0% of the aggregate gross proceeds from each sale of the Placement Shares. It is expressly acknowledged and agreed that neither the Company nor the Agent will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to the Agent and the Agent does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. Sale of Placement Shares by Agent.

(a) On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, upon the Agent's acceptance of the terms of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, the Agent, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the NASDAQ Global Market (the "**Exchange**"), to sell the Placement Shares up to the amount specified in, and otherwise in accordance with the terms of, such Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that the Agent will be successful in selling Placement Shares, (ii) the Agent will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by the Agent to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Placement Shares as required under this Agreement and (iii) the Agent shall be under no obligation to purchase Placement Shares on a principal basis pursuant to this Agreement, except as otherwise agreed by the Agent and the Company. The Agent will provide written confirmation to the Company no later than the opening of the Trading Day immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the compensation payable by the Company to the Agent pursuant to Section 2 with respect to such sales, and the Net Proceeds (as defined below) payable to the Company, with an itemization of the deductions made by the Agent (as set forth in Section 5(b)) from the gross proceeds that it receives from such sales. Subject to the terms of the Placement Notice, the Agent may sell Placement Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4), including sales made directly on or through the Exchange or any other existing trading market for the Common Stock, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices and/or any other method permitted by law, including, but not limited to privately negotiated transactions, subject, in the case of privately negotiated transactions, to the prior written consent by the Company. "**Trading Day**" means any day on which Common Stock is traded on the Exchange.

(b) During the term of this Agreement, the Agent shall not, directly or indirectly, engage in (i) any short sale of any security of the Company, as defined in Regulation SHO, (ii) any sale of any security of the Company that the Agent does not own or any sale which is consummated by the delivery of a security of the Company borrowed by, or for the account of, the Agent or (iii) any market making, bidding, stabilization or other trading activity with regard

to the Common Stock or related derivative securities, in each case if such activity would be prohibited under Regulation M or other anti-manipulation rules under the Securities Act or any successors laws.

4. Suspension of Sales.

(a) The Company or the Agent may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on Schedule 2, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on Schedule 2), suspend any sale of Placement Shares (a "**Suspension**"); *provided*, *however*, that such Suspension shall not affect or impair any party's obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. While a Suspension is in effect any obligation under Sections 7(l), 7(m), and 7(n) with respect to the delivery of certificates, opinions, or comfort letters to the Agent, shall be waived. Each of the parties agrees that no such notice under this Section 4 shall be effective against any other party unless it is made to one of the individuals named on Schedule 2 hereto, as such Schedule may be amended from time to time.

(b) Notwithstanding any other provision of this Agreement, during any period in which the Company is in possession of material non-public information, the Company and the Agent agree that (i) no sale of Placement Shares will take place, (ii) the Company shall not request the sale of any Placement Shares, and (iii) the Agent shall not be obligated to sell or offer to sell any Placement Shares.

5. Settlement and Delivery to the Agent.

(a) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the third (3rd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "**Settlement Date**"). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the "**Net Proceeds**") will be equal to the aggregate sales price received by the Agent, after deduction for (i) the Agent's commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, and (ii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(b) Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting the Agent's or its designee's account (provided the Agent shall have given the Company written notice of such designee at least one Trading Day prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, the Agent will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its

obligation to deliver Placement Shares on a Settlement Date through no fault of the Agent, the Company agrees that in addition to and in no way limiting the rights and obligations set forth in Section 10(a) hereto, it will (i) hold the Agent harmless against any loss, claim, damage, or reasonable and documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company or its transfer agent (if applicable) and (ii) pay to the Agent (without duplication) any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

(c) Limitations on Offering Size. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares if, after giving effect to the sale of such Placement Shares, the aggregate gross sales proceeds of Placement Shares sold pursuant to this Agreement would exceed the lesser of (A) together with all sales of Placement Shares under this Agreement, the Maximum Amount and (B) the amount authorized from time to time to be issued and sold under this Agreement by the Company's board of directors or a duly authorized committee thereof, and notified to the Agent in writing. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares pursuant to this Agreement at a price lower than the minimum price authorized from time to time by the Company's board of directors or a duly authorized committee thereof.

6. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with Agent that as of the date of this Agreement and as of each Applicable Time (as defined below), unless such representation, warrant or agreement specifies a different time:

(a) The Company and the transactions contemplated by this Agreement meet the requirements for and comply with the applicable conditions set forth in Form S-3 (including General Instructions I.A and I.B) under the Securities Act. 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) Each document filed or to be filed pursuant to the Exchange Act and incorporated by reference in the Prospectus complied or will comply when so filed in all material respects with the Exchange Act and the applicable rules and regulations of the Commission thereunder, (ii) 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, (iii) 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 and (iv) 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 or the Prospectus based upon information relating to the Agent furnished to the Company in writing by the Agent expressly for use therein.

(c) The Company is not an "ineligible issuer" in connection with the offering of the Placement Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Any Issuer Free Writing Prospectus 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 Issuer Free Writing Prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) 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 Issuer Free Writing Prospectuses, if any, furnished to you before first use, the Company has not prepared, used or referred to, and will not, without your prior consent, which consent shall not be unreasonably withheld, conditioned or delayed, prepare, use or refer to, any free writing prospectus. Each Issuer Free Writing Prospectus, as of its issue date and as of each Applicable Time, did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, including any incorporated document deemed to be a part thereof that has not been superseded or modified. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by the Agent specifically for use therein. Each Issuer Free Writing Prospectus, as of its issue date and as of each Applicable Time, did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, including any incorporated document deemed to be a part thereof that has not been superseded or modified. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by the Agent specifically for use therein.

(d) The Registration Statement and the offer and sale of Placement Shares as contemplated hereby meet the requirements of Rule 415 and comply in all material respects with said Rule. The Company has not distributed and, prior to the later to occur of each Settlement Date and completion of the distribution of the Placement Shares, will not distribute any offering material in connection with the offering or sale of the Placement Shares other than the Registration Statement and the Prospectus and any Issuer Free Writing Prospectus to which the Agent has consented, such consent not to be unreasonably withheld, conditioned or delayed. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act and is currently listed on the Exchange under the trading symbol "OCUL." The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Exchange, nor has the Company received any notification that the Commission or the Exchange is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements of the Exchange.

(e) 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 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.

(f) The Company has no subsidiaries.

(g) This Agreement has been duly authorized, executed and delivered by the Company.

(h) The authorized capital stock of the Company conforms as to legal matters to the description thereof contained in the Prospectus.

(i) The shares of Common Stock outstanding prior to the issuance of the Placement Shares have been duly authorized and are validly issued, fully paid and non-assessable.

(j) The Placement Shares 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 Placement Shares will not be subject to any preemptive or similar rights that have not been validly waived.

(k) 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 Placement Shares.

(l) 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 Prospectus.

(m) 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 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 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.

(n) The Prospectus filed as part of the Registration Statement as originally filed or as part of any amendment thereto, or filed pursuant to Rule 424, complied when so filed in all material respects with the Securities Act and the applicable rules and regulations of the Commission thereunder.

(o) The Company is not, and after giving effect to the offering and sale of the Placement Shares 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 (the "**Investment Company Act**").

(p) 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.

(q) 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.

(r) Except as described in 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 Placement Shares registered pursuant to the Registration Statement, other than rights that have been validly waived.

(s) 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.

(t) 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.

(u) (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:

(1) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control, the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, "**Sanctions**"), nor

(2) 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 and sale of the Placement Shares, or lend, contribute or otherwise make available such proceeds to any joint venture partner or other Person:

(1) 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

(2) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering of the Placement Shares, 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.

(v) Subsequent to the respective dates as of which information is given in each of the Registration Statement 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 Agent has 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 and the Prospectus, respectively.

(w) 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 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 Prospectus.

(x) 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 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 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 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.

(y) No material labor dispute with the employees of the Company exists, except as described in the 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.

(z) 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 Prospectus.

(aa) The Company has not taken and will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares.

(bb) 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 Prospectus.

(cc) 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 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.

(dd) Except as described in the 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.

(ee) The statistical and market-related data contained in the 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.

(ff) 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.

(gg) 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.

(hh) From the time of the initial filing of the Company's first registration statement with the Commission 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**").

(ii) 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. Other than as disclosed in the Registration Statement and the Prospectus, 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.

(jj) The studies, tests and preclinical and clinical trials conducted by or on behalf of the Company that are described in the Registration Statement 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; 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 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.

(kk) Except for the Agent, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(ll) The Company is not a party to any agreement with an agent or underwriter for any other "at the market" or continuous equity transaction.

(mm) The Company acknowledges and agrees that Agent has informed the Company that the Agent may, to the extent permitted under the Securities Act and the Exchange Act, purchase and sell Common Stock for its own account while this Agreement is in effect, *provided*, that (i) no such purchase or sales shall take place while a Placement Notice is in effect (except to the extent the Agent may engage in sales of Placement Shares purchased or deemed purchased from the Company as a "riskless principal" or in a similar capacity) and (ii) the Company shall not be deemed to have authorized or consented to any such purchases or sales by the Agent.

Any certificate signed by an officer of the Company and delivered to the Agent or to counsel for the Agent pursuant to or in connection with this Agreement shall be deemed to be a representation and warranty by the Company, as applicable, to the Agent as to the matters set forth therein.

7. Covenants of the Company. The Company covenants and agrees with Agent that:

(a) Registration Statement Amendments. After the date of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by Agent under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 or similar rule), (i) the Company will notify the Agent promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference or amendments or supplements that do not name the Agent or do not relate to, or which would not reasonably be expected to have a material impact on, the transactions contemplated by this Agreement, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus that relate to the transactions contemplated by this Agreement or for additional information that relate to the transactions contemplated by this Agreement, (ii) the Company will prepare and file with the Commission, promptly upon the Agent's request, any amendments or supplements to the Registration Statement or Prospectus that, in such Agent's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by the Agent (*provided*, *however*, that the failure of the Agent to make such request shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement and *provided, further*, that, in the event the Company does not comply with the Agent's request, the Agent may cease making sales under this Agreement until such amendment or supplement is filed); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus relating to the Placement Shares unless a copy thereof has been submitted to Agent within a reasonable period of time before the filing and the Agent has not objected thereto (*provided*, *however*, that the failure of the Agent to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement) and the Company will furnish to the Agent at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (iv) the Company will cause each amendment or supplement to the Prospectus that relates to the transaction contemplated by this Agreement, other than documents incorporated by reference, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) or, in the case of any document to be incorporated therein by reference, to be filed with the Commission as required pursuant to the Exchange Act, within the time period prescribed (the determination to file or not file any amendment or supplement with the Commission under this Section 7(a), based on the Company's reasonable opinion or reasonable objections, shall be made exclusively by the Company).

(b) Notice of Commission Stop Orders. The Company will advise the Agent, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in

any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued. The Company will advise the Agent promptly after it receives any request by the Commission for any amendments to the Registration Statement or any amendment or supplements to the Prospectus or any Issuer Free Writing Prospectus or for additional information related to the offering of the Placement Shares or for additional information related to the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus.

(c) Delivery of Prospectus; Subsequent Changes. During any period in which a Prospectus relating to the Placement Shares is required to be delivered by the Agent under the Securities Act with respect to the offer and sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 or similar rule), the Company will comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If the Company has omitted any information from the Registration Statement pursuant to Rule 430B, it will use its best efforts to comply with the provisions of and make all requisite filings with the Commission pursuant to said Rule 430B and to notify the Agent promptly of all such filings. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an 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 then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify the Agent to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance; *provided*, *however*, that the Company may delay any such amendment or supplement if, in the reasonable judgment of the Company, it is in the best interests of the Company to do so.

(d) Listing of Placement Shares. Prior to the date of the first Placement Notice, the Company will use its reasonable best efforts to cause the Placement Shares to be listed on the Exchange.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to the Agent and its counsel (at the reasonable expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which a Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as the Agent may from time to time reasonably request and, at the Agent's reasonable request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided*, *however*, that the Company shall not be required to furnish any document (other than the Prospectus) to the Agent to the extent such document is available on EDGAR.

(f) Earnings Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

(g) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."

(h) Notice of Other Sales. Without the prior written consent of the Agent, the Company will not, directly or indirectly, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock during the period beginning on the fifth (5th) Trading Day immediately prior to the date on which any Placement Notice is delivered to Agent hereunder and ending on the fifth (5th) Trading Day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice (or, if the Placement Notice has been terminated or suspended prior to the sale of all Placement Shares covered by a Placement Notice, the date of such suspension or termination); and will not directly or indirectly in any other "at the market" or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock prior to the later of the termination of this Agreement and the sixtieth (60th) day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice; *provided*, *however*, that such restrictions will not be required in connection with the Company's issuance or sale of (i) Common Stock, options to purchase Common Stock or other equity-based awards or Common Stock issuable upon the exercise of options, or the vesting of any of the foregoing, pursuant to any employee or director stock option or benefits plan, stock ownership plan or dividend reinvestment plan (but not Common Stock subject to a waiver to exceed plan limits in its dividend reinvestment plan) of the Company whether now in effect or hereafter implemented, (ii) Common Stock issuable upon conversion of securities or the exercise of warrants, options or other rights in effect or outstanding, and disclosed in filings by the Company available on EDGAR or otherwise in writing to the Agent or (iii) Common Stock or securities convertible into or exchangeable for shares of Common Stock as consideration for mergers, acquisitions, other business combinations or strategic alliances, joint ventures, marketing or distribution arrangements, collaboration agreements, co-promotion agreements, intellectual property license agreements or offered and sold in privately negotiated transactions with vendors, customers, strategic partners or potential strategic partners, occurring after the date of this Agreement which are not issued for capital raising purposes and conducted in a manner so as not to be integrated with the offering of Placement Shares hereby.

(i) Change of Circumstances. The Company will, at any time during the pendency of a Placement Notice, advise the Agent promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document required to be provided to the Agent pursuant to this Agreement.

(j) Due Diligence Cooperation. The Company will cooperate with any reasonable due diligence review conducted by the Agent or its representatives in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices, as the Agent may reasonably request.

(k) Required Filings Relating to Placement of Placement Shares. To the extent that the filing of an additional prospectus supplement with the Commission with respect to a placement of Placement Shares becomes required under the Securities Act, the Company agrees that on such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) (each and every filing date under Rule 424(b), a "**Filing Date**"), which prospectus supplement will set forth, within the relevant period, the amount of Placement Shares sold through the Agent, the Net Proceeds to the Company and the compensation payable by the Company to the Agent with respect to such Placement Shares, and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market.

(l) Representation Dates; Certificate. Prior to the date of the first Placement Notice and each time the Company:

(i) files the Prospectus relating to the Placement Shares or amends or supplements (other than a prospectus supplement relating solely to an offering of securities other than the Placement Shares) the Registration Statement or the Prospectus relating to the Placement Shares by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of documents by reference into the Registration Statement or the Prospectus relating to the Placement Shares;

(ii) files an annual report on Form 10-K under the Exchange Act (including any Form 10-K/A containing amended financial information or a material amendment to the previously filed Form 10-K);

(iii) files its quarterly reports on Form 10-Q under the Exchange Act; or

(iv) files a current report on Form 8-K containing amended financial information (other than information "furnished" pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a "**Representation Date**");

the Company shall furnish the Agent (but in the case of clause (iv) above only if the Agent reasonably determines that the information contained in such Form 8-K is material) with a certificate dated the Representation Date, in the form attached hereto as Exhibit 7(l). The

requirement to provide a certificate under this Section 7(l) shall be waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the earlier to occur of the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date) and the next occurring Representation Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date when the Company relied on such waiver and did not provide the Agent with a certificate under this Section 7(l), then simultaneously with or prior to the time the Company delivers the Placement Notice or the Agent sells any Placement Shares pursuant to such Placement Notice, the Company shall provide the Agent with a certificate in conformity with this Section 7(l) dated as of the date of such Placement Notice.

(m) Legal Opinion. (1) Prior to the date of the first Placement Notice and (2) within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 7(l) for which no waiver is applicable, the Company shall cause to be furnished to the Agent a written opinion and negative assurance letter of Wilmer Cutler Pickering Hale and Dorr LLP ("**Company Counsel**"), or other counsel satisfactory to the Agent, in form and substance reasonably satisfactory to Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided, however*, the Company shall be required to furnish to Agent no more than one opinion and negative assurance letter hereunder per calendar quarter; *provided, further*, that in lieu of such opinions and negative assurance letters for subsequent periodic filings under the Exchange Act, counsel may furnish the Agent with a letter (a "**Corporate Reliance Letter**") to the effect that the Agent may rely on a prior opinion and negative assurance letter delivered under this Section 7(m) to the same extent as if it were dated the date of such letter (except that statements in such prior opinion and negative assurance letter shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of the date of the Corporate Reliance Letter).

(n) Intellectual Property Opinion. (1) Prior to the date of the first Placement Notice and (2) within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 7(l) (other than pursuant to Section 7(l)(iii)) and for which no waiver is applicable, the Company shall cause to be furnished to the Agent a written opinion of Dardi & Herbert, PLLC ("**Intellectual Property Counsel**"), or other counsel satisfactory to the Agent, in form and substance satisfactory to Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided, however*, the Company shall be required to furnish to Agent no more than one opinion hereunder per calendar year; *provided, further*, that in lieu of such opinions for subsequent periodic filings under the Exchange Act, counsel may furnish the Agent with a letter (a "**Intellectual Property Reliance Letter**") to the effect that the Agent may rely on a prior opinion delivered under this Section 7(n) to the same extent as if it were dated the date of such letter (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of the date of the Intellectual Property Reliance Letter).

(o) Comfort Letter. (1) Prior to the date of the first Placement Notice and (2) within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 7(l) for which no waiver is applicable, the Company shall cause its independent registered public accounting firm to furnish the Agent letters (the "**Comfort Letters**"), dated the date the Comfort Letter is delivered, which shall meet the requirements set forth in this Section 7(o); *provided*, that if requested by the Agent, the Company shall cause a Comfort Letter to be furnished to the Agent within ten (10) Trading Days of the date of occurrence of any material transaction or event, including the restatement of the Company's financial statements. The Comfort Letter from the Company's independent registered public accounting firm shall be in a form and substance reasonably satisfactory to the Agent, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to underwriters in connection with registered public offerings (the first such letter, the "**Initial Comfort Letter**") and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(p) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or would reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of Common Stock or (ii) sell, bid for, or purchase Common Stock in violation of Regulation M, or pay anyone any compensation for soliciting purchases of the Placement Shares other than the Agent.

(q) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that it will not be or become, at any time prior to the termination of this Agreement, required to register as an "investment company," as such term is defined in the Investment Company Act.

(r) No Offer to Sell. Other than an Issuer Free Writing Prospectus approved in advance by the Company and the Agent in its capacity as agent hereunder (such approval not to be unreasonably withheld, conditioned or delayed), neither the Agent nor the Company (including its agents and representatives, other than the Agent in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Placement Shares hereunder.

(s) Blue Sky and Other Qualifications. The Company will use its commercially reasonable efforts, in cooperation with the Agent, to qualify the Placement Shares for offering and sale, or to obtain an exemption for the Placement Shares to be offered and sold, under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Agent may designate and to maintain such qualifications and exemptions in effect for so long as required for the distribution of the Placement Shares (but in no event for less than one year from the date of this Agreement); *provided*, *however*, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in

respect of doing business in any jurisdiction in which it is not otherwise so subject. In each jurisdiction in which the Placement Shares have been so qualified or exempt, the Company will file such statements and reports as may be required by the laws of such jurisdiction to continue such qualification or exemption, as the case may be, in effect for so long as required for the distribution of the Placement Shares (but in no event for less than one year from the date of this Agreement).

(t) Sarbanes-Oxley Act. The Company will maintain and keep accurate books and records reflecting its assets and maintain internal accounting controls in a manner designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and including those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company, (ii) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of the Company's consolidated financial statements in accordance with generally accepted accounting principles, (iii) that receipts and expenditures of the Company are being made only in accordance with management's and the Company's directors' authorization, and (iv) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on its financial statements. The Company will maintain such controls and other procedures, including, without limitation, those required by Sections 302 and 906 of the Sarbanes-Oxley Act, and the applicable regulations thereunder that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, including, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure and to ensure that material information relating to the Company is made known to them by others within those entities, particularly during the period in which such periodic reports are being prepared.

(u) Secretary's Certificate; Further Documentation. Prior to the date of the first Placement Notice, the Company shall deliver to the Agent a certificate of the Secretary of the Company and attested to by an executive officer of the Company, dated as of such date, certifying as to (i) the Certificate of Incorporation of the Company, (ii) the By-laws of the Company, (iii) the resolutions of the Board of Directors of the Company or a duly authorized committee thereof, authorizing the execution, delivery and performance of this Agreement and the issuance of the Placement Shares and (iv) the incumbency of the officers duly authorized to execute this Agreement and the other documents contemplated by this Agreement. Within five (5) Trading Days of each Representation Date, the Company shall have furnished to the Agent such further information, certificates and documents as the Agent may reasonably request.

(v) Emerging Growth Company Status. The Company will promptly notify the Agent if the Company ceases to be an Emerging Growth Company at any time during the term of this Agreement.

8. Payment of Expenses. The Company will pay all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation and filing of the Registration Statement, including any fees required by the Commission, and the printing or electronic delivery of the Prospectus as originally filed and of each amendment and supplement thereto, in such number as the Agent shall reasonably deem necessary, (ii) the printing and delivery to the Agent of this Agreement and such other documents as may be required in connection with the offering, purchase, sale, issuance or delivery of the Placement Shares, (iii) the preparation, issuance and delivery of the Placement Shares to the Agent, including any stock or other transfer taxes and any capital duties, stamp duties or other duties or taxes payable upon the sale, issuance or delivery of the Placement Shares to the Agent, (iv) the fees and disbursements of the counsel, accountants and other advisors to the Company, (v) the reasonable and documented fees and expenses of Agent, including but not limited to the fees and expenses of the counsel to the Agent, payable upon the execution of this Agreement, in an amount not to exceed $50,000, (vi) the qualification or exemption of the Placement Shares under state securities laws in accordance with the provisions of Section 7(s) hereof, including filing fees, but excluding fees of the Agent's counsel, (vii) the printing and delivery to the Agent of copies of any Permitted Issuer Free Writing Prospectus and the Prospectus and any amendments or supplements thereto in such number as the Agent shall reasonably deem necessary, (viii) the preparation, printing and delivery to the Agent of copies of the blue sky survey, (ix) the fees and expenses of the transfer agent and registrar for the Common Stock, (x) the filing and other fees incident to any review by FINRA of the terms of the sale of the Placement Shares including the fees of the Agent's counsel (subject to the cap, set forth in clause (v) above), and (xi) the fees and expenses incurred in connection with the listing of the Placement Shares on the Exchange.

9. Representations and Covenants of Agent. The Agent represents and warrants that it is duly registered as a broker-dealer under FINRA, the Exchange Act and the applicable statutes and regulations of each state in which the Placement Shares will be offered and sold, except such states in which Agent is exempt from registration or such registration is not otherwise required. Agent shall continue, for the term of this Agreement, to be duly registered as a broker-dealer under FINRA, the Exchange Act and the applicable statutes and regulations of each state in which the Placement Shares will be offered and sold, except such states in which Agent is exempt from registration or such registration is not otherwise required, during the term of this Agreement.

10. Conditions to Agent's Obligations. The obligations of the Agent hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder, to the completion by the Agent of a due diligence review satisfactory to it in its reasonable judgment, and to the continuing satisfaction (or waiver by the Agent in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective. The Registration Statement shall have become effective and shall be available for the (i) resale of all Placement Shares issued to the Agent and not yet sold by the Agent and (ii) sale of all Placement Shares contemplated to be issued by any Placement Notice.

(b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company of any request for additional information from the

Commission or any other federal or state Governmental Authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state Governmental Authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, the Prospectus or material incorporated documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) No Misstatement or Material Omission. Agent shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change in the authorized capital stock of the Company or any material adverse effect on the Company or any development that would cause a material adverse effect, or a downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities) by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities (other than asset backed securities), the effect of which, in the case of any such action by a rating organization described above, in the reasonable judgment of the Agent (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.

(e) Legal Opinions. The Agent shall have received the opinions and negative assurance letters of Company Counsel and Intellectual Property Counsel required to be delivered pursuant to Section 7(m) and Section 7(n) on or before the date on which such delivery of such opinions and negative assurance letters are required pursuant to Section 7(m) and Section 7(n).

(f) Comfort Letter. The Agent shall have received the Comfort Letter required to be delivered pursuant to Section 7(o) on or before the date on which such delivery of such Comfort Letter is required pursuant to Section 7(o).

(g) Representation Certificate. The Agent shall have received the certificate required to be delivered pursuant to Section 7(l) on or before the date on which delivery of such certificate is required pursuant to Section 7(l).

(h) No Suspension. Trading in the Common Stock shall not have been suspended on the Exchange and the Common Stock shall not have been delisted from the Exchange.

(i) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(l), the Company shall have furnished to the Agent such appropriate further information, opinions, certificates, letters and other documents as the Agent may reasonably request and which are customarily furnished by an issuer of securities in connection with a securities offering. All such opinions, certificates, letters and other documents will be in compliance with the provisions hereof.

(j) Securities Act Filings Made. All filings with the Commission required by Rule 424 with respect to the Placement Shares to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

(k) Approval for Listing. The Placement Shares shall either have been (i) approved for listing on the Exchange, subject only to notice of issuance, or (ii) the Company shall have filed an application for listing of the Placement Shares on the Exchange at, or prior to, the issuance of any Placement Notice and the Exchange shall have reviewed such application and not provided any objections thereto.

(l) FINRA. If applicable, FINRA shall have raised no objection to the terms of this offering and the amount of compensation allowable or payable to the Agent as described in the Prospectus.

(m) No Termination Event. There shall not have occurred any event that would permit the Agent to terminate this Agreement pursuant to Section 12(a).

11. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless the Agent, its affiliates and their respective partners, members, directors, officers, employees and agents and each person, if any, who controls the Agent or any affiliate within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act as follows:

(i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading, or arising out of any untrue statement or alleged untrue statement of a material fact included in any related Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; *provided* that any such settlement is effected with the written consent of the Company, which consent shall not unreasonably be delayed or withheld; and

(iii) against any and all expense whatsoever, as incurred (including the fees and disbursements of counsel), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission (whether or not a party), to the extent that any such expense is not paid under (i) or (ii) above,

provided, however, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made solely in reliance upon and in conformity with the Agent Information (as defined below).

(b) Agent Indemnification. Agent agrees to indemnify and hold harmless the Company and its directors and each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 11(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto), the Prospectus (or any amendment or supplement thereto) or any Issuer Free Writing Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with information relating to the Agent and furnished to the Company in writing by the Agent expressly for use therein. The Company hereby acknowledges that the only information that the Agent has furnished to the Company expressly for use in the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus (or any amendment or supplement thereto) are the statements set forth in the seventh and eighth paragraphs under the caption "Plan of Distribution" in the Prospectus Supplement (the "**Agent Information**").

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 11 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 11, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 11 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 11 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the

indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action or counsel reasonably satisfactory to the indemnified party, in each case, within a reasonable time after receiving notice of the commencement of the action; in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm (plus local counsel) admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 11 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (1) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation, proceeding or claim and (2) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 11 is applicable in accordance with its terms but for any reason is held to be unavailable or insufficient from the Company or the Agent, the Company and the Agent will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted) to which the Company and the Agent may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Agent on the other hand. The relative benefits received by

the Company on the one hand and the Agent on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by the Agent (before deducting expenses) from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Agent, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Agent agree that it would not be just and equitable if contributions pursuant to this Section 11(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 11(d) shall be deemed to include, for the purpose of this Section 11(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 11(c) hereof. Notwithstanding the foregoing provisions of this Section 11(d), the Agent shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 11(d), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of the Agent, will have the same rights to contribution as that party, and each director of the Company and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 11(d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 11(d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 11(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 11(c) hereof.

12. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 11 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of the Agent, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

13. Termination.

(a) The Agent may terminate this Agreement, by notice to the Company, as hereinafter specified at any time (1) if there has been, since the time of execution of this Agreement or since the date as of which information is given in the Prospectus, any change, or any development or event involving a prospective change, in the condition, financial or otherwise, or in the business, properties, earnings, results of operations or prospects of the Company, whether or not arising in the ordinary course of business, which individually or in the aggregate, in the sole judgment of the Agent is material and adverse and makes it impractical or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (2) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of the Agent, impracticable or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (3) if trading in the Common Stock has been suspended or limited by the Commission or the Exchange, or if trading generally on the Exchange has been suspended or limited, or minimum prices for trading have been fixed on the Exchange, (4) if any suspension of trading of any securities of the Company on any exchange or in the over-the-counter market shall have occurred and be continuing, (5) if a major disruption of securities settlements or clearance services in the United States shall have occurred and be continuing, or (6) if a banking moratorium has been declared by either U.S. Federal or New York authorities. Any such termination shall be without liability of any party to any other party except that the provisions of Section 8 (Payment of Expenses), Section 11 (Indemnification and Contribution), Section 12 (Representations and Agreements to Survive Delivery), Section 18 (Governing Law and Time; Waiver of Jury Trial) and Section 19 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination. If the Agent elects to terminate this Agreement as provided in this Section 13(a), the Agent shall provide the required notice as specified in Section 14 (Notices).

(b) The Company shall have the right, by giving ten (10) days notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 8, Section 11, Section 12, Section 18 and Section 19 hereof shall remain in full force and effect notwithstanding such termination.

(c) The Agent shall have the right, by giving ten (10) days notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 8, Section 11, Section 12, Section 18 and Section 19 hereof shall remain in full force and effect notwithstanding such termination.

(d) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 13(a), (b), or (c) above or otherwise by mutual agreement of the parties; *provided, however*, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 8, Section 11, Section 12, Section 18 and Section 19 shall remain in full force and effect.

(e) Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided*, *however*, that such termination shall not be effective until the close of business on the date of receipt of such notice by the Agent or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.

14. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified in this Agreement, and if sent to the Agent, shall be delivered to:

Cantor Fitzgerald & Co.
499 Park Avenue
New York, NY 10022
Attention: Capital Markets/Jeffrey Lumby
Facsimile: (212) 307-3730
Email: jlumby@cantor.com

and:

Cantor Fitzgerald & Co.
499 Park Avenue
New York, NY 10022
Attention: General Counsel
Facsimile: (212) 829-4708

with a copy to:

Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
Attention: Patrick O'Brien, Esq.
Facsimile: (617) 235-0392
Email: patrick.obrien@ropesgray.com

and if to the Company, shall be delivered to:

Ocular Therapeutix, Inc.
34 Crosby Drive, Suite 105
Bedford, MA 01730
Attention: Chief Financial Officer
Facsimile: (781) 357-4001
Email: bsmith@ocutx.com

with a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Attention: Brian A. Johnson, Esq.
Facsimile: (212) 230-8888
Email: brian.johnson@wilmerhale.com

Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day (as defined below) or, if such day is not a Business Day, on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "**Business Day**" shall mean any day on which the Exchange and commercial banks in the City of New York are open for business.

An electronic communication ("**Electronic Notice**") shall be deemed written notice for purposes of this Section 14 if sent to the electronic mail address specified by the receiving party under separate cover. Electronic Notice shall be deemed received at the time the party sending Electronic Notice receives verification of receipt by the receiving party. Any party receiving Electronic Notice may request and shall be entitled to receive the notice on paper, in a nonelectronic form ("**Nonelectronic Notice**") which shall be sent to the requesting party within ten (10) days of receipt of the written request for Nonelectronic Notice.

15. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and the Agent and their respective successors and the parties referred to in Section 11 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; *provided*, *however*, that the Agent may assign its rights and obligations hereunder to an affiliate thereof without obtaining the Company's consent.

16. Adjustments for Stock Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any stock split, stock dividend or similar event effected with respect to the Placement Shares.

17. Entire Agreement; Amendment; Severability; Waiver. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant

hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and the Agent. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement. No implied waiver by a party shall arise in the absence of a waiver in writing signed by such party. No failure or delay in exercising any right, power, or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any right, power, or privilege hereunder.

18. **GOVERNING LAW AND TIME; WAIVER OF JURY TRIAL. THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAWS. SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME. EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.**

19. **CONSENT TO JURISDICTION. EACH PARTY HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH ANY TRANSACTION CONTEMPLATED HEREBY, AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT, THAT SUCH SUIT, ACTION OR PROCEEDING IS BROUGHT IN AN INCONVENIENT FORUM OR THAT THE VENUE OF SUCH SUIT, ACTION OR PROCEEDING IS IMPROPER. EACH PARTY HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF (CERTIFIED OR REGISTERED MAIL, RETURN RECEIPT REQUESTED) TO SUCH PARTY AT THE ADDRESS IN EFFECT FOR NOTICES TO IT UNDER THIS AGREEMENT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW.**

20. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile or electronic transmission.

21. Construction. The section and exhibit headings herein are for convenience only and shall not affect the construction hereof. References herein to any law, statute, ordinance, code, regulation, rule or other requirement of any Governmental Authority shall be deemed to refer to such law, statute, ordinance, code, regulation, rule or other requirement of any Governmental Authority as amended, reenacted, supplemented or superseded in whole or in part and in effect from time to time and also to all rules and regulations promulgated thereunder.

22. Permitted Free Writing Prospectuses. The Company represents, warrants and agrees that, unless it obtains the prior written consent of the Agent, which consent shall not be unreasonably withheld, conditions or delayed, and the Agent represents, warrants and agrees that, unless it obtains the prior written consent of the Company, which consent shall not be unreasonably withheld, conditions or delayed, it has not made and will not make any offer relating to the Placement Shares that would constitute an Issuer Free Writing Prospectus, or that would otherwise constitute a "free writing prospectus," as defined in Rule 405, required to be filed with the Commission. Any such free writing prospectus consented to by the Agent or by the Company, as the case may be, is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company represents and warrants that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus," as defined in Rule 433, and has complied and will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping. For the purposes of clarity, the parties hereto agree that all free writing prospectuses, if any, listed in Exhibit 21 hereto are Permitted Free Writing Prospectuses.

23. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

(a) the Agent is acting solely as agent in connection with the offering of the Placement Shares and in connection with each transaction contemplated by this Agreement and the process leading to such transactions, and no fiduciary or advisory relationship between the Company or any of its respective affiliates, stockholders (or other equity holders), creditors or employees or any other party, on the one hand, and the Agent, on the other hand, has been or will be created in respect of any of the transactions contemplated by this Agreement, irrespective of whether or not the Agent has advised or is advising the Company on other matters, and the Agent has no obligation to the Company with respect to the transactions contemplated by this Agreement except the obligations expressly set forth in this Agreement;

(b) it is capable of evaluating and understanding, and understands and accepts, the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) neither the Agent nor its affiliates have provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated by this Agreement and it has consulted its own legal, accounting, regulatory and tax advisors to the extent it has deemed appropriate;

(d) it is aware that the Agent and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and the Agent and its affiliates have no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship or otherwise; and

(e) it waives, to the fullest extent permitted by law, any claims it may have against the Agent or its affiliates for breach of fiduciary duty or alleged breach of fiduciary duty in connection with the sale of Placement Shares under this Agreement and agrees that the Agent and its affiliates shall not have any liability (whether direct or indirect, in contract, tort or otherwise) to it in respect of such a fiduciary duty claim or to any person asserting a fiduciary duty claim on its behalf or in right of it or the Company, employees or creditors of Company.

24. Definitions. As used in this Agreement, the following terms have the respective meanings set forth below:

"**Applicable Time**" means (i) each Representation Date, (ii) the time of each sale of any Placement Shares pursuant to this Agreement and (iii) each Settlement Date.

"**Governmental Authority**" means (i) any federal, provincial, state, local, municipal, national or international government or governmental authority, regulatory or administrative agency, governmental commission, department, board, bureau, agency or instrumentality, court, tribunal, arbitrator or arbitral body (public or private); (ii) any self-regulatory organization; or (iii) any political subdivision of any of the foregoing.

"**Issuer Free Writing Prospectus**" means any "issuer free writing prospectus," as defined in Rule 433, relating to the Placement Shares that (1) is required to be filed with the Commission by the Company, (2) is a "road show" that is a "written communication" within the meaning of Rule 433(d)(8)(i) whether or not required to be filed with the Commission, or (3) is exempt from filing pursuant to Rule 433(d)(5)(i) because it contains a description of the Placement Shares or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g).

"**Rule 172**," "**Rule 405**," "**Rule 415**," **Rule 424**," "**Rule 430B**," and "**Rule 433**" refer to such rules under the Securities Act.

All references in this Agreement to financial statements and schedules and other information that is "contained," "included" or "stated" in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information that is incorporated by reference in the Registration Statement or the Prospectus, as the case may be.

All references in this Agreement to the Registration Statement, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to EDGAR; all references in this Agreement to any Issuer Free Writing Prospectus (other than any Issuer Free Writing Prospectuses that, pursuant to Rule 433, are not required to be filed with the Commission) shall be deemed to include the copy thereof filed with the Commission pursuant to EDGAR; and all references in this Agreement to "supplements" to

the Prospectus shall include, without limitation, any supplements, “wrappers” or similar materials prepared in connection with any offering, sale or private placement of any Placement Shares by the Agent outside of the United States.

[*Signature Page Follows*]

If the foregoing correctly sets forth the understanding between the Company and the Agent, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and the Agent.

Very truly yours,

OCULAR THERAPEUTIX, INC.

By: /s/ W. Bradford Smith
Name: W. Bradford Smith
Title: Chief Financial Officer

ACCEPTED as of the date first-above written:

CANTOR FITZGERALD & CO.

By: /s/ Jeffrey Lumby
Name: Jeffrey Lumby
Title: Senior Managing Director

SCHEDULE 1

Form of Placement Notice

From: Ocular Therapeutix, Inc.

To: Cantor Fitzgerald & Co.
Attention: [●]

Subject: Placement Notice

Date: [●], 201[●]

Ladies and Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement between Ocular Therapeutix, Inc., a Delaware corporation (the "**Company**"), and Cantor Fitzgerald & Co. ("**Agent**"), dated November [●], 2016, the Company hereby requests that the Agent sell up to [●] of the Company's common stock, par value $0.0001 per share, at a minimum market price of $[●] per share, during the time period beginning [month, day, time] and ending [month, day, time].

SCHEDULE 2

Notice Parties

The Company

Amar Sawhney, Ph.D. (asawhney@ocutx.com)

Brad Smith (bsmith@ocutx.com)

The Agent

Jeffrey Lumby (jlumby@cantor.com)

Joshua Feldman (jfeldman@cantor.com)

Sameer Vasudev (svasudev@cantor.com)

With copies to:

CFControlledEquityOffering@cantor.com

Exhibit 7(l)

Form of Representation Date Certificate Pursuant to Section 7(l)

The undersigned, the duly qualified and elected [●] of Ocular Therapeutix, Inc., a Delaware corporation (the "Company"), does hereby certify in such capacity and on behalf of the Company, pursuant to Section 7(l) of the Sales Agreement, dated November [●], 2016 (the "Sales Agreement"), between the Company and Cantor Fitzgerald & Co., that to the best of the knowledge of the undersigned:

(i) The representations and warranties of the Company in Section 6 of the Sales Agreement are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date; *provided*, *however*, that such representations and warranties also shall be qualified by the disclosure included or incorporated by reference in the Registration Statement and Prospectus; and

(ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

Capitalized terms used herein without definition shall have the meanings given to such terms in the Sales Agreement.

OCULAR THERAPEUTIX, INC.

By: _____
Name: _____
Title: _____

Date: [●]

Exhibit 21

Permitted Free Writing Prospectus

None.

Exhibit 5.1

WILMERHALE
+1 212 230 8800 (t)
+1 212 230 8888 (f)
wilmerhale.com

November 29, 2016

Ocular Therapeutix, Inc.
34 Crosby Drive, Suite 105
Bedford, MA 01730

Re: Prospectus Supplement to Registration Statement on Form S-3

Ladies and Gentlemen:

This opinion is being furnished to you in connection with (i) the Registration Statement on Form S-3 (File No. 333-210777) (the "Registration Statement") filed by Ocular Therapeutix, Inc., a Delaware corporation (the "Company"), with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), for the registration of, among other things, an indeterminate number of shares of the Company's common stock, $0.0001 par value per share (the "Common Stock"), which may be issued from time to time on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, at an initial aggregate offering price not to exceed $150,000,000, as set forth in the Registration Statement and the prospectus contained therein (the "Base Prospectus") and (ii) the prospectus supplement, dated November 29, 2016 (the "Prospectus Supplement" and, together with the Base Prospectus, the "Prospectus") relating to the issuance and sale from time to time by the Company of shares of Common Stock with an aggregate offering price of up to $40,000,000 (the "Shares").

The Shares are to be issued and sold by the Company pursuant to a Controlled Equity Offering℠ Sales Agreement, dated November 29, 2016, between the Company and Cantor Fitzgerald & Co. (the "Sales Agreement"). The Sales Agreement is being filed with the Commission as Exhibit 1.1 to a Current Report on Form 8-K of the Company.

We are acting as counsel for the Company in connection with the issue and sale by the Company of the Shares pursuant to the Sales Agreement. We have examined and relied upon copies of the Registration Statement and the Prospectus, as filed with the Commission, including the exhibits thereto. We have also examined and relied upon the Restated Certificate of Incorporation of the Company (as amended or restated from time to time, the "Certificate of Incorporation"); the Amended and Restated By-laws of the Company (as amended or restated from time to time); records of meetings and actions of stockholders and of the Board of Directors of the Company, including committees thereof, and corporate proceedings of the Company regarding the authorization of the execution and delivery of the Sales Agreement and the authorization and issuance of the Shares, as provided to us by the Company; the Sales Agreement; certificates of representatives of the Company; certificates of public officials; and such other documents, instruments and certificates as we have deemed necessary as a basis for the opinion hereinafter expressed.

In our examination of the documents referred to above, we have assumed the genuineness of all signatures, the legal capacity of all individual signatories, 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 such original documents, and the completeness and accuracy of the corporate records and stock books of the Company provided to us by the Company.

We have relied as to certain matters on information obtained from public officials and officers of the Company, and we have assumed that (i) the Shares will be issued and sold in compliance with applicable federal and state securities laws and in the manner stated in the Registration Statement, the Prospectus and any applicable prospectus supplement; (ii) there will be sufficient shares of Common Stock authorized under the Certificate of Incorporation and not otherwise reserved for issuance; and (iii) the Company will be validly existing as a corporation and in good standing under the laws of the State of Delaware.

We have assumed that there will not have occurred, prior to the date of issuance of the Shares, any change in law affecting the validity of such Shares and that at the time of the issuance and sale of the Shares, the Board of Directors of the Company (or any committee thereof acting pursuant to authority properly delegated to such committee by the Board of Directors) shall not have taken any action to rescind or otherwise reduce its prior authorization of the issuance of the Shares.

We express no opinion herein as to the laws of any state or jurisdiction other than the General Corporation Law of the State of Delaware and the federal laws of the United States of America. We also express no opinion herein with respect to compliance by the Company with the securities or “blue sky” laws of any state or other jurisdiction of the United States or of any foreign jurisdiction. In addition, we express no opinion and make no statement herein with respect to the antifraud laws of any jurisdiction.

Based upon and subject to the foregoing, we are of the opinion that the Shares have been duly authorized for issuance and, when issued and paid for in accordance with the terms and conditions of the Sales Agreement, the Shares will be validly issued, fully paid and non-assessable.

It is understood that this opinion is to be used only in connection with the offer and sale of the Shares while the Registration Statement is in effect.

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 in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act as an exhibit to the Current Report on Form 8-K to be filed by the Company in connection with the issuance and sale of the Shares and to the use of our name therein and in the related Prospectus Supplement 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

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 drug product candidates are designed to provide extended delivery of therapeutic agents to the eye. Our lead product candidates are DEXTENZA (dexamethasone insert), for the treatment of post-surgical ocular inflammation and pain, allergic conjunctivitis and inflammatory dry eye disease, and OTX-TP, for the treatment of glaucoma and ocular hypertension, which are extended delivery, drug-eluting inserts that are placed into the canaliculus through a natural opening called the punctum located in the inner portion of the eyelid near the nose. Our intracanalicular inserts combine our hydrogel technology with U.S. Food and Drug Administration, or FDA, approved therapeutic agents with the goal of providing extended delivery of drug to the eye. We also have an intravitreal hydrogel 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 intravitreal depot is designed to be delivered via intravitreal injection to release therapeutic agents, such as antibodies to vascular endothelial growth factor, or VEGF, over an extended period. We have entered into a collaboration, option and license with Regeneron Pharmaceuticals, Inc., or Regeneron, for the development and potential commercialization of products containing our extended-delivery hydrogel depot in combination with Regeneron's large molecule VEGF-targeting compounds, with the initial focus on the VEGF trap aflibercept, currently marketed under the brand name Eylea. In addition to our ongoing product development, we currently market our first commercial product, ReSure Sealant, a hydrogel-based ophthalmic wound sealant approved by the FDA 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.

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 extended-delivery, drug-eluting intracanalicular inserts, which we formerly referred to as punctum plugs. Our intracanalicular inserts are designed to release a therapeutic agent to the surface of the eye over an extended period. The goal for our intracanalicular depot 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, extended delivery of therapeutic agents to improve patient outcomes.

DEXTENZA

Our most advanced product candidate, DEXTENZA, incorporates the FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient into a hydrogel-based drug-eluting insert for intracanalicular use. In September 2015, we submitted to the FDA a New Drug Application, or NDA, for DEXTENZA for the treatment of post-surgical ocular pain. On July 25, 2016, we announced that we had received a Complete Response Letter, or CRL, from the FDA regarding our NDA for DEXTENZA. In the CRL, the concerns raised by the FDA pertained to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of our manufacturing facility performed by the FDA New England District Office, or the District Office, in February 2016 that were documented on FDA Form 483. The CRL did not identify any efficacy or safety concerns with respect to the clinical data provided in the NDA nor any need for additional clinical trials for the approval of the NDA. In November 2016, we received notice from the District Office accepting that our responses satisfactorily addressed the remaining corrective actions in the Form 483. We have had ongoing communications with the FDA, including the District Office and offices within the Center for Drug Evaluation and Research, or CDER, including the Office of Process and Facilities, with regard to manufacturing issues and our plans for a resubmission to the NDA. In October 2016, we met with the FDA to discuss our plans for resubmission to the NDA and to attempt to gain clarity on the likelihood of a re-inspection of our manufacturing facility. The FDA indicated that a decision as to whether a re-inspection is needed will be made during its review of our resubmission. We anticipate the resubmission to the NDA in December 2016 and plan to include the letter from the District Office accepting that our responses satisfactorily addressed the remaining corrective actions in the Form 483 in our resubmission. Adequate resolution of the Form 483 manufacturing deficiencies with the District Office is a prerequisite to the approval of the

NDA for DEXTENZA, although the final decision as to the adequacy of our manufacturing processes is made by CDER, with input from the Office of Process and Facilities, as part of the NDA review process. We anticipate that the FDA will classify the resubmission of our NDA and determine whether a re-inspection is needed within 30 days of the NDA resubmission date. We expect that a decision by the FDA to conduct a re-inspection of our manufacturing facility would result in a classification of the resubmission to the NDA as a class 2, or major review, and would take up to six months to complete. If no re-inspection is needed, we expect the FDA to classify the NDA resubmission as a class 1, or minor review, and take up to two months to complete.

In March and April 2015, we reported topline results from two Phase 3 clinical trials of DEXTENZA for the treatment of post-surgical ocular inflammation and pain. The data from these two completed Phase 3 clinical trials and a prior Phase 2 clinical trial are being used to support our NDA for post-surgical ocular pain. In the first Phase 3 clinical trial, DEXTENZA met both primary efficacy endpoints, absence of pain in the study eye at day 8 and absence of inflammatory cells in the anterior chamber of the study eye at day 14, with statistical significance. In the second Phase 3 clinical trial, DEXTENZA 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 November 2016, we reported topline results from a third Phase 3 clinical trial of DEXTENZA for the treatment of post-surgical ocular inflammation and pain. In this third Phase 3 clinical trial, DEXTENZA met both primary efficacy endpoints, absence of pain at day 8 and absence of inflammatory cells at day 14, with statistical significance. See "— Recent Developments" below for more information regarding this third Phase 3 clinical trial. Subject to receiving approval for the pain indication pursuant to the initial NDA, we plan to submit an NDA supplement for DEXTENZA for the treatment of post-surgical ocular inflammation.

DEXTENZA is also in Phase 3 clinical development for the treatment of allergic conjunctivitis. We announced topline results of our first Phase 3 clinical trial for allergic conjunctivitis in October 2015 and in We announced topline results of our second Phase 3 clinical trial for this indication in June 2016. We met the primary efficacy endpoint for ocular itching in the first Phase 3 trial but did not meet the primary efficacy endpoint for conjunctival redness in this trial. We did not meet the sole primary endpoint for ocular itching in the second Phase 3 trial. Certain post-hoc analyses of the second Phase 3 trial for DEXTENZA for the treatment of allergic conjunctivitis have led us to believe that a placebo insert which is present through the timepoints chosen as the primary efficacy endpoints may enhance the performance of the placebo. As such, we believe a fast-resorbing placebo insert may lessen the placebo response we observed in the completed Phase 3 trial. Although post-hoc analyses performed using an unlocked clinical trial database can result in the introduction of bias, we believe that these analyses provide important information regarding DEXTENZA. We have completed the design of a fast-resorbing placebo insert and plan to conduct a non-significant risk study in humans in the first half of 2017 with a clinical research organization comparing this insert to the longer resorbing insert used in our DEXTENZA trials. Depending on the results of this study, we may incorporate a longer resorbing insert into the placebo arm of a future Phase 3 clinical trial. In the second Phase 3 clinical trial, as well as other DEXTENZA clinical trials completed to date regardless of indication, DEXTENZA has exhibited a strong safety profile and has been generally well-tolerated. There were no serious adverse events observed in the second Phase 3 clinical trial.

Finally, DEXTENZA is in Phase 2 clinical development for the treatment of inflammatory dry eye disease. We announced topline results from an exploratory Phase 2 clinical trial for this indication in December 2015. We are assessing our plans for our dry eye program going forward and may focus future efforts on an intracanalicular insert containing an immunosuppressant drug.

If our NDA for DEXTENZA for the treatment of post-surgical ocular pain is approved by the FDA in the first half of 2017, we expect to commercially launch this product in the United States in the second half of 2017. We expect to sell DEXTENZA in the United States through a direct sales force, although we plan to use a contract sales organization, or CSO, to initially hire and deploy this sales force. We intend to prepare for the commercialization process by conducting surgical demonstrations to key surgeons and educating them on the potential benefits of DEXTENZA. We may also supplement the sales force with a co-promotional arrangement with another ophthalmology company with an existing sales force. We expect to apply for a transitional pass-through reimbursement status code from the Center for Medicare and Medicaid Services, or CMS, for DEXTENZA for the treatment of post-surgical ocular pain. We would expect pass-through reimbursement status to remain in effect for three years if we receive this status code. We expect to submit to the CMS for a J code for DEXTENZA for the treatment of other indications, including allergic conjunctivitis, if we receive marketing approval from the FDA for these indications.

OTX-TP

Our second product candidate, OTX-TP, incorporates travoprost, an FDA-approved prostaglandin analog that reduces elevated intraocular pressure, or IOP, as its active pharmaceutical ingredient, into a hydrogel-based drug-eluting intracanalicular insert. OTX-TP is being developed as a treatment for glaucoma and ocular hypertension. We reported topline results from a Phase 2b clinical trial for this indication in October 2015. We completed an End-of-Phase 2 review with the FDA in April 2016 and initiated the first of two Phase 3 clinical trials of OTX-TP in September 2016. We expect each of the two Phase 3 trials to enroll approximately 550 patients at 50 sites in the United States. Based on the feedback from the FDA, the Phase 3 clinical trial design will include an OTX-TP treatment arm and a placebo-controlled comparator arm that will use a non-drug eluting hydrogel-based intracanalicular insert. There will not be a requirement for either a timolol comparator or a validation arm. No eye drops, placebo or active, will be administered in either the OTX-TP treatment arm or the placebo-controlled arm. The primary efficacy endpoint will be superiority in the reduction of IOP from baseline in the OTX-TP treatment arm compared to the placebo arm at three diurnal time points at each of three measurement dates, including 2 weeks, 6 weeks and 12 weeks. We expect that the FDA will require that OTX-TP show both a statistically superior reduction of intraocular pressure, when compared to the placebo, as a primary efficacy endpoint, and a clinically meaningful reduction of intraocular pressure in the absolute prior to granting marketing approval.

Back-of-the-eye Program

In addition to DEXTENZA and OTX-TP, we are engaged in the preclinical development of our 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 extended-delivery hydrogel depot in combination with anti-angiogenic drugs, such as protein-based anti-VEGF drugs or small molecule anti-angiogenic drugs, such as tyrosine kinase inhibitors, or TKIs, for the treatment of retinal diseases such as wet AMD, retinal vein occlusion and diabetic macular edema. Our initial goal for this program is to provide extended delivery of a protein-based large molecule or small molecule TKI drug targeting VEGF over a four to six month period following administration of a bioresorbable hydrogel incorporating the drug by an injection into the vitreous humor, thereby reducing the frequency of the current monthly or bi-monthly intravitreal injection regimen for wet AMD and other retinal diseases.

Regeneron Collaboration

In October 2016, we entered into a strategic collaboration, option and license agreement, or Collaboration Agreement, with Regeneron, for the development and potential commercialization of products containing our extended-delivery hydrogel depot in combination with Regeneron's large molecule VEGF-targeting compounds for the treatment of retinal diseases, with the initial focus on the VEGF trap aflibercept, currently marketed under the brand name Eylea. The Collaboration Agreement does not cover the development of any products that deliver small molecule drugs, including TKIs, or deliver large molecule drugs other than those that target VEGF proteins. Under the terms of the Collaboration Agreement, we and Regeneron have agreed to conduct a joint research program with the aim of developing an extended delivery formulation of aflibercept that is suitable for advancement into clinical development. A joint research committee comprised of an equal number of representatives from each of Regeneron and us is responsible for reviewing, approving and overseeing the parties' research and development activities with respect to licensed product candidates and making any modifications to those activities. In general, Regeneron has final decision making authority over matters on which the joint research committee deadlocks, following escalation to designated executive officer representatives of the parties, except for matters that would impose a material increase in costs or obligations on us beyond those costs and obligations included in the mutually agreed collaboration plan. We granted Regeneron an option, or the Option, to enter into an exclusive, worldwide license under our intellectual property to develop and commercialize products containing our extended-delivery hydrogel depot in combination with Regeneron's large molecule VEGF-targeting compounds, or Licensed Products.

If the Option is exercised, Regeneron will conduct further preclinical development and an initial clinical trial under a collaboration plan. We are obligated to reimburse Regeneron for certain development costs during the period through the completion of the initial clinical trial, subject to a cap of $25 million, which cap may be increased

by up to $5 million under certain circumstances. Regeneron will be responsible for funding an initial preclinical tolerability study. We do not expect our funding requirements to be material over the next twelve months. If Regeneron elects to proceed with further development beyond the initial clinical trial, it will be solely responsible for conducting and funding further development and commercialization of product candidates. If the Option is exercised, Regeneron is required to use commercially reasonable efforts to research, develop and commercialize at least one Licensed Product. Such efforts shall include initiating the dosing phase of a subsequent clinical trial within specified time periods following the completion of the first-in-human clinical trial or the initiation of preclinical toxicology studies, subject to certain extensions.

Under the terms of the Collaboration Agreement, Regeneron has agreed to pay us $10 million upon exercise of the Option. We are also eligible to receive up to $145 million per Licensed Product upon the achievement of specified development and regulatory milestones, $100 million per Licensed Product upon first commercial sale of such Licensed Product and up to $50 million based on the achievement of specified sales milestones for all Licensed Products. In addition, we are entitled to tiered, escalating royalties, in a range from a high-single digit to a low-to-mid teen percentage of net sales of Licensed Products.

ReSure

Following our receipt of FDA approval for ReSure Sealant, we commercially launched this product in the United States in 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.

Market Background

Our clinical stage product candidates and our marketed product are based on a proprietary bioresorbable hydrogel technology platform that uses polyethylene glycol, or 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 the needs of specific clinical indications. We have used this platform to engineer each of our intracanalicular insert product candidates, ReSure Sealant and our intravitreal 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 high purity product.

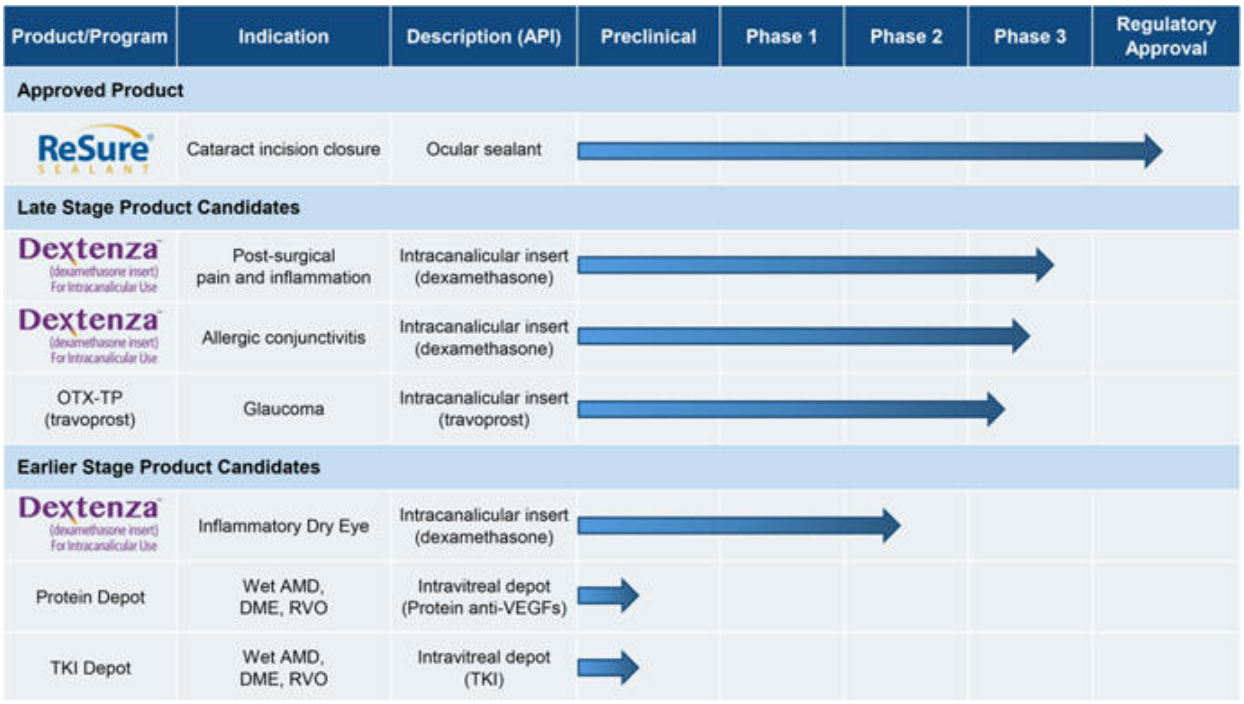
Our product candidates target large and growing markets. Transparency Market Research, a provider of business information reports and services, estimates that the annual worldwide market for ophthalmic medications was $16 billion as of 2012 and is expected to increase to $21.6 billion by 2018.

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.

Product Pipeline

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.



Recent Developments

In November 2016, we reported topline results from a third Phase 3 clinical trial of DEXTENZA for the treatment of post-surgical ocular inflammation and pain. This third Phase 3 clinical trial was a prospective, randomized, parallel-arm, vehicle-controlled, multicenter, double-masked trial. We enrolled 438 patients in this trial who were undergoing clear corneal cataract surgery at 21 sites in the United States. Immediately following surgery, patients were randomized in a 1:1 ratio to receive either DEXTENZA or a placebo vehicle control intracanalicular insert without active drug. We evaluated patients at days 2, 4, 8, 14, 30 and 45. As in the first two Phase 3 clinical trials, the two primary efficacy measures in the third Phase 3 clinical trial 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 endpoint for absence of inflammatory cells, there needed to be a complete absence of inflammatory cells. 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 inflammatory cells in the anterior chamber of the study eye at day 14. 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. For clarification of the endpoints, the day of surgery and insertion of DEXTENZA or the placebo is considered to be day 1.

We evaluated as secondary efficacy measures the 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 also the level of flare in the anterior chamber of the study eye. The secondary analyses on primary efficacy measures were intended to be exploratory assessments that can be used to support the results from the primary endpoints.

In this trial, DEXTENZA successfully met its two primary efficacy endpoints for inflammation and pain, achieving statistically significant differences between the treatment group and the placebo group for the absence of inflammatory cells on day 14 and the absence of pain on day 8, respectively. Of patients treated with DEXTENZA, 52.3% showed an absence of inflammatory cells in the anterior chamber of the study eye on day 14, compared to 31.1% of those receiving the placebo vehicle control intracanalicular inserts ($p< 0.0001$). Of patients treated with

DEXTENZA, 79.6% reported absence of pain in the study eye on day 8, compared to 61.3% of those receiving the placebo vehicle control intracanalicular inserts ($p < 0.0001$). Secondary analyses on the primary efficacy measures have also been completed. DEXTENZA achieved each of the secondary endpoints related to absence of inflammatory cells and absence of pain with statistical significance compared to placebo at each of the pre-specified timepoints, with the exception of the endpoint for the absence of inflammatory cells at day 2 (which is the day following surgery). Additional secondary endpoints including flare, as well as an assessment of all safety data, continue to be evaluated.

There were no serious adverse events observed in this Phase 3 clinical trial that were considered treatment-related by the trial investigator. There were three patients that experienced a serious adverse event in the DEXTENZA treatment group (1.4% incidence), consisting of lower gastrointestinal hemorrhage, retinal detachment and acute cardiac failure. There were two patients that experienced a serious adverse event in the vehicle control group (0.9% incidence), consisting of nephrolithiasis and hypoxia. No patients experienced a treatment-emergent adverse event leading to withdrawal from the trial. There were 63 adverse events noted in the DEXTENZA group and 86 adverse events noted in the vehicle control group. The most common ocular treatment-emergent adverse events consisted of eye inflammation and increased ocular pressure (defined as an increase greater than 10mm Hg). There were 18 patients (8.3% incidence) in the DEXTENZA group and 45 patients (20.4% incidence) in the vehicle control group with eye inflammation. There were 16 patients (7.4% incidence) in the DEXTENZA group and 6 patients (2.7% incidence) in the vehicle control group with increased intraocular pressure. All of the patients in the DEXTENZA group who experienced increased intraocular pressure had an onset at day 2, which is believed to be related to the surgical procedure, and only two patients in the DEXTENZA group experienced persistent increased intraocular pressure greater than 10mm Hg beyond day 2.

RISK FACTORS

Ocular Therapeutix, Inc. ("we", "us", or "our") is filing information for the purposes of updating and superseding the risk factor disclosure contained in its prior public filings, including those previously set forth in Part II, Item IA, "Risk Factors" of its Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission (the "SEC") on March 10, 2016, and its Quarterly Report on Form 10-Q for the period ended September 30, 2015, filed with the SEC on November 9, 2016.

You should carefully consider the following risk factors, in addition to other information included in our other filings with the SEC, in evaluating us and our business. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

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 losses were $28.6 million for the year ended December 31, 2014, $39.7 million for the year ended December 31, 2015 and $31.9 million for the nine months ended September 30, 2016. As of September 30, 2016, we had an accumulated deficit of $161.1 million. Through September 30, 2016, we have financed our operations primarily through private placements of our preferred stock, public offerings of our common stock and borrowings under credit facilities. In June 2015, we completed a follow-on offering of our common stock, which resulted in the sale of 4,600,000 shares consisting of 3,200,000 shares being sold by us and 1,400,000 shares being sold by certain stockholders of the Company, including those shares sold in connection with the exercise by the underwriters of their option to purchase additional shares. We received net proceeds from the follow-on offering of approximately $65.6 million 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 seal 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 intracanalicular depot product candidates, DEXTENZA and OTX-TP;
- conduct joint research and development under the strategic collaboration we entered into recently with Regeneron Pharmaceuticals, Inc., or Regeneron, for the development and potential commercialization of products containing our extended-delivery hydrogel depot in combination with Regeneron's large molecule vascular endothelial growth factor, or VEGF, targeting compounds to treat retinal diseases;
- continue the research and development of our other product candidates;
- seek to identify and develop additional product candidates, including through preclinical development activities associated with our back-of-the-eye program;
- seek marketing approvals for any of our product candidates that successfully complete clinical development;
- develop and expand our sales, marketing and distribution capabilities for any of our product candidates, including potentially DEXTENZA, for which we may obtain marketing approval;

- scale up our manufacturing processes and capabilities to support sales of commercial products, our ongoing clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval, and expand our facilities to accommodate this scale up and the expected growth in personnel;
- renovate our new facility, including research and development laboratories, manufacturing space and office space, which we estimate will have a total cost to us of between $4.0 million and $5.0 million, net of a landlord provided construction allowance of up to $2.8 million, plus the expected purchase of $2.0 to $2.5 million in manufacturing and research and development capital equipment for our new facility;
- 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
- continue to 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 or our current or future collaborators 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. In July 2016, we received a Complete Response Letter, or CRL, from the FDA regarding our new drug application, or NDA, for DEXTENZA for the treatment of post-surgical ocular pain. In the CRL, the concerns raised by the FDA pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of our manufacturing facility performed by the FDA New England District Office, or the District Office, in February 2016 that were documented on FDA Form 483. In November 2016, we received notice from the District Office accepting that our responses satisfactorily addressed the remaining corrective actions in the Form 483. Since receiving the CRL, we have also had ongoing communications with the FDA, including the New England District Office and offices within the Center for Drug Evaluation and Research, or CDER, including the Office of Process and Facilities, with regard to the manufacturing issues and our plan for a resubmission of our NDA. In October 2016, we met with the FDA to discuss plans for resubmission to the NDA and to attempt to gain clarity on the likelihood of a re-inspection of our manufacturing facility. The FDA indicated that a decision as to

whether a re-inspection is needed will be made during its review of our resubmission. We anticipate the resubmission to the NDA in December 2016 and plan to include the letter from the District Office accepting that our responses satisfactorily addressed the remaining corrective actions in the Form 483 in our resubmission. Adequate resolution of the Form 483 manufacturing deficiencies with the District Office is a prerequisite to the approval of the NDA for DEXTENZA, although the final decision as to the adequacy of our manufacturing processes is made by CDER, with input from the Office of Process and Facilities, as part of the NDA review process. We anticipate that the FDA will classify the resubmission of our NDA and determine whether a re-inspection is needed within 30 days of the NDA resubmission date. We expect that a decision by the FDA to conduct a re-inspection of our manufacturing facility would result in a classification of the resubmission to the NDA as a class 2, or major review, and would take up to six months to complete. If no re-inspection is needed, we expect the FDA to classify the NDA resubmission as a class 1, or minor review, and take up to two months to complete. While the FDA has indicated to us it intends to classify the resubmission to the NDA as a class 1 or class 2 resubmission, it is not required to use such classifications for our resubmission and it is possible that review by the FDA could take as long as our initial NDA review cycle of 10 months, or longer if additional issues are identified. We will need to resolve the issues in the CRL and obtain approval upon resubmission of our NDA before we can commercialize and begin to generate revenue from sales of DEXTENZA.

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

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct late stage clinical trials for our extended-delivery drug delivery product candidates, in particular DEXTENZA 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 any of our product candidates, including DEXTENZA, for which we may obtain marketing approval. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

As of September 30, 2016, we had cash and cash equivalents and marketable securities of $75.7 million. Based on our current plans and forecasted expenses, we believe that our existing cash and cash equivalents and marketable securities will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements into the fourth 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 costs of expanding our facilities to accommodate our manufacturing needs and expected growth in personnel;
- the progress, costs and outcome of the clinical trials of our extended-delivery drug delivery product candidates, in particular DEXTENZA and OTX-TP;
- the progress and status of our collaboration with Regeneron, including any development costs for which we reimburse Regeneron, the potential exercise by Regeneron of its option for a license for the

development and potential commercialization of products containing our extended-delivery hydrogel depot in combination with Regeneron's large molecule VEGF-targeting compounds, and our potential receipt of future milestone payments from Regeneron;

- the costs of advancing our internal development efforts for the back-of-the-eye program through the remaining preclinical steps and potentially into an initial clinical trial;
- 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, including our current NDA for DEXTENZA;
- the amounts we receive, if any, from Regeneron for option exercise, development, regulatory and sales milestones and royalty payments under our collaboration;
- the extent to which we choose to establish additional 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 significant revenue from sales of any product for several years, if at all. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

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

Until such time, if ever, as we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through a combination of revenue from sales of ReSure Sealant and potential payments under our collaboration with Regeneron, equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. We do not have any committed external source of funds other than the amounts we are entitled to receive from Regeneron for potential option exercise, development, regulatory and sales milestones and royalty payments under our collaboration. 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, or SVB and MidCap Financial SBIC, LP, or MidCap. In December 2015, we amended this facility to

increase the aggregate principal amount to $15.6 million and extend both the interest-only payment period and the maturity date. Our obligations under this facility 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 facility. 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 and 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 and cash equivalents and marketable securities and potential payments under our collaboration with Regeneron 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.

We have broad discretion in the use of our available cash and other sources of funding and may not use them effectively.

Our management has broad discretion in the use of our available cash and other sources of funding and could spend those resources 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 our available cash in a manner that does not produce income or that loses value.

Risks Related to Product Development

We depend heavily on the success of our intracanalicular insert and other product candidates, in particular DEXTENZA 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 drug-eluting intracanalicular insert product candidates for diseases and conditions of the front of the eye. In particular, we are investing substantial resources to complete the development of DEXTENZA for post-surgical ocular inflammation and pain, allergic conjunctivitis and inflammatory dry eye disease and OTX-TP for glaucoma and ocular hypertension. We cannot accurately predict when or if any of our 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 DEXTENZA and OTX-TP.

The commercial success of our intracanalicular insert 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 and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- partnering successfully with our current and future collaborators, including Regeneron;
- gaining 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.

In certain cases, such as in our collaboration with Regeneron, many of these factors may be beyond our control, including clinical development and sales, marketing and distribution efforts. If we or our collaborators 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 intracanalicular insert 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 intracanalicular insert 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 DEXTENZA that we completed in 2013 in which we were evaluating DEXTENZA for post-surgical ocular inflammation and pain, DEXTENZA 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 completed Phase 3 clinical trials of DEXTENZA at day 14. In the first and third Phase 3 clinical trials, DEXTENZA met both primary endpoints for post-surgical ocular inflammation and pain with statistical significance. However, in the second Phase 3 clinical trial, DEXTENZA met only one of the two primary efficacy endpoints with statistical significance. In this second trial, DEXTENZA 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 DEXTENZA did not meet the first primary endpoint with statistical significance. The FDA has informed us that the hierarchy of the two primary endpoints for post-surgical ocular inflammation and pain is applicable in connection with their review of our NDA seeking approval for DEXTENZA for an ocular pain indication. However, the FDA has also informed us that pain endpoints from the Phase 2 and first two Phase 3 trials, with respect to which we received favorable data, would support the NDA submission. Therefore, in September 2015, we submitted to the FDA an NDA for DEXTENZA for an ocular pain indication using the existing data from our completed Phase 2 and first two 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. In July 2016, we received a CRL from the FDA regarding our NDA for DEXTENZA. In the CRL, the concerns raised by the FDA pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of our manufacturing facility. When we submit our response regarding these deficiencies, we will also need to furnish to the FDA a safety update regarding all completed trials of DEXTENZA, regardless of indication, dosage form or dose level.

We announced topline results from a third Phase 3 clinical trial of DEXTENZA for post-surgical ocular inflammation and pain in November 2016, which we plan to use to support the potential labeling expansion of DEXTENZA's indications for use to include inflammation. We modified the design of this third Phase 3 clinical trial compared to our first two Phase 3 clinical trials of DEXTENZA based on our learnings from these prior trials. In this trial, DEXTENZA successfully met its two primary efficacy endpoints for inflammation and pain, achieving statistically significant differences between the treatment group and the placebo group for the absence of inflammatory cells on day 14 and the absence of pain on day 8, respectively. Secondary analyses on the primary efficacy measures have also been completed. DEXTENZA achieved each of the secondary endpoints related to absence of inflammatory cells and absence of pain with statistical significance compared to placebo at each of the pre-specified timepoints, with the exception of the endpoint for the absence of inflammatory cells at day 2 (which is the day following surgery). Additional secondary endpoints including flare, as well as an assessment of all safety data, continue to be evaluated. Based on the results of our third Phase 3 clinical trial of DEXTENZA, and subject to receiving approval for the pain indication pursuant to the initial NDA, we plan to submit an NDA supplement for DEXTENZA for the treatment of post-surgical ocular inflammation. Although we believe our planned approach for seeking marketing approval of DEXTENZA is supported by our discussions with the FDA and by the absence of

any efficacy or safety concerns identified by the FDA in the CRL with respect to the clinical data provided in the NDA, the FDA could nonetheless not grant marketing approval of DEXTENZA for the pain indication until we obtain complete results from the third Phase 3 clinical trial, or at all.

In our first Phase 3 clinical trial of DEXTENZA for allergic conjunctivitis, DEXTENZA met one of the two primary endpoints. DEXTENZA achieved the primary endpoint for ocular itching associated with allergic conjunctivitis but not the primary endpoint for conjunctival redness, in each case measured on day 7 after insertion of the depot. The difference in the mean scores for ocular itching between the DEXTENZA group and the placebo group was greater than 0.5 units on a five point scale at all time points on day 7 post-insertion and was greater than 1.0 unit at a majority of the time points on day 7 post-insertion. The DEXTENZA group did not achieve these pre-specified endpoints on day 7 post-insertion with respect to conjunctival redness. In our second Phase 3 clinical trial of DEXTENZA for allergic conjunctivitis, DEXTENZA did not meet the sole primary endpoint for ocular itching. The single primary endpoint of the second Phase 3 clinical trial was the difference in the mean scores in ocular itching between the treatment group and the placebo comparator group at three time points on day 7 following insertion of the depots. While mean ocular itching was seen to be numerically lower (more favorable) in the DEXTENZA treatment group compared to the placebo group measured at each of the three specified times on day 7 following insertion of the depots, at 3, 5, and 7 minutes by -0.18, -0.29, and -0.29 units, respectively, on a five point scale, this difference did not reach statistical significance. In addition, the trial did not achieve the requirement of at least a 0.5 unit difference at all three time points on day 7 following insertion of the depots and at least a 1.0 unit difference at the majority of the three time points between the treatment group and the placebo group on day 7 following insertion of the depots. Further, in our prior Phase 2 clinical trial of DEXTENZA in which we were evaluating DEXTENZA for allergic conjunctivitis, DEXTENZA met one of the two primary efficacy measures. The DEXTENZA 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 DEXTENZA 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. Even if we obtain favorable clinical trial results in any additional Phase 3 clinical trials of DEXTENZA for allergic conjunctivitis, including meeting all primary efficacy measures, we may not obtain approval for DEXTENZA to treat allergic conjunctivitis or ocular itching associated with allergic conjunctivitis, or the FDA may require that we conduct additional clinical trials. Post-hoc analyses that we performed on the results of our completed Phase 3 clinical trials for allergic conjunctivitis may not be predictive of success in any future Phase 3 clinical trial. Although we believe that these analyses provide important information regarding DEXTENZA and are helpful in understanding the results of this trial and determining the appropriate criteria for future clinical trials, post-hoc analyses performed using an unlocked clinical trial database can result in the introduction of bias and are given less weight by regulatory authorities than pre-specified analyses.

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 reported topline efficacy results from our Phase 2b clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension in October 2015. In this trial, on day 60 at the 8:00 a.m. time point, the OTX-TP group experienced a mean intraocular pressure lowering effect of 4.7 mmHg, compared with intraocular pressure lowering of 6.4 mmHg for the timolol arm. On day 90 at the 8:00 a.m. time point, the OTX-TP group experienced an intraocular pressure lowering effect of 5.1 mmHg, compared with an intraocular pressure lowering effect of 7.2 mmHg in the timolol arm. Also in this trial, on day 60, the OTX-TP group experienced a mean diurnal intraocular pressure lowering effect of 3.3 mmHg compared to baseline 5.9 mmHg compared for the timolol group. On day 90, the OTX-TP group experienced a mean diurnal intraocular pressure, or IOP, lowering effect of 3.6 mmHg compared to baseline, versus 6.3 mmHg for the timolol group. We expect that our planned Phase 3 clinical trials for OTX-TP, one of which we initiated during the third quarter of 2016, will be powered with an appropriate number of patients to measure with statistical significance the superiority of OTX-TP as compared to a placebo vehicle intracanalicular insert in the reduction of mean IOP from baseline at all of the nine diurnal time points at week 2, week 6 and week 12 visits. The trial design will not have eye drops, placebo or active, administered in either the treatment or the placebo-controlled arm. However, 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, including as a result of differences in trial design. If we do not achieve our primary endpoint in the Phase 3 clinical trials with statistical significance, we may not obtain marketing approval for OTX-TP.

In addition, post-hoc analyses that we performed on the results of our completed Phase 2b clinical trial may not be predictive of success in our planned Phase 3 clinical trials. Post-hoc analyses performed using an unlocked clinical trial database can result in the introduction of bias and are given less weight by regulatory authorities than pre-specified analyses.

The success of our intracanalicular insert product candidates is dependent upon retention following insertion and during the course of intended therapy. As such, we continue to conduct non-significant risk Investigational Device Exemption, or IDE, medical device, or NSR, studies in the United States for our intracanalicular insert in an effort to increase the rate of retention. All NSR studies that we have performed to date have involved placebo vehicle control intracanalicular inserts without active drug. If we determine to make any future changes to the design or composition of our depots, such changes could affect the outcome of any subsequent clinical trials using these updated depots. For example, in our Phase 2b clinical trial of OTX-TP, we used a different version of intracanalicular insert than either of the inserts 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 the OTX-TP depot, that was 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 depot used in the Phase 2a clinical trial. To achieve this, we modified the design of the OTX-TP depot to enlarge it in order to enable the depot to carry a greater amount of drug. In addition, we incorporated minor structural changes to improve retention rates. In our Phase 2b clinical trials, OTX-TP depots could be visualized in approximately 88% of eyes by the day 60 visit. By the day 90 visit, the ability to visualize OTX-TP had declined to approximately 42% of eyes as the hydrogel softened, liquefied and had either advanced further down in the canaliculus or had cleared through the nasolacrimal duct. We are conducting additional NSR studies on additional modified depot designs, including a polyethylene glycol, or PEG, tip on the proximal end of the depot that have been incorporated into the design of the Phase 3 trials of OTX-TP. If in our Phase 3 clinical trials the retention rates for our depots 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 extended-delivery drug delivery products.

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 intracanalicular insert 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 intracanalicular insert 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. 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 intracanalicular insert product candidates, outside the United States. We generally plan to conduct our later stage and pivotal clinical trials of our intracanalicular insert 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 would 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 extended-delivery drug delivery 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 DEXTENZA for the treatment of post-surgical ocular inflammation and pain 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 DEXTENZA 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 extended-delivery drug delivery 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.

Each of our two Phase 3 clinical trials of OTX-TP are expected to enroll an aggregate of approximately 550 patients at 50 sites in the United States and will be the largest clinical trials we will have conducted to date. Patients randomized into the placebo control arm will not receive any glaucoma medications during the course of the trials. Our inability to enroll a sufficient number of patients in the Phase 3 clinical trials or any of our other 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 extended-delivery drug delivery 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 extended-delivery drug delivery 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 each of our first two Phase 3 clinical trials of DEXTENZA for the treatment of post-surgical ocular inflammation and pain, there were two subjects that experienced serious adverse events in the DEXTENZA group, none of which were ocular in nature or considered by the investigator to be related to the study treatment. In our third Phase 3 clinical trial of DEXTENZA for the

treatment of post-surgical ocular inflammation and pain, there were three subjects that experienced serious adverse events in the DEXTENZA group, one of which was ocular in nature and none of which were 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 three completed Phase 3 clinical trials, which was hypopyon, or inflammatory cells in the anterior chamber. In our earlier Phase 2 clinical trial of DEXTENZA 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 DEXTENZA group of this Phase 2 clinical trial of DEXTENZA, the only adverse event that occurred more than once for the same subject was reduced visual acuity, which occurred twice but these were not considered by the investigator to be related to the study treatment.

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 of the eyelids and ocular surface, which was noted in three patients in our pilot studies and in five patients in our Phase 2a clinical trial. No hyperemia-related adverse events were noted in any of the patients treated with OTX-TP in our Phase 2b clinical trial. There were no serious adverse events reported in our Phase 2b clinical trial; however two OTX-TP subjects and two timolol subjects discontinued study participation due to ocular adverse events. Ocular adverse events were reported for 39.4% and 37.5% of subjects in the OTX-TP and timolol groups, respectively. The most frequently reported ocular adverse events were dacryocanaliculitis, or inflammation of the lacrimal ducts, acquired dacryostenosis, or closing of the tear ducts, and eyelid oedema. In the Phase 2b clinical trial, inflammatory reaction at the administration site (punctal area) and lacrimal structure injury were each noted in one OTX-TP subject as compared to higher percentages in prior trials. In the Phase 2b trial, the majority of ocular adverse events, including the most frequently reported adverse events, were assessed by the investigators as treatment related. 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.

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 extended 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 platform for other front-of-the-eye diseases and conditions. We are also developing a hydrogel-based drug delivery depot designed to release therapeutic antibodies and small molecules such as tyrosine kinase inhibitors, or TKIs, to modulate the biologic activity of 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. In October 2016, we entered into a collaboration with Regeneron for the development and potential commercialization of products containing our extended-delivery hydrogel depot in combination with Regeneron’s large molecule VEGF-targeting compounds for the treatment of retinal diseases. Our existing product candidates and any other potential product candidates that we or our collaborators 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 or our current or future collaborators develop based upon our technological approach, we will not be able to obtain substantial product revenues or revenue from collaboration agreements, including our collaboration with Regeneron, 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 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 an inspection by the FDA in March 2015, for example, we received an FDA Form 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 submitted our response, which was accepted by the FDA, and updated our procedures. In addition, in February 2016, as part of the ongoing review of our NDA for DEXTENZA, the FDA conducted a pre-NDA approval inspection of our manufacturing operations. As a result of this inspection, we received an FDA Form 483 containing inspectional observations focused on process controls, analytical testing and physical security procedures related to manufacture of our drug product for stability and commercial production purposes. We addressed some observations before the inspection was closed and responded to the FDA with a corrective action plan to complete the inspection process. In July 2016, we received a CRL from the FDA regarding our NDA for DEXTENZA. The concerns raised in the CRL pertain to the deficiencies in manufacturing processes raised in the February Form 483 letter. In November 2016, we received notice from the District Office accepting that our responses satisfactorily addressed the remaining corrective actions in the Form 483. In October 2016, we met with the FDA to discuss plans for resubmission to the NDA and to attempt to gain clarity on the likelihood of a re-inspection of our manufacturing facility. The FDA indicated that a decision as to whether a re-inspection is needed will be made during its review of our resubmission. We anticipate the resubmission to the NDA in December 2016 and plan to include the letter from the District Office accepting that our responses satisfactorily addressed the remaining corrective actions in to the Form 483 in our resubmission. Adequate resolution of the Form 483 manufacturing deficiencies with the District Office is a prerequisite to the approval of the NDA for DEXTENZA, although the final decision as to the adequacy of our manufacturing processes is made by CDER, with input from the Office of Process and Facilities, as part of the NDA review process. We anticipate that the FDA will classify the resubmission and determine whether a re-inspection is needed within 30 days of the NDA resubmission date. The satisfactory resolution of the manufacturing deficiencies raised in the CRL and passing any required re-inspection of our manufacturing facility is required before our NDA for DEXTENZA for the treatment of post-surgical ocular pain can be approved.

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 $7.7 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, 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 intracanalicular insert retention rate for our intracanalicular insert 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 have not conducted any clinical trials to date comparing the effectiveness of DEXTENZA directly to currently approved alternative treatments for either post-surgical ocular inflammation and pain or allergic conjunctivitis, it is possible that the market acceptance of DEXTENZA, if it is approved for marketing, could be less than if we had conducted such trials. Although market research we have commissioned indicates that a majority of ophthalmologists believe DEXTENZA could become a new standard of care due to its potential ability to improve compliance with limited toxicity concerns, market acceptance for DEXTENZA could be substantially less than such research indicates, and we may not be able to achieve the market share we anticipate.

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 may determine to build a direct sales force to sell DEXTENZA, if approved for marketing, and may initially use a contract sales organization to staff a dedicated team of sales representatives. We may also consider co-promotional arrangements with larger ophthalmology companies. We expect that a direct sales force will be required to effectively market and sell OTX-TP, if approved for marketing. We will also rely on Regeneron to commercialize our extended-delivery hydrogel depot in combination with Regeneron's large molecule VEGF-targeting compounds. 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, including our collaboration with Regeneron, 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 or intravitreal injections.

Because the active pharmaceutical ingredients in our product candidates, other than those developed under the Regeneron collaboration, 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 intracanalicular insert product candidates largely relate to the hydrogel composition of the intracanalicular inserts and certain drug-release features of the depots. 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, extended-delivery product candidates that could compete with our intracanalicular insert 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, including our collaborator Regeneron, are exploring in early stage development alternative means to deliver anti-VEGF and TKI products in an extended-delivery 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 DEXTENZA 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 intra-operative product. If DEXTENZA is categorized as an intra-operative product, it will not be subject to separate reimbursement, which could likewise limit its market acceptance.

We expect to apply for a transitional pass-through reimbursement status from the Centers for Medicare and Medicaid Services, or CMS, for DEXTENZA for the treatment of post-surgical ocular pain, subject to the approval of the NDA resubmission we expect to file with the FDA for this indication. We expect pass-through status would remain in effect for up to three years depending on when we apply for and receive this reimbursement status. We expect to submit to the CMS for a standard J code for DEXTENZA for the treatment of other indications, including allergic conjunctivitis, as well as for our OTX-TP product candidate, if our clinical trials are successful and if our NDA filings and NDA supplements are approved by the FDA. There are no assurances that we will be successful in obtaining and retaining reimbursement for our product candidate.

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 $10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $10.0 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

We will depend heavily on our collaboration with Regeneron for the success of our extended-delivery hydrogel depot in combination with Regeneron's large molecule VEGF-targeting compounds. If Regeneron does not exercise its option, terminates our collaboration agreement or is unable to meet its contractual obligations, it could negatively impact our business.

In October 2016, we entered into a strategic collaboration, option and license agreement, or Collaboration Agreement, with Regeneron for the development and potential commercialization of products containing our extended-delivery hydrogel depot in combination with Regeneron's large molecule VEGF-targeting compounds. Our ability to generate revenues from the Collaboration Agreement will depend on our and Regeneron's abilities to successfully perform the functions assigned to each of us under the Collaboration Agreement. We did not receive any upfront payment under the Collaboration Agreement, although Regeneron has an option to enter into an exclusive, worldwide license, with the right to sublicense, under our intellectual property to develop and commercialize products containing our extended-delivery hydrogel depot in combination with Regeneron's large molecule VEGF-targeting compounds. Regeneron has agreed to pay us $10 million upon exercise of the option. The option is exclusive until 12 months after Regeneron has received a product candidate in accordance with a collaboration plan and non-exclusive for an additional six months following the end of the exclusive period. Under the Collaboration Agreement, we are obligated to reimburse Regeneron for certain development costs incurred by Regeneron under the collaboration plan during the period through the completion of the initial clinical trial, subject to a cap of $25 million, which cap may be increased by up to $5 million under certain circumstances. We are also entitled to receive under the terms of the Collaboration Agreement specified development, regulatory and sales milestone payments, as well as royalty payments.

If Regeneron has not exercised the option during the designated option period, the Collaboration Agreement will expire. If Regeneron exercises the option, the Collaboration Agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of the later of 10 years from the date of first commercial sale in such country or the expiration of all patent rights covering the licensed product in such country. The Collaboration Agreement may be terminated by Regeneron at any time after exercise of the option upon 60 days' prior written notice. Either party may, subject to a cure period, terminate the Collaboration Agreement in the event of the other party's uncured material breach, in addition to other specified termination rights.

If we are unable to achieve the preclinical milestones set forth in the collaboration plan, Regeneron may not exercise the option, in which case we would not receive the $10 million payment in connection with such option and would have incurred significant development expenses. Even if Regeneron does exercise its option, we or Regeneron may not be successful in achieving the necessary preclinical, clinical, regulatory and sales milestones in connection with the collaboration. Further, if Regeneron were to breach or terminate the Collaboration Agreement or if Regeneron elects not to exercise the option we granted it and not to proceed in the collaboration, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our intravitreal depot product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our intravitreal depot product candidates. We may not be able to seek and obtain a viable, alternative collaborator to partner for the development and commercialization of the licensed products on similar terms or at all.

We have entered into collaborations with third parties to develop certain product candidates, and in the future 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 have in the past entered into collaboration agreements with third parties, including our collaboration with Regeneron, and 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 additional 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, and our collaboration with Regeneron, 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.

Our collaboration with Regeneron poses, and any future collaborations likely will 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 "Risk Factors" section 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 other 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 conducting preclinical testing of protein-based anti-VEGF compounds in collaboration with several pharmaceutical companies to explore the feasibility of delivering their drugs using our intravitreal depot. We are exploring broader collaborations for the development and potential commercialization of our intravitreal depot technology in combination with protein-based anti-VEGF drugs 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.

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 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.

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 and intend to distribute through qualified independent distributors.

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 DEXTENZA for the treatment of post-surgical ocular inflammation and pain. 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 our product candidates, including OTX-TP for the treatment of glaucoma and ocular hypertension. 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. For example, Integra LifeSciences Holdings Corporation, another licensee of Incept, has filed suit against HyperBranch Medical Technology, Inc. alleging infringement of several patents which we also license. This enforcement action could result in one or more of these patents being invalidated or rendered unenforceable. 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, 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 four issued patents outside of the United States for two of our three intracanalicular insert product candidates, and two of these expire by 2019. We have two licensed patent families in Europe and certain other parts of the world for our intravitreal drug delivery product candidates, but only one patent issuance, to date, outside of the United States. 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 intracanalicular inserts and the drug-release design scheme of our depots. 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 expired in approximately December 2015 and which have claims that ReSure Sealant could be considered as having infringed. 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 and other substantial performance obligations on us. 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 and Marketing of Our Product Candidates and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we or any current or future collaborator of ours is not able to obtain, or if there are delays in obtaining, required regulatory approvals, we or they will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

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.

As part of the ongoing review of the NDA for DEXTENZA for post-surgical ocular pain, the FDA has completed inspections of three sites from our two completed Phase 3 clinical trials for compliance with the study protocol and Good Clinical Practices. During the first of these inspections, the FDA identified storage temperature excursions for the investigational product that is labeled to be stored in a refrigerated condition between two degrees and eight degrees Celsius. We also had previously addressed a minor temperature deviation report during the conduct of the Phase 3 trials and communicated a response to the trial sites. In addition, while investigating the report stemming from the FDA inspection, several more noteworthy temperature excursions were found to have occurred that had not been fully reported. Because of the limited nature of the temperature excursions and historical product testing, including testing on product stored at elevated temperatures, we believe it is unlikely that drug product performance was significantly impacted. We have also implemented a corrective action plan to address clinical compliance and prevent recurrence in other clinical studies. However, if the FDA determines as part of its review of our NDA that the temperature excursions and associated protocol deviations compromised any of the results from our completed Phase 3 clinical trials, the FDA may request additional site specific data analyses or even exclude certain study subjects from sites in which the temperature excursions were determined to be significant in duration before considering approval of the NDA.

Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA, the EMA and regulatory authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition,

varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we or any current or future collaborator of ours ultimately obtains may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Accordingly, if we or any current or future collaborator of ours experiences delays in obtaining approval or if we or they fail to obtain approval of our product candidates, 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 foreign 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.

Even if we, or any current or future collaborators, obtain marketing approvals for our product candidates, 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 current or future collaborators, 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 for ReSure Sealant. The first post-approval study, identified as the Clinical PAS, was 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. We submitted the final study report of the Clinical PAS to the FDA in June 2016 and the FDA has confirmed the Clinical PAS has been completed. 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 ReSure Sealant. In December 2015, the CMS denied our application for a tracking or research code for ReSure Sealant commercial use. In cooperation with the FDA, we have identified another option for conducting this registry study while maintaining the objective for linking ReSure Sealant use to the Medicare database through a partnership with a third party. In July 2016, the FDA approved the Device Exposure Registry protocol, which should allow us to complete the study in one to two years. We are required to provide periodic reports to the FDA on the progress of this post-approval study until it is completed. Following review of the results from these post-approval studies, or if we are unable to complete the Device Exposure Registry, 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, 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 current or 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.

Accordingly, assuming we, or any current or future collaborators, receive marketing approval for one or more of our product candidates, we, and any current or future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and any current or future collaborators, are not able to comply with post-approval regulatory requirements, we, and any current or future collaborators, could have the marketing approvals for our products withdrawn by regulatory authorities and our, or any current or future collaborators', ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

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 FDCA relating to the promotion or manufacturing of drug products or medical devices may lead to investigations by the FDA, Department of Justice, or DOJ, and state Attorneys General alleging violations of the FDCA, 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 of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled 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;
- injunctions or the imposition of civil or criminal penalties;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation; or
- litigation involving patients using our products.

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. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our relationships with healthcare providers, physicians and third-party payors will be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, in the event of a violation, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription and use of ReSure Sealant and any other product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians and third-party payors 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. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal 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, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim;
- 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 Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals, with data collection beginning in August 2013; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, 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 and may require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare 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.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines

and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our financial results. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell any future products that we successfully develop from our product candidates in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will 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, damages, fines, imprisonment, exclusion of products from 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, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Current and future legislation may increase the difficulty and cost for us and any current or future collaborators to obtain marketing approval of our other product candidates and affect the prices we, or they, may obtain.

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, among other things, prevent or delay marketing approval of our other product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that 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, or any collaborators, may receive for any approved products.

For example, 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 the PPACA. Among the provisions of the PPACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient products to be covered under Medicare Part D;
- extension of manufacturers’ Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;

- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within the CMS to test innovative payment and service delivery models.

Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent legislation, will continue until 2025. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several 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 and otherwise affect the prices we may obtain for any of our product candidates for which regulatory approval is obtained.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Moreover, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any collaborators to more stringent product labeling and post-marketing testing and other requirements.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, such as the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. 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, or any current or future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product 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 business could be materially harmed.

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.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health-care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we, our collaborators 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, our collaborators 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 current or future collaborators or 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. In June 2016, we entered into a lease agreement for new general office research and development and manufacturing space that we intend to relocate to beginning in 2017 as part of our expansion. We expect to incur significant expenses in renovating this facility and purchasing capital equipment. 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, including the move to, and buildout of, our new facility, 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

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control all matters submitted to stockholders for approval.

Our executive officers, directors and principal stockholders, in the aggregate, beneficially own a large portion of our capital stock. 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 our stockholders might otherwise receive a premium for their 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.

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 of our common stock and thereby affect the ability of our stockholders to sell their shares.

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

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, our stockholders may not be able to sell their common stock at or above the price at which they purchased it. The market price for our common stock may be influenced by many factors, including:

- our success in commercializing ReSure Sealant and any product candidates, including potentially DEXTENZA, for which we obtain marketing approval;
- the outcome of our NDA filing for DEXTENZA for the treatment of post-surgical ocular pain;
- 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 and the efforts of our current and future collaborators 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;
- the ability to secure third party reimbursement for our product candidates;
- 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 DEXTENZA, 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.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock. If such persons sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our stock incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, and, in any event, we have filed a registration statement permitting shares of common stock issued on exercise of options to be freely sold in the public market. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain holders of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or, along with certain holders of shares of our common stock issuable upon exercise of warrants issued to lenders, to include their shares in registration statements that we may file for ourselves or other stockholders. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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 expect to continue to take advantage of some or all of the available exemptions. 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 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 our stockholders' 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 our stockholders' sole source of gain for the foreseeable future.