
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from _____ to _____

Commission file number: 001-36554

Ocular Therapeutix, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

**34 Crosby Drive, Suite 105
Bedford, MA**
(Address of principal executive offices)

20-5560161
(I.R.S. Employer
Identification Number)

01730
(Zip Code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

As of November 1, 2016, there were 24,879,887 shares of Common Stock, \$0.0001 par value per share, outstanding.

Ocular Therapeutix, Inc.

INDEX

	<u>Page</u>
<u>PART I – FINANCIAL INFORMATION</u>	
Item 1. Financial Statements (unaudited)	2
Balance Sheets as of September 30, 2016 and December 31, 2015	2
Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2016 and 2015	3
Statements of Cash Flows for the nine months ended September 30, 2016 and 2015	4
Notes to Financial Statements	5
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	16
Item 3. Quantitative and Qualitative Disclosures About Market Risk	33
Item 4. Controls and Procedures	33
<u>PART II – OTHER INFORMATION</u>	
Item 1. Legal Proceedings	34
Item 1A. Risk Factors	34
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	70
Item 6. Exhibits	70

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “predict,” “project,” “target,” “potential,” “goals,” “will,” “would,” “could,” “should,” “continue” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our plans to develop and commercialize our product candidates based on our proprietary bioresorbable hydrogel technology platform;
- our ongoing and planned clinical trials, including our third Phase 3 clinical trial of DEXTENZA™ for the treatment of post-surgical ocular inflammation and pain, our Phase 3 clinical trials of DEXTENZA for the treatment of allergic conjunctivitis, our Phase 2 clinical trial of DEXTENZA for inflammatory dry eye disease and our Phase 2b clinical trial and additional clinical trials of OTX-TP for the treatment of glaucoma and ocular hypertension;
- the timing of and our ability to submit applications for, obtain and maintain regulatory approvals for DEXTENZA, including the New Drug Application we submitted to the U.S. Food and Drug Administration, or FDA, for the treatment of post-surgical ocular pain, OTX-TP and our other product candidates;
- our commercialization of ReSure Sealant;
- the potential advantages of ReSure Sealant and our product candidates;
- the rate and degree of market acceptance and clinical utility of our products and our ability to secure reimbursement for our products;
- the preclinical development of our intravitreal depot with protein-based or small molecule drugs, including tyrosine kinase inhibitors, or TKIs, for the treatment of wet age-related macular degeneration and other back-of-the-eye diseases;
- the strategic collaboration, option and license agreement we recently entered into with Regeneron Pharmaceuticals, Inc. under which will collaborate on the development of a sustained-release formulation of the vascular endothelial growth factor, or VEGF, trap aflibercept for the treatment of wet age-related macular degeneration, or wet AMD, and other serious retinal diseases;
- our estimates regarding the potential market opportunity for DEXTENZA, OTX-TP, ReSure Sealant and our other product candidates;
- our commercialization, marketing and manufacturing plans, capabilities and strategy;
- the costs of manufacturing, sales, marketing, distribution and other commercialization efforts with respect to ReSure Sealant and any additional products, including DEXTENZA, for which we obtain marketing approval in the future;
- our intellectual property position;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our plans to raise additional capital, including through equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements;
- the impact of government laws and regulations; and
- our competitive position.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to the Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Ocular Therapeutix, Inc.

Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 52,234	\$ 30,784
Marketable securities	23,513	74,280
Accounts receivable	243	193
Inventory	126	134
Prepaid expenses and other current assets	708	1,592
Total current assets	76,824	106,983
Property and equipment, net	3,795	3,095
Restricted cash	1,728	228
Total assets	<u>\$ 82,347</u>	<u>\$ 110,306</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,680	\$ 1,957
Accrued expenses and deferred rent	2,791	3,379
Deferred revenue	—	42
Notes payable, net of discount, current	3,772	—
Total current liabilities	8,243	5,378
Deferred rent, long-term	32	68
Notes payable, net of discount, long-term	11,778	15,272
Total liabilities	<u>20,053</u>	<u>20,718</u>
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at September 30, 2016 and December 31, 2015, no shares issued or outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized at September 30, 2016 and December 31, 2015, 24,879,887 and 24,750,281 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	2	2
Additional paid-in capital	223,344	218,830
Accumulated deficit	(161,057)	(129,176)
Accumulated other comprehensive income (loss)	5	(68)
Total stockholders' equity	62,294	89,588
Total liabilities and stockholders' equity	<u>\$ 82,347</u>	<u>\$ 110,306</u>

The accompanying notes are an integral part of these financial statements.

Ocular Therapeutix, Inc.

Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Product revenue	\$ 477	\$ 388	\$ 1,334	\$ 960
Collaboration revenue	—	41	42	354
Total revenue:	<u>477</u>	<u>429</u>	<u>1,376</u>	<u>1,314</u>
Costs and operating expenses:				
Cost of product revenue	112	91	316	227
Research and development	5,686	8,263	19,737	19,725
Selling and marketing	1,294	798	4,175	2,709
General and administrative	2,623	2,451	8,002	6,575
Total costs and operating expenses	<u>9,715</u>	<u>11,603</u>	<u>32,230</u>	<u>29,236</u>
Loss from operations	<u>(9,238)</u>	<u>(11,174)</u>	<u>(30,854)</u>	<u>(27,922)</u>
Other income (expense):				
Interest income	69	53	236	121
Interest expense	(426)	(406)	(1,262)	(1,316)
Other income (expense), net	(1)	3	(1)	6
Total other expense, net	<u>(358)</u>	<u>(350)</u>	<u>(1,027)</u>	<u>(1,189)</u>
Net loss	<u>(9,596)</u>	<u>(11,524)</u>	<u>(31,881)</u>	<u>(29,111)</u>
Net loss per share, basic and diluted	\$ (0.39)	\$ (0.47)	\$ (1.29)	\$ (1.28)
Weighted average common shares outstanding, basic and diluted	<u>24,853,880</u>	<u>24,713,597</u>	<u>24,792,087</u>	<u>22,757,646</u>
Comprehensive loss:				
Net loss	\$ (9,596)	\$ (11,524)	\$ (31,881)	\$ (29,111)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	(5)	(8)	73	(16)
Total other comprehensive income (loss)	<u>(5)</u>	<u>(8)</u>	<u>73</u>	<u>(16)</u>
Total comprehensive loss	<u>\$ (9,601)</u>	<u>\$ (11,532)</u>	<u>\$ (31,808)</u>	<u>\$ (29,127)</u>

The accompanying notes are an integral part of these financial statements.

Ocular Therapeutix, Inc.**Statements of Cash Flows
(In thousands)
(Unaudited)**

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$(31,881)	\$(29,111)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	4,233	3,304
Non-cash interest expense	106	112
Depreciation and amortization expense	628	554
(Gain)/loss on disposal of property and equipment	1	(3)
Purchase of premium on marketable securities	(17)	(25)
Amortization of premium on marketable securities, net	173	187
Changes in operating assets and liabilities:		
Accounts receivable	(50)	140
Prepaid expenses and other current assets	884	(320)
Inventory	8	(14)
Accounts payable	(289)	(360)
Accrued expenses and deferred rent	(143)	534
Deferred revenue	(42)	(105)
Net cash used in operating activities	<u>(26,389)</u>	<u>(25,107)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(1,239)	(1,305)
Purchases of investments	(14,000)	(75,011)
Proceeds from sale of property and equipment	2	7
Change in restricted cash	(1,500)	—
Maturities of investments	64,684	39,826
Net cash provided by (used in) investing activities	<u>47,947</u>	<u>(36,483)</u>
Cash flows from financing activities:		
Proceeds from exercise of common stock options	153	175
Proceeds from issuance of public offerings, net	—	65,612
Proceeds from issuance of common stock pursuant to employee stock purchase plan	128	148
Payments of insurance costs financed by a third-party	(389)	(540)
Net cash (used in) provided by financing activities	<u>(108)</u>	<u>65,395</u>
Net increase in cash and cash equivalents	21,450	3,805
Cash and cash equivalents at beginning of period	<u>30,784</u>	<u>37,393</u>
Cash and cash equivalents at end of period	<u>\$ 52,234</u>	<u>\$ 41,198</u>
Supplemental disclosure of non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable and accrued expenses	\$ 134	\$ 668

The accompanying notes are an integral part of these financial statements.

Ocular Therapeutix, Inc.

Notes to the Financial Statements
(Amounts in thousands, except share and per share data)
(Unaudited)

1. Nature of the Business and Basis of Presentation

Ocular Therapeutix, Inc. (the “Company”) was incorporated on September 12, 2006 under the laws of the State of Delaware. The Company is a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology. The Company’s bioresorbable hydrogel-based product candidates are designed to provide sustained delivery of therapeutic agents to the eye. Since inception, the Company’s operations have been primarily focused on organizing and staffing the Company, acquiring rights to intellectual property, business planning, raising capital, developing its technology, identifying potential product candidates, undertaking preclinical studies and clinical trials, manufacturing initial quantities of its products and product candidates and building the initial sales and marketing infrastructure for the commercialization of the Company’s approved product and product candidates.

The Company’s most advanced product candidate, DEXTENZA, is in Phase 3 clinical development for the treatment of post-surgical ocular inflammation and pain, and in September 2015, the Company submitted to the Food and Drug Administration (“FDA”) a New Drug Application, or NDA, for DEXTENZA for the treatment of post-surgical ocular pain. On July 25, 2016, the Company announced that it had received a Complete Response Letter, or CRL, from the FDA regarding the 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 the Company’s manufacturing facility in February 2016 that were documented on FDA Form 483. The CRL did not provide any details as to which manufacturing deficiencies identified during the facility inspection remained open since the last response submitted by the Company. 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. On August 3, 2016, the Company announced that it had received a letter (“FDA District Office Letter”) from the FDA New England District Office (“District Office”) providing additional details pertaining to the manufacturing facility inspection observations. The FDA District Office Letter stated that the corrective actions included in the Company’s prior responses appear as a whole to adequately address the ten inspectional observations raised in the Form 483 letter the Company received in February 2016 from the FDA, with one exception which relates to the proposed process for identity testing of an incoming inert gas component used in the Company’s manufacturing process. The FDA District Office Letter also requested evidence (e.g., a final report) when the planned migration of analytical testing from manual to an automatic integration is complete. There were no other issues identified in the FDA District Office Letter. The Company has had ongoing communications with the FDA including the New England District Office and offices within the Center for Drug Evaluation and Research (“CDER”), including the Office of Process and Facilities, with regard to manufacturing issues and the Company’s plans for a resubmission of its NDA. In October 2016, the Company met with the FDA to discuss plans for resubmission to the NDA and to attempt to gain clarity on the possibility of a re-inspection of the Company’s manufacturing facility. The FDA indicated that a decision as to whether a re-inspection is needed will be made during their review of the Company’s resubmission. The Company anticipates the close-out of corrective actions to address the FDA District Office Letter and the resubmission of the NDA in the fourth quarter of 2016. Adequate resolution of the outstanding Form 483 manufacturing deficiencies is a prerequisite to the approval of the NDA for DEXTENZA, although the final decision as to the adequacy of the Company’s manufacturing processes is made by CDER as part of the NDA review process. The Company anticipates that the FDA will classify the resubmission of the NDA and determine whether a re-inspection is needed within 30 days of the NDA resubmission date. The Company expects that a decision by the FDA to conduct a re-inspection of the Company’s manufacturing facility would result in a classification of the resubmission of the NDA as a class 2, or major review, and would take up to 6 months to complete. If no re-inspection is needed, the Company expects the FDA to classify the NDA resubmission as a class 1, or minor review, and take approximately 2 months to complete.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations, regulatory approval, uncertainty of market acceptance of products and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization.

As of September 30, 2016, the Company’s lead product candidates were in development. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval and adequate reimbursement or that any approved products will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants. The Company does not expect to generate

[Table of Contents](#)

significant revenue from sales of any product for several years, if at all. Accordingly, the Company will need to obtain additional capital to finance its operations. If the Company is unable to raise capital when needed or on attractive terms, the Company could be forced to delay, reduce or eliminate its research and development programs or any future commercialization efforts or to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to the Company. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. Based on its current plans and forecasted expenses, the Company believes that its existing cash and cash equivalents and marketable securities will enable it to fund its operating expenses, debt service obligations and capital expenditure requirements into the fourth quarter of 2017.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”).

Unaudited Interim Financial Information

The balance sheet at December 31, 2015 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of September 30, 2016 and for the three and nine months ended September 30, 2016 and 2015 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission, (“SEC”), for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with the Company’s audited financial statements and the notes thereto for the year ended December 31, 2015 included in the Company’s Annual Report on Form 10-K on file with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company’s financial position as of September 30, 2016 and results of operations and cash flows for the nine months ended September 30, 2016 and 2015 have been made. The results of operations for the nine months ended September 30, 2016 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2016.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, revenue recognition, the accrual of research and development expenses and the valuation of common stock and stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company’s estimates.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company’s cash equivalents and marketable securities at September 30, 2016 and December 31, 2015, were carried at fair value determined according to the fair value hierarchy described above (see Note 3). The carrying value of accounts receivable, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these assets and liabilities. The carrying value of the Company’s outstanding notes payable (see Note 7) approximates fair value reflecting interest rates currently available to the Company.

Marketable Securities

The Company's marketable securities are classified as available-for-sale and are carried at fair value with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses and declines in value judged to be other than temporary are included as a component of other income (expense), net based on the specific identification method. Fair value is determined based on quoted market prices.

[Table of Contents](#)

At September 30, 2016, marketable securities by security type consisted of:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
United States treasury notes	\$ 23,508	\$ 5	\$ —	\$ 23,513
Total	<u>\$ 23,508</u>	<u>\$ 5</u>	<u>\$ —</u>	<u>\$ 23,513</u>

At December 31, 2015, marketable securities by security type consisted of:

	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Estimated Fair Value</u>
United States treasury notes	\$ 44,587	\$ —	\$ (53)	\$ 44,534
Agency bonds	29,761	—	(15)	29,746
Total	<u>\$ 74,348</u>	<u>\$ —</u>	<u>\$ (68)</u>	<u>\$ 74,280</u>

At September 30, 2016 and December 31, 2015, marketable securities consisted of investments that mature within one year.

Restricted Cash

As of September 30, 2016 and December 31, 2015, the Company held a certificate of deposit of \$1,728 and \$228, respectively, as security deposits for the lease of the Company's future and current corporate headquarters. In June 2016, the Company opened an additional certificate of deposit of \$1,500 as a security deposit for the new lease related to the Company's future corporate headquarters. (see Note 11) The Company has classified these as long-term restricted cash on its balance sheet.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on advancing its bioresorbable hydrogel-based product candidates exclusively for ophthalmology. All tangible assets are held in the United States.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders.

Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing the net income (loss) by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per share is computed by dividing the diluted net income (loss) by the weighted average number of common shares, including potential dilutive common shares assuming the dilutive effect of outstanding stock options, unvested restricted common shares and common stock warrants, as determined using the treasury stock method. For periods in which the Company has reported net losses, diluted net loss per share is the same as basic net loss per share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

The Company reported a net loss for the three and nine months ended September 30, 2016 and 2015. The following common stock equivalents outstanding as of September 30, 2016 and 2015 were excluded from the computation of diluted net loss per share for the three and nine months ended September 30, 2016 and 2015, because they had an anti-dilutive impact:

	<u>As of September 30,</u>	
	<u>2016</u>	<u>2015</u>
Options to purchase common stock	2,975,311	2,099,901
Non-vested restricted stock	—	7,109
Warrants for the purchase of common stock	18,939	18,939
Total options, warrants and restricted stock	<u>2,994,250</u>	<u>2,125,949</u>

Recently Issued and Adopted Accounting Pronouncements

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

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), (“ASU 2014-09”). ASU 2014-09 outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of Effective Date. The amendments in ASU 2015-14 defer the effective date of ASU 2014-09 for all entities by one year. The standard will be effective for public entities for annual reporting periods beginning after December 15, 2017 and interim periods within those periods. Early adoption is permitted, but it cannot be any earlier than 2017 for calendar year-end entities. Companies may use either a full retrospective or a modified retrospective approach to adopt ASU 2014-09. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements and footnote disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases (ASC 842) (“ASU 2016-02”). ASU 2016-02 requires lessees to recognize most leases on the balance sheet. This is expected to increase both reported assets and liabilities. The new lease standard does not substantially change lessor accounting. For public companies, the standard will be effective for the first interim reporting period within annual periods beginning after December 15, 2018, although early adoption is permitted. Lessees and lessors will be required to apply the new standard at the beginning of the earliest period presented in the financial statements in which they first apply the new guidance, using a modified retrospective transition method. The requirements of this standard include a significant increase in required disclosures. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements and footnote disclosures.

In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers: Principal versus Agent Considerations (Reporting Revenue Gross versus Net) (“ASU 2016-08”). ASU 2016-08 clarifies the implementation guidance on principal versus agent considerations. The guidance includes indicators to assist an entity in determining whether it controls a specified good or service before it is transferred to the customers. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements for ASU 2014-09. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements and footnote disclosures.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (“ASU 2016-09”). ASU 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. The amendments in this update will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements and footnote disclosures.

In April 2016, the FASB, issued ASU No. 2016-10, Identifying Performance Obligations and Licensing (Topic 606), (“ASU 2016-10”) which amends certain aspects of the FASB’s new revenue standard, ASU 2014-09. ASU 2016-10 identifies performance obligations and provides licensing implementation guidance. The effective date for ASU 2016-10 is the same as the effective date of ASU No. 2014-09. The standard will be effective for public entities for annual reporting periods beginning after December 15, 2017 and interim periods within those periods. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements and footnote disclosures.

In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients (“ASU 2016-12”). ASU 2016-12 provides for amendments to ASU No. 2014-09, Revenue from Contracts with Customers, amending the guidance on transition, collectability, noncash consideration and the presentation of sales and other similar taxes. Specifically, ASU 2016-12 clarifies that, for a contract to be considered completed at transition, all (or substantially all) of the revenue must have been recognized under legacy GAAP. In addition, ASU 2016-12 clarifies how an entity should evaluate the collectability threshold and when an entity can recognize nonrefundable consideration received as revenue if an arrangement does not meet the standard’s contract criteria. The Company is currently assessing the impact that adopting this new accounting guidance will have on its financial statements and footnote disclosures.

[Table of Contents](#)

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, Classification of Certain Cash Receipts and Cash Payments (ASU 2016-15). ASU 2016-15 is intended to clarify guidance on the classification of certain cash receipts and payments in the statement of cash flows and to eliminate the diversity in practice related to such classifications. The guidance in ASU 2016-15 is required for annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company is currently assessing the potential impact of the adoption of ASU 2016-15 on its statement of cash flows.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2016 and December 31, 2015 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of September 30, 2016 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	\$ —	\$ 51,987	\$ —	\$ 51,987
Marketable securities:				
United States treasury notes	—	23,513	—	23,513
Total	<u>\$ —</u>	<u>\$ 75,500</u>	<u>\$ —</u>	<u>\$ 75,500</u>

	Fair Value Measurements as of December 31, 2015 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	\$ —	\$ 29,879	\$ —	\$ 29,879
Marketable securities:				
United States treasury notes	—	44,534	—	44,534
Agency bonds	—	29,746	—	29,746
Total	<u>\$ —</u>	<u>\$104,159</u>	<u>\$ —</u>	<u>\$104,159</u>

4. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2016	December 31, 2015
Accrued payroll and related expenses	\$ 1,366	\$ 1,582
Accrued professional fees	557	471
Accrued research and development expenses	373	430
Accrued insurance	—	389
Accrued other	495	507
	<u>\$ 2,791</u>	<u>\$ 3,379</u>

As of December 31, 2015, the Company's accrued insurance represents premiums for the period from July 2015 through June 2016 which the Company financed with a third-party.

5. Income Taxes

The Company did not provide for any income taxes in its statement of operations for the three and nine month periods ended September 30, 2016 or 2015. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at September 30, 2016 and December 31, 2015, it was more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized.

The Company has not recorded any amounts for unrecognized tax benefits as of September 30, 2016 or December 31, 2015. As of September 30, 2016 and December 31, 2015, the Company had no accrued interest or tax penalties recorded related to income taxes. The Company's income tax return reporting periods since December 31, 2013 are open to income tax audit examination by the federal and state tax authorities. In addition, because the Company has net operating loss carryforwards, the Internal Revenue Service is permitted to audit earlier years and propose adjustments up to the amount of net operating losses generated in those years.

6. Feasibility Agreements

The Company had a feasibility agreement with a biotechnology company, entered into in 2014. Under this agreement, the biotechnology company would pay up to \$700, of which \$250 was a non-refundable payment due upon contract execution and \$450 was due upon the achievement of certain milestones. The Company recognized the total expected payments under the contract which included only the non-refundable payments on a straight-line basis over the estimated performance period. When a contingent milestone payment was earned, the additional consideration to be received was added to the total expected payments under the contract then recognized over the estimated performance period. In January 2015, the first milestone under the feasibility agreement was achieved triggering a non-refundable payment due of \$250 such that the total non-refundable payments that were recognized over the estimated performance period totaled \$500. This agreement was terminated in the second quarter of 2016 and the Company does not have any further obligations. The Company recognized no revenue and \$41 of revenue for the three months ended September 30, 2016 and 2015, respectively. The Company recognized \$42 and \$354 of revenue for the nine months ended September 30, 2016 and 2015, respectively. As of September 30, 2016, the Company had no deferred revenue. As of December 31, 2015, the Company had deferred revenue of \$42.

7. Notes Payable

The Company has outstanding borrowings under a credit and security agreement entered into in 2014 and amended in December 2015 (the "Amended 2014 Credit Facility") totaling \$15,600, which is collateralized by substantially all of the Company's personal property, other than its intellectual property. The Company is obligated to make monthly interest-only payments under the Amended 2014 Credit Facility until December 31, 2016 and, thereafter, is required to make monthly payments of principal and interest from January 1, 2017 through December 1, 2019. The stated interest rate under the Amended 2014 Credit Facility is 8.25%. In addition, a final payment equal to 3.75% of amounts drawn under the Amended 2014 Credit Facility is due upon the new maturity date. The effective annual interest rate of the outstanding debt under the Amended 2014 Credit Facility is 10.6%.

There are no financial covenants associated with the Amended 2014 Credit Facility; however, there are negative covenants restricting the Company's activities, including limitations on dispositions, mergers or acquisitions; encumbering its intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. The obligations under the Amended 2014 Credit Facility are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the Company's business, operations or financial or other condition.

On June 20, 2016, the Company entered into a First Amendment (the "First Amendment") to the Amended 2014 Credit Facility to revise the definition of "Permitted Liens" to include a security deposit letter of credit as a permitted lien. There were no other changes to the Amended 2014 Credit Facility.

As of September 30, 2016, the annual repayment requirements for the Amended 2014 Credit Facility, inclusive of the final payment of \$585 due at expiration, were as follows:

<u>Year Ending December 31,</u>	<u>Principal</u>	<u>Interest and Final Payment</u>	<u>Total</u>
2016	\$ —	\$ 327	\$ 327
2017	5,200	1,105	6,305
2018	5,200	670	5,870
2019	5,200	820	6,020
	<u>\$15,600</u>	<u>\$ 2,922</u>	<u>\$18,522</u>

8. Common Stock and Preferred Stock

On July 30, 2014, the Company completed its IPO, which resulted in the sale of 5,000,000 shares of its common stock at a public offering price of \$13.00 per share resulting in net proceeds of approximately \$57,337 after deducting underwriting discounts and other offering costs. Upon closing the IPO, all outstanding shares of the Company's redeemable convertible preferred stock were automatically converted into 12,440,205 shares of common stock. Additionally upon closing the IPO, the Company adopted an amended and restated certificate of incorporation increasing the number of its authorized shares of its common stock to 100,000,000 shares. In conjunction with the IPO and the amended and restated certificate of incorporation, the Company is authorized to issue 5,000,000 shares of preferred stock, \$0.0001 par value, all of which is undesignated.

On August 19, 2014, the Company completed the sale of an additional 750,000 shares of common stock at the initial public offering price of \$13.00 per share to the underwriters of the Company's IPO pursuant to the exercise of their over-allotment option. The Company received additional net proceeds of approximately \$9,068 after deducting underwriting discounts.

In June 2015, the Company completed a follow-on offering of its common stock at a public offering price of \$22.00 per share. The offering consisted of 4,600,000 shares of common stock, of which 3,200,000 shares were issued and sold by the Company and 1,400,000 shares were 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. The Company received net proceeds from the follow-on offering of approximately \$65,612 after deducting underwriting discounts and offering expenses.

9. Warrants

Warrants for the purchase of 18,939 shares of common stock remain outstanding at September 30, 2016 at a weighted average exercise price of \$7.92 per share and an expiration date of April 17, 2021. No warrants were exercised during the nine months ended September 30, 2016. During the nine months ended September 30, 2015, warrants covering 70,769 shares were exercised via net share settlement and the Company issued 54,010 shares of common stock as a result of the exercise.

10. Stock-Based Awards

2014 Stock Incentive Plan

The 2014 Stock Incentive Plan (the "2014 Plan") provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The number of shares of common stock that may be issued under the 2014 Plan is subject to increase on the first day of each fiscal year, beginning on January 1, 2015 and ending on December 31, 2024 in an amount equal to the lesser of a pre-determined formula or as determined by the Company's board of directors. On January 1, 2016, the number of shares available for issuance under the 2014 Plan increased by 990,012. As of September 30, 2016, 1,468,261 shares remained available for issuance under the 2014 Plan.

2014 Employee Stock Purchase Plan

The Company has a 2014 Employee Stock Purchase Plan (the "ESPP"). The number of shares of common stock that may be issued under the ESPP will automatically increase on the first day of each fiscal year, commencing on January 1, 2015 and ending on December 31, 2024 in an amount equal to the lesser of a pre-determined formula or as determined by the Company's board of directors. On January 1, 2016, the number of shares available for issuance under the 2014 Plan increased by 123,752. During the nine months ended September 30, 2016, 30,501 shares of common stock were issued for total proceeds of \$128. As of September 30, 2016, 299,342 shares remained available for issuance under the ESPP.

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and restricted common stock in the following expense categories of its statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	\$ 438	\$ 400	\$1,413	\$1,116
Selling and marketing	115	89	350	247
General and administrative	816	742	2,470	1,941
	<u>\$ 1,369</u>	<u>\$ 1,231</u>	<u>\$4,233</u>	<u>\$3,304</u>

[Table of Contents](#)

As of September 30, 2016, the Company had an aggregate of \$9,881 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.48 years.

As of September 30, 2016, there were outstanding unvested service-based stock options held by nonemployees for the purchase of 7,511 shares of common stock.

11. Commitments and Contingencies

Leases

The Company leases office, laboratory and manufacturing space in Bedford, Massachusetts and certain office equipment under non-cancelable operating leases that expire in June 2017, June 2018 and July 2027.

Future minimum lease payments as of September 30, 2016 for its operating leases that expire in June 2017 and June 2018 are as follows:

<u>Years Ending December 31,</u>	
2016	\$ 207
2017	676
2018	<u>262</u>
Total	<u>\$1,145</u>

During the three months ended September 30, 2016 and 2015, the Company recognized \$194 and \$193, respectively, of rental expense, related to its office, laboratory and manufacturing space and office equipment. During the nine months ended September 30, 2016 and 2015, the Company recognized \$582 and \$583, respectively, of rental expense, related to its office, laboratory and manufacturing space and office equipment.

On June 17, 2016, the Company entered into a lease agreement for approximately 70,712 square feet of general office, research and development and manufacturing space in Bedford, Massachusetts. The lease term will commence on February 1, 2017 and expire on July 31, 2027. No base rent will be due under the lease until August 1, 2017. The initial annual base rent is approximately \$1,200 and will increase annually beginning on February 1 of each year. The Company is obligated to pay all real estate taxes and costs related to the premises, including costs of operations, maintenance, repair, and replacement and management of the new leased premises. The Company posted a customary letter of credit in the amount of approximately \$1,500 as a security deposit. The Company intends to relocate its corporate headquarters to the new leased premises beginning in 2017 and intends to relocate all of its operations to the new leased premises by 2018. The lease agreement allows for a landlord provided construction allowance not to exceed approximately \$2,800 to be applied to the total construction costs of the new leased premises. The construction allowance must be used on or before December 31, 2017, or it will be deemed forfeited with no further obligation by the landlord of the new leased premises.

Future minimum lease payments as of September 30, 2016 for its operating lease expiring in July 2027 are as follows:

<u>Years Ending December 31,</u>	
2016	\$ —
2017	486
2018	1,199
2019	1,235
2020	1,270
Thereafter	<u>9,245</u>
Total	<u>\$13,435</u>

Intellectual Property Licenses

The Company has a license agreement with Incept, LLC (“Incept”) (Note 12) to use and develop certain patent rights (the “Incept License”). Under the Incept License, as amended and restated, the Company was granted a worldwide, perpetual, exclusive license to develop and commercialize products that are delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to ophthalmic diseases or conditions. The Company is obligated to pay low single-digit royalties on net sales of commercial products developed using the licensed technology, commencing with the date of the first commercial sale of such products and until the expiration of the last to expire of the patents covered by the license. Any of the Company’s sublicensees also will be obligated to pay Incept a royalty equal to a low single-digit percentage of net sales made by it and will be bound by the terms of the agreement to the same extent as the Company. The Company is obligated to reimburse Incept for its share of the reasonable fees and costs incurred by Incept in connection with the prosecution of the patent applications licensed to the Company under the Incept License. Through September 30, 2016, royalties paid under this agreement related to product sales were \$81.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements as of December 31, 2015 or September 30, 2016.

Purchase Commitments

Purchase commitments represent non-cancelable contractual commitments associated with certain clinical trial activities within the clinical research organization.

Manufacturing Commitments

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

12. Related Party Transactions

The Company has a license agreement with Incept to use and develop certain patent rights that it entered into in 2007 (see Note 11). Incept and certain owners of Incept are shareholders of the Company. In addition, certain employees of the Company are shareholders of Incept. The Company’s President and Chief Executive Officer (“CEO”) is a general partner of Incept.

In April 2014, the Company granted 28,437 shares of restricted common stock to its CEO, which grant was in lieu of \$250 of the CEO’s 2015 base salary. During 2015, due to an administrative error, the Company did not appropriately adjust the base salary to reflect this reduction. As a result, the Company paid the full base salary for 2015. Upon discovery of the error, the CEO promptly repaid the full \$250 to the Company on April 1, 2016. The Company recorded a reduction to payroll expense in the first quarter of 2016. The effect of this error on the statement of operations was considered immaterial for all related periods.

The Company has a Master Service Agreement with Axtria, Inc. (“Axtria”) in which Axtria will provide certain sales and marketing analytics to the Company. Jaswinder Chadha, co-founder and CEO of Axtria, is also a member of the Company’s Board of Directors and a cousin to the Company’s President and CEO. Through September 30, 2016, payments paid to Axtria under this agreement were \$137.

13. Subsequent Event

On October 10, 2016, the Company entered into a Collaboration, Option and License Agreement (the “Collaboration Agreement”) with Regeneron Pharmaceuticals, Inc. (“Regeneron”) for the development and potential commercialization of products containing the Company’s sustained-release hydrogel depot in combination with Regeneron’s large molecule VEGF-targeting compounds for the treatment of retinal diseases. 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, the Company and Regeneron have agreed to conduct a joint research program with the aim of developing a sustained-release formulation of aflibercept, currently marketed under the tradename Eylea, that is suitable for advancement into clinical development. The Company has granted Regeneron an option (the “Option”) to enter into an exclusive, worldwide license to develop and commercialize products containing the Company’s sustained-release hydrogel depot in combination with Regeneron’s large molecule VEGF-targeting compounds (“Licensed Products”).

If the Option is exercised, Regeneron will conduct further preclinical development and an initial clinical trial under a collaboration plan. The Company is 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 \$25,000, which cap may be increased by up to \$5,000 under certain circumstances. If Regeneron elects to proceed with further development following the completion of the collaboration plan, 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 the Company \$10,000 upon the exercise of the Option. The Company is also eligible to receive up to \$145,000 per Licensed Product upon the achievement of specified development and regulatory milestones, \$100,000 per Licensed Product upon first commercial sale of such Licensed Product and up to \$50,000 based on the achievement of specified sales milestones for all Licensed Products. In addition, the Company is 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.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 10, 2016. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the “Risk Factors” section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described, in or implied, by the forward-looking statements contained in the following discussion and analysis.

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 sustained 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 sustained-release, 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 sustained 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 a sustained period. We have entered into a collaboration with Regeneron Pharmaceuticals, Inc., or Regeneron, for the development and potential commercialization of products containing our sustained-release hydrogel depot in combination with Regeneron’s large molecule VEGF-targeting compounds. In addition to our ongoing product development, we have launched our first commercial product, ReSure Sealant, a hydrogel-based ophthalmic wound sealant approved by the FDA in January 2014 to seal corneal incisions following cataract surgery. ReSure Sealant is the first and only surgical sealant to be approved by the FDA for ophthalmic use.

Our most advanced product candidate, 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 pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of our manufacturing facility in February 2016 that were documented on FDA Form 483. The CRL did not provide any details as to which manufacturing deficiencies identified during the facility inspection remained open since the last response submitted by us. 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. On August 3, 2016, we announced that we received a letter from the FDA New England District Office, or the District Office, providing additional details pertaining to the manufacturing facility inspection observations. We refer to this letter as the FDA District Office Letter. The FDA District Office Letter stated that the corrective actions included in our prior responses as a whole appear to adequately address the ten inspectional observations raised in the Form 483 letter we received in February 2016 from the FDA, with one exception which relates to the proposed process for identity testing of an incoming inert gas component used in our manufacturing process. The FDA District Office Letter also requested evidence (e.g., a final report) when the planned migration of analytical testing from manual to an automatic integration is complete. There were no other issues identified in the FDA District Office Letter. We have 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 plans for a resubmission of 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 possibility 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 their review of our resubmission. We anticipate the close-out of corrective actions to address the FDA District Office Letter and the resubmission of the NDA in the fourth quarter of 2016. Adequate resolution of the outstanding Form 483 manufacturing deficiencies 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 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 of the NDA as a class 2, or major review, and would take up to 6 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 approximately 2 months to complete.

We have completed two Phase 3 clinical trials of DEXTENZA for 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

[Table of Contents](#)

pain. In October 2015, we initiated a third Phase 3 clinical trial for the treatment of post-surgical ocular inflammation and pain, and we have completed enrollment and follow-up of 436 patients in this trial. We anticipate having topline efficacy data available from this third trial in the fourth quarter of 2016. If the results of our third Phase 3 clinical trial of DEXTENZA are favorable 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. In addition, at the 2016 Ocular Surgery News annual meeting, we reported positive results from a third party conducted, patient-reported outcomes study of patients who were administered DEXTENZA for the treatment of post-surgical ocular inflammation and pain in the first two Phase 3 clinical trials. In this patient-reported outcomes survey, the majority of participants preferred DEXTENZA over eye drops. Other results from the survey included: 100% of participants stated the DEXTENZA insert was comfortable; 96% of participants rated their overall experience with DEXTENZA as very convenient or extremely convenient; 88% of participants stated that if they were to undergo cataract surgery again, they would request DEXTENZA; and 84% of participants stated they were willing to pay more for DEXTENZA than eye drops.

DEXTENZA is also in Phase 3 clinical development for the treatment of allergic conjunctivitis. In October 2015, we announced topline results of our first Phase 3 clinical trial for allergic conjunctivitis and in June 2016 we announced topline results of our second Phase 3 clinical trial for this indication. 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. The single primary endpoint of the second Phase 3 trial was the difference in the mean scores in ocular itching between the treatment group and the placebo comparator group at three time points 7 days 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 7 days 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 second Phase 3 trial did not achieve the requirement of at least a 0.5 unit difference at all three time points 7 days 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 7 days following insertion of the depots. The second Phase 3 trial also assessed conjunctival redness as a secondary endpoint. The differences in the mean scores in conjunctival redness between the DEXTENZA treatment group and the placebo group 7 days following insertion of the depots at 7, 15 and 20 minutes were -0.35, -0.39 and -0.42, respectively, compared with values of -0.26, -0.32 and -0.41, respectively, at the same time points 7 days following insertion of the depots in the first Phase 3 trial. The results from the second Phase 3 trial contrast with those achieved in the first Phase 3 clinical trial of DEXTENZA for the treatment of allergic conjunctivitis in which the primary endpoint of treatment of ocular itching associated with allergic conjunctivitis was successfully achieved, with mean ocular itching scores being lower in the DEXTENZA group at 3, 5, and 7 minutes by -1.02, -0.87, and -1.04 units, respectively ($p < 0.0001$), 7 days following insertion of the depots.

We performed additional post hoc analyses that were not pre-specified in the trial protocol for this second 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 and are helpful in understanding the results of this trial and determining the appropriate criteria for future clinical trials. In the second Phase 3 trial, there was a greater variability in ocular itching exhibited by patients over the multiple allergen challenges 7, 14 and 28 days following insertion of the depots, compared to the first Phase 3 trial. In a post hoc analysis, when ocular itching scores were averaged over these multiple visits, a statistically significant reduction of symptoms over the entire one month intended duration of sustained-release, single dose therapy was observed in the DEXTENZA treatment group relative to the placebo vehicle group. Furthermore, other post hoc analyses have led us to believe that a placebo depot which is present through the timepoints chosen as the primary efficacy endpoints may enhance the performance of the placebo. As such, a fast-resorbing placebo depot may lessen this placebo response. We have completed the design of a fast-resorbing placebo depot and plan to conduct a non-significant risk study in humans in the first half of 2017 with a clinical research organization comparing this depot to the longer resorbing depot used in our DEXTENZA trials. 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 by the second half of 2017. We expect to sell DEXTENZA in the United States through a direct sales force although we may initially use a contract sales organization, or CSO, to hire and deploy this sales force. We intend to prepare for the commercialization process by conducting surgical demonstrations to key surgeons and then expanding our sales force through the hiring of additional regional managers and representatives in the second half of 2017. 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 of Medicare and Medicaid Services, or

[Table of Contents](#)

CMS, for DEXTENZA for the treatment of post-surgical ocular pain. We would expect pass-through reimbursement status to remain in effect for up to three years depending on the timing of when we apply for and if we receive this status code. CMS has recently proposed to provide up to three full years of pass-through payments for eligible products regardless of when the pass-through code is issued. Currently, CMS provides pass-through payments for no less than two years but no more than three years, depending upon when in a given calendar year a pass-through application is approved. This recent proposal by CMS, if approved, is expected to become effective in January 2017. We expect to submit to CMS for J code for DEXTENZA for the treatment of other indications, including allergic conjunctivitis, if we receive marketing approval from the FDA for these indications.

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 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 treatment 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 all of the nine diurnal time points at 2 weeks, 6 weeks and 12 weeks.

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 sustained-release 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 retinovascular diseases such as wet AMD, retinal vein occlusion and diabetic macular edema. Our initial goal for this program is to provide sustained release of an anti-VEGF drug or a TKI drug 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 back-of-the-eye diseases. 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 sustained-release hydrogel depot in combination with Regeneron's large molecule VEGF-targeting compounds for the treatment of retinal diseases. 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 a sustained-release 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 sustained-release 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 the Company \$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.

[Table of Contents](#)

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.

We have generated limited revenue to date. All of our sustained-release drug delivery products are in various phases of clinical and preclinical development. We do not expect sales of ReSure Sealant to generate revenue that is sufficient for us to achieve profitability. Instead, our ability to generate product revenue sufficient to achieve profitability will depend heavily on our obtaining marketing approval for and commercializing products with greater market potential, including one or both of DEXTENZA and OTX-TP. Since inception, we have incurred significant operating losses. Our net loss was \$9.6 million for the three months ended September 30, 2016 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.

Our total costs and operating expenses were \$9.7 million and \$32.2 million for the three and nine months ended September 30, 2016, respectively, including \$1.4 million and \$4.2 million, respectively, in non-cash stock-based compensation expense. We anticipate that our operating expenses will increase substantially as we pursue the clinical development of our most advanced product candidates, DEXTENZA and OTX-TP; continue the research and development of our other product candidates; continue the internal development of our intravitreal hydrogel depot for the sustained delivery of protein-based or small molecule anti-angiogenic drugs, such as anti-VEGF drugs and TKI drugs for the treatment of wet AMD and other back-of-the-eye diseases and seek marketing approval for any such product candidate for which we obtain favorable pivotal clinical trial results. We expect to continue to incur substantial additional expenses for product manufacturing, sales, marketing and distribution for our product candidates for which we obtain marketing approval. In addition, we will continue to incur additional costs associated with operating as a public company.

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 funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

In July 2014, we completed an initial public offering, or IPO, of our common stock, and in August 2014 the underwriters in our IPO exercised their over-allotment option in full. We received total net proceeds of approximately \$66.4 million from the issuance and sale of 5,750,000 shares of common stock, including in connection with the exercise by the underwriters of their over-allotment option, after deducting underwriting discounts and offering costs. In June 2015, we completed a follow-on offering of our common stock at a public offering price of \$22.00 per share. The offering consisted of 4,600,000 shares of common stock, of which 3,200,000 shares were issued and sold by us and 1,400,000 shares were sold by certain of our stockholders, 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 commissions and offering expenses. 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. See “—Liquidity and Capital Resources.”

Financial Operations Overview

Revenue

From our inception through September 30, 2016, we have generated limited amounts of revenue from the sales of our products. Our ReSure Sealant product received premarket approval, or PMA, from the FDA in January 2014. We commenced sales of ReSure Sealant in the first quarter of 2014, have received only limited revenues from ReSure Sealant to date and anticipate only limited sales for 2016. ReSure Sealant is currently our only source of revenue from product sales. We may generate revenue in the future if we successfully develop one or more of our product candidates and receive marketing approval for any such product candidate or if we enter into longer-term collaboration agreements with third parties.

In October 2014, we entered into a feasibility agreement with a biotechnology company relating to our intravitreal drug delivery depot. Under this agreement, the biotechnology company had agreed to pay us up to \$0.7 million, of which \$0.3 million was a non-refundable up-front payment due upon contract execution and \$0.4 million was due upon the achievement of certain milestones. We recognized the total expected payments under the contract which included only the non-refundable payments on a straight-line basis over the estimated performance period. When a contingent milestone payment was earned, the additional consideration received was added to the total expected payments under the contract and then recognized over the estimated performance period. In January 2015,

[Table of Contents](#)

we achieved the first milestone under the feasibility agreement triggering a payment due of \$0.3 million. Through September 30, 2016, we have recognized revenue of \$0.5 million related to this agreement. The agreement is terminated and there are no additional performance obligations or milestones that will be recognized.

Operating Expenses

Research and Development Expenses

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

- employee-related expenses, including salaries, related benefits and payroll taxes, travel and stock-based compensation expense for employees engaged in research and development, clinical and regulatory and other related functions;
- expenses incurred in connection with the clinical trials of our product candidates, including with the investigative sites that conduct our clinical trials and under agreements with contract research organizations, or CROs;
- expenses relating to regulatory activities, including filing fees paid to the FDA for our submissions for product approvals;
- expenses associated with developing our pre-commercial manufacturing capabilities and manufacturing clinical study materials;
- ongoing research and development activities relating to our core bioresorbable hydrogel technology and improvements to this technology;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and supplies;
- costs relating to the supply and manufacturing of product inventory, prior to approval by the FDA or other regulatory agencies of our products; and
- expenses associated with preclinical development activities.

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

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

[Table of Contents](#)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands)			
ReSure Sealant	\$ 32	\$ 100	\$ 203	\$ 233
DEXTENZA for post-surgical ocular inflammation and pain	429	415	2,122	1,157
DEXTENZA for allergic conjunctivitis	14	2,715	2,815	4,309
DEXTENZA for inflammatory dry eye disease	17	128	101	613
OTX-TP for glaucoma	782	645	1,362	1,693
Unallocated expenses	4,412	4,260	13,134	11,720
Total research and development expenses	<u>\$ 5,686</u>	<u>\$ 8,263</u>	<u>\$ 19,737</u>	<u>\$ 19,725</u>

We expect that our expenses will increase substantially in connection with our ongoing activities including costs related to clinical trials and other research and development activities for our DEXTENZA and OTX-TP product candidates and other research and development activities.

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

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

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance and administrative functions. General and administrative expenses also include facility-related costs and professional fees for legal, patent, consulting and accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued development and commercialization of our product candidates. We also anticipate to continue to incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

Selling and Marketing Expenses

Selling and marketing expenses consist primarily of salaries and related costs for personnel in selling and marketing functions as well as consulting and advertising and promotion costs. In addition, we invested in sales and marketing resources in anticipation of an earlier approval of our surgical sealant product in the United States than we ultimately received from the FDA, as a result of a change in designation from a 510(k) to a PMA regulatory path. During the three and nine months ended September 30, 2016 and 2015, we incurred selling and marketing expenses in connection with ReSure Sealant, which we commercialized in the first quarter of 2014.

[Table of Contents](#)

We expect selling and marketing expenses to increase in preparation for the potential commercial launch of our DEXTENZA product candidate for the treatment of post-surgical ocular pain, subject to resubmission and approval of our NDA by the FDA and the potential label expansion to include post-surgical ocular inflammation, subject to submission and approval of an NDA supplement.

Other Income (Expense)

Interest Income. Interest income consists primarily of interest income earned on cash and cash equivalents and marketable securities.

Interest Expense. Interest expense consists of interest expense on our debt. We borrowed \$15.0 million in aggregate principal amount in April 2014 with an interest only period that extended through September 2015. In December 2015, we amended our credit facility to increase the aggregate principal amount to \$15.6 million, extend the interest-only payment period through December 2016, and extend the maturity date to December 1, 2019.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. During the nine months ended September 30, 2016, there were no material changes to our critical accounting policies. Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report on Form 10-K filed with the SEC on March 10, 2016 and the notes to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- revenue recognition
- accrued research and development expenses; and
- stock-based compensation

Accordingly, we believe the policies set forth in our Annual Report on Form 10-K are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

Results of Operations
Comparison of the Three Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the three months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		Increase (Decrease)
	2016	2015	
	(in thousands)		
Revenue:			
Product revenue	\$ 477	\$ 388	\$ 89
Collaboration revenue	—	41	(41)
Total revenue	<u>477</u>	<u>429</u>	<u>48</u>
Costs and operating expenses:			
Cost of product revenue	112	91	21
Research and development	5,686	8,263	(2,577)
Selling and marketing	1,294	798	496
General and administrative	2,623	2,451	172
Total costs and operating expenses	<u>9,715</u>	<u>11,603</u>	<u>(1,888)</u>
Loss from operations	<u>(9,238)</u>	<u>(11,174)</u>	<u>1,936</u>
Other income (expense):			
Interest income	69	53	16
Interest expense	(426)	(406)	(20)
Other income (expense), net	(1)	3	(4)
Total other expense, net	<u>(358)</u>	<u>(350)</u>	<u>(8)</u>
Net loss	<u><u>\$ (9,596)</u></u>	<u><u>\$ (11,524)</u></u>	<u><u>\$ 1,928</u></u>

Revenue

We generated no revenue from our feasibility agreements during the three months ended September 30, 2016 compared to \$41,000 for the three months ended September 30, 2015. We generated \$0.5 million of revenue during the three months ended September 30, 2016 from sales of our ReSure Sealant product compared to \$0.4 million for the three months ended September 30, 2015.

Research and Development Expenses

	Three Months Ended September 30,		Increase (Decrease)
	2016	2015	
	(in thousands)		
Direct research and development expenses by program:			
ReSure Sealant	\$ 32	\$ 100	\$ (68)
DEXTENZA for post-surgical ocular inflammation and pain	429	415	14
DEXTENZA for allergic conjunctivitis	14	2,715	(2,701)
DEXTENZA for inflammatory dry eye disease	17	128	(111)
OTX-TP for glaucoma and ocular hypertension	782	645	137
Unallocated expenses:			
Personnel costs (including stock-based compensation)	2,826	2,386	440
All other costs	1,586	1,874	(288)
Total research and development expenses	<u><u>\$ 5,686</u></u>	<u><u>\$ 8,263</u></u>	<u><u>\$ (2,577)</u></u>

[Table of Contents](#)

Research and development expenses were \$5.7 million for the three months ended September 30, 2016, compared to \$8.3 million for the three months ended September 30, 2015. Research and development costs decreased by \$2.6 million primarily due to a decrease of \$2.7 million in costs incurred in connection with the clinical trials of our DEXTENZA product candidate for the treatment of post-surgical ocular inflammation and pain, our DEXTENZA product candidate for the treatment of allergic conjunctivitis, our DEXTENZA product candidate for the treatment of inflammatory dry eye disease and our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension and a decrease of \$0.3 million in unallocated all other costs offset in part by an increase of \$0.4 million in unallocated personnel costs.

For the three months ended September 30, 2016, we incurred \$1.2 million in direct research and development expenses for our sustained-release drug delivery product candidates for the front of the eye, including \$0.4 million for our DEXTENZA product candidate for the treatment of post-surgical ocular inflammation and pain which was in Phase 3 clinical trials, \$14,000 for our DEXTENZA product candidate for the treatment of allergic conjunctivitis which was in a Phase 3 clinical trial, \$17,000 for our DEXTENZA product candidate for the treatment of inflammatory dry eye disease which was in an exploratory Phase 2 clinical trial and \$0.8 million for our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension which was in a Phase 3 clinical trial. For the three months ended September 30, 2015, we incurred \$3.9 million in direct research and development expenses for our sustained-release drug delivery product candidates for the front of the eye, including \$0.4 million for our DEXTENZA product candidate for the treatment of ocular inflammation and pain following cataract surgery which was in Phase 3 clinical trials, \$2.7 million for our DEXTENZA product candidate for the treatment of allergic conjunctivitis which was in a Phase 3 clinical trial, \$0.1 million for our DEXTENZA product candidate for the treatment of inflammatory dry eye disease which was in an exploratory Phase 2 clinical trial and \$0.6 million for our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension which was in Phase 2b clinical trials. Unallocated research and development expense increased \$0.1 million for the three months ended September 30, 2016, compared to the three months ended September 30, 2015, due to an increase in personnel costs of \$0.4 million due to additional hiring primarily in our clinical, regulatory and quality department and an increase in stock-based compensation expense offset by a decrease of \$0.3 million in unallocated all other costs.

Selling and Marketing Expenses

	Three Months Ended September 30,		Increase (Decrease)
	2016	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 593	\$ 359	\$ 234
Professional, advertising and promotion costs	463	250	213
Facility-related and other	238	189	49
Total selling and marketing expenses	<u>\$ 1,294</u>	<u>\$ 798</u>	<u>\$ 496</u>

Selling and marketing expenses were \$1.3 million for the three months ended September 30, 2016, compared to \$0.8 million for the three months ended September 30, 2015. The increase of \$0.5 million was primarily due to an increase of \$0.2 million in personnel costs relating to additional hiring and additional stock-based compensation expense, an increase of \$0.2 million in professional fees including consulting, trade shows and conferences, and an increase of \$50,000 in facility-related and other costs.

General and Administrative Expenses

	Three Months Ended September 30,		Increase (Decrease)
	2016	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 1,444	\$ 1,387	\$ 57
Professional, insurance and consultant fees	945	793	152
Facility-related and other	234	271	(37)
Total general and administrative expenses	<u>\$ 2,623</u>	<u>\$ 2,451</u>	<u>\$ 172</u>

General and administrative expenses were \$2.6 million for the three months ended September 30, 2016, compared to \$2.5 million for the three months ended September 30, 2015. The increase of \$0.2 million was primarily due an increase of \$0.1 million in personnel relating to additional hiring and stock-based compensation expense and an increase of \$0.2 million in professional,

[Table of Contents](#)

insurance and consultant fees offset by a decrease in facility-related and other costs of \$37,000. Professional, insurance and consultant fees increased primarily due to an increase in consulting fees relating to activities to support our operating as a public company including legal and professional services.

Other Income (Expense), Net

Other expense, net was \$0.4 million for the three months ended September 30, 2016, compared to \$0.4 million for the three months ended September 30, 2015.

Comparison of the Nine Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,		Increase (Decrease)
	2016	2015	
(in thousands)			
Revenue:			
Product revenue	\$ 1,334	\$ 960	\$ 374
Collaboration revenue	42	354	(312)
Total revenue	<u>1,376</u>	<u>1,314</u>	<u>62</u>
Costs and operating expenses:			
Cost of product revenue	316	227	89
Research and development	19,737	19,725	12
Selling and marketing	4,175	2,709	1,466
General and administrative	8,002	6,575	1,427
Total costs and operating expenses	<u>32,230</u>	<u>29,236</u>	<u>2,994</u>
Loss from operations	<u>(30,854)</u>	<u>(27,922)</u>	<u>(2,932)</u>
Other income (expense):			
Interest income	236	121	115
Interest expense	(1,262)	(1,316)	54
Other income (expense), net	(1)	6	(7)
Total other expense, net	<u>(1,027)</u>	<u>(1,189)</u>	<u>162</u>
Net loss	<u><u>\$ (31,881)</u></u>	<u><u>\$ (29,111)</u></u>	<u><u>\$ (2,770)</u></u>

Revenue

We generated \$42,000 of revenue from our feasibility agreements during the nine months ended September 30, 2016 compared to \$0.4 million for the nine months ended September 30, 2015. We generated \$1.3 million of revenue during the nine months ended September 30, 2016 from sales of our ReSure Sealant product compared to \$1.0 million for the nine months ended September 30, 2015.

Research and Development Expenses

	Nine Months Ended September 30,		Increase (Decrease)
	2016	2015	
(in thousands)			
Direct research and development expenses by program:			
ReSure Sealant	\$ 203	\$ 233	\$ (30)
DEXTENZA for post-surgical ocular inflammation and pain	2,122	1,157	965
DEXTENZA for allergic conjunctivitis	2,815	4,309	(1,494)
DEXTENZA for inflammatory dry eye disease	101	613	(512)
OTX-TP for glaucoma and ocular hypertension	1,362	1,693	(331)
Unallocated expenses:			
Personnel costs (including stock-based compensation)	8,392	6,970	1,422
All other costs	4,742	4,750	(8)
Total research and development expenses	<u><u>\$19,737</u></u>	<u><u>\$19,725</u></u>	<u><u>\$ 12</u></u>

[Table of Contents](#)

Research and development expenses were \$19.7 million for the nine months ended September 30, 2016, compared to \$19.7 million for the nine months ended September 30, 2015. Research and development costs remained unchanged as a result of an decrease of \$1.4 million in costs incurred in connection with the clinical trials of our DEXTENZA product candidate for the treatment of post-surgical ocular inflammation and pain, our DEXTENZA product candidate for the treatment of allergic conjunctivitis, our DEXTENZA product candidate for the treatment of inflammatory dry eye disease and our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension and an increase of \$1.4 million in unallocated personnel costs.

For the nine months ended September 30, 2016, we incurred \$6.4 million in direct research and development expenses for our sustained-release drug delivery product candidates for the front of the eye, including \$2.1 million for our DEXTENZA product candidate for the treatment of post-surgical ocular inflammation and pain which was in Phase 3 clinical trials, \$2.8 million for our DEXTENZA product candidate for the treatment of allergic conjunctivitis which was in a Phase 3 clinical trial, \$0.1 million for our DEXTENZA product candidate for the treatment of inflammatory dry eye disease which was in an exploratory Phase 2 clinical trial and \$1.4 million for our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension which was in Phase 3 clinical trials. For the nine months ended September 30, 2015, we incurred \$7.8 million in direct research and development expenses for our sustained-release drug delivery product candidates for the front of the eye, including \$1.2 million for our DEXTENZA product candidate for the treatment of ocular inflammation and pain following cataract surgery which was in Phase 3 clinical trials, \$4.3 million for our DEXTENZA product candidate for the treatment of allergic conjunctivitis which entered into a Phase 3 clinical trial, \$0.6 million for our DEXTENZA product candidate for the treatment of inflammatory dry eye disease which was in an exploratory Phase 2 clinical trial and \$1.7 million for our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension which was in Phase 2b clinical trials. Unallocated research and development expense increased \$1.4 million for the nine months ended September 30, 2016, compared to the nine months ended September 30, 2015, due to an increase in personnel costs of \$1.4 million due to additional hiring primarily in our clinical, regulatory and quality departments.

Selling and Marketing Expenses

	Nine Months Ended September 30,		Increase (Decrease)
	2016	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 1,770	\$ 1,075	\$ 695
Professional, advertising and promotion costs	1,612	1,149	463
Facility-related and other	793	485	308
Total selling and marketing expenses	<u>\$4,175</u>	<u>\$ 2,709</u>	<u>\$ 1,466</u>

Selling and marketing expenses were \$4.2 million for the nine months ended September 30, 2016, compared to \$2.7 million for the nine months ended September 30, 2015. The increase of \$1.5 million was primarily due to an increase of \$0.7 million in personnel costs relating to additional hiring and additional stock-based compensation expense, an increase of \$0.5 million in professional fees including consulting, trade shows and conferences and advertising and promotion costs, and an increase of \$0.3 million in facility-related and other costs.

General and Administrative Expenses

	Nine Months Ended September 30,		Increase (Decrease)
	2016	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	\$4,261	\$3,850	\$ 411
Professional, insurance and consultant fees	2,921	1,947	974
Facility-related and other	820	778	42
Total general and administrative expenses	<u>\$8,002</u>	<u>\$6,575</u>	<u>\$ 1,427</u>

General and administrative expenses were \$8.0 million for the nine months ended September 30, 2016, compared to \$6.6 million for the nine months ended September 30, 2015. The increase of \$1.4 million was primarily due to an increase of \$0.4 million in personnel costs relating to additional hiring and additional stock-based compensation expense, an increase of \$1.0 million in professional, insurance and consultant fees and an increase of \$42,000 in facility-related and other costs. Professional, insurance and consultant fees increased primarily due to an increase in consulting fees of \$0.7 million relating to activities to support our operating as a public company including legal and professional services.

Other Income (Expense), Net

Other expense, net was \$1.0 million for the nine months ended September 30, 2016, compared to \$1.2 million for the nine months ended September 30, 2015. The decrease of \$0.2 million was related to an increase in interest income of \$0.1 million and a decrease in interest expense of \$0.1.

Liquidity and Capital Resources

Since inception, we have incurred significant operating losses. We have generated limited revenue to date. In the first quarter of 2014, we began recognizing revenue from sales of ReSure Sealant. All of our sustained drug delivery products are in various phases of clinical and preclinical development. We do not expect sales of ReSure Sealant to generate revenue that is sufficient for us to achieve profitability. Instead, our ability to generate product revenue sufficient to achieve profitability will depend heavily on our obtaining marketing approval for and commercializing products with greater market potential, including one or both of DEXTENZA and OTX-TP.

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 July 2014, we closed our IPO, and in August 2014 the underwriters in our IPO exercised their over-allotment option in full. We received total net proceeds of approximately \$66.4 million from the issuance and sale of 5,750,000 shares of common stock, including in connection with the exercise by the underwriters of their over-allotment option, after deducting underwriting discounts and offering costs. In June 2015, we completed a follow-on offering of our common stock at a public offering price of \$22.00 per share. The offering consisted of 4,600,000 shares of common stock, of which 3,200,000 shares were issued and sold by us and 1,400,000 shares were sold by certain stockholders, 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 commissions, and offering expenses.

As of September 30, 2016, we had cash and cash equivalents and marketable securities of \$75.7 million. In April 2014, we borrowed \$15.0 million in aggregate principal amount under a new credit facility and used \$1.9 million of this amount to repay \$1.7 million aggregate principal amount of indebtedness and pay \$0.2 million of other amounts due in connection with our termination of a prior credit facility. In December 2015, we amended our credit facility to increase the aggregate principal amount to \$15.6 million, extend the interest-only payment period through December 2016, and extend the maturity date to December 1, 2019. The outstanding borrowings under this facility bear interest at an annual rate equal to 8.25%. See “—Contractual Obligations and Commitments” for additional information.

Cash Flows

As of September 30, 2016, we had cash and cash equivalents and marketable securities of \$75.7 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

[Table of Contents](#)

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

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Cash used in operating activities	\$ (26,389)	\$ (25,107)
Cash provided by (used in) investing activities	47,947	(36,483)
Cash (used in) provided by financing activities	(108)	65,395
Net increase in cash and cash equivalents	<u>\$ 21,450</u>	<u>\$ 3,805</u>

Operating activities. Net cash used in operating activities was \$26.4 million for the nine months ended September 30, 2016, primarily resulting from our net loss of \$31.9 million partially offset by non-cash charges of \$5.0 million. Our net loss was primarily attributed to research and development activities and our general and administrative expenses, as we had minimal product revenue in the period. Our net non-cash charges during the nine months ended September 30, 2016 consisted primarily of \$4.2 million of stock-based compensation expense. Net cash used by changes in our operating assets and liabilities during the nine months ended September 30, 2016 consisted primarily of a decrease in accounts payable and accrued expenses of \$0.4 million and a decrease in prepaid expenses and other current assets of \$0.9 million. The changes in prepaid expenses and other current assets, accounts payable and accrued expenses were due to increased product development activities and the timing of vendor invoicing and payments.

Net cash used in operating activities was \$25.1 million for the nine months ended September 30, 2015, primarily resulting from our net loss of \$29.1 million partially offset by non-cash charges of \$4.1 million. Our net loss was primarily attributed to research and development activities and our general and administrative expenses, as we had minimal product revenue in the period. Our net non-cash charges during the nine months ended September 30, 2015 consisted primarily of \$3.3 million of stock-based compensation expense. Net cash used by changes in our operating assets and liabilities during the nine months ended September 30, 2015 consisted primarily of an increase in accounts payable and accrued expenses of \$0.2 million and an increase in prepaid expenses and other current assets of \$0.3 million. The changes in prepaid expenses and other current assets, accounts payable and accrued expenses were due to increased product development activities and the timing of vendor invoicing and payments.

Investing activities. Net cash provided by investing activities for the nine months ended September 30, 2016 totaled \$47.9 million and net cash used in investing activities for the nine months ended September 30, 2015 totaled \$36.5 million. For the nine months ended September 30, 2016, net cash provided is primarily due to the sale of marketable securities of \$64.7 million offset by the purchase of marketable securities of \$14.0 million and an increase in restricted cash of \$1.5 million. For the nine months ended September 30, 2016, the purchases of property and equipment, primarily laboratory equipment was \$1.2 million. For the nine months ended September 30, 2015, net cash used is primarily due to the purchase of marketable securities of \$75.0 million offset by the sale of marketable securities of \$39.8 million. For the nine months ended September 30, 2015, the purchases of property and equipment, primarily laboratory equipment and additional investment in a manufacturing clean room was \$1.3 million. In June 2016, we entered into a lease agreement for approximately 70,712 square feet of general office, research and development and manufacturing space. We expect to spend approximately \$6.5 million to \$7.0 million, of which up to \$2.8 million would be reimbursed by a landlord provided construction allowance, on improvements to this newly leased space. In addition, we expect to spend \$2.0 million to \$2.5 million on manufacturing and research and development capital equipment for the new facility.

Financing activities. Net cash used in financing activities for the nine months ended September 30, 2016 was \$0.1 million and net cash provided by financing activities for the nine months ended September 30, 2015 was \$65.4 million. Net cash used in financing activities for the nine months ended September 30, 2016 consisted of payments of \$0.4 million for insurance costs financed by a third party offset by proceeds from issuance of common stock pursuant to our employee stock purchase plan of \$0.1 million and \$0.2 million from the exercise of common stock options. Net cash provided by financing activities for the nine months ended September 30, 2015 consisted primarily of proceeds of \$65.6 million, net of underwriting discounts and other offering expenses, related to our follow-on offering, proceeds from the exercise of common stock options of \$0.2 million; and proceeds from issuance of common stock pursuant to our employee stock purchase plan of \$0.1 million partially offset by payments of \$0.5 million for insurance costs financed by a third party.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the clinical trials of our products in development and increase our sales and marketing resources.

[Table of Contents](#)

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

- pursue the clinical development of our most advanced intracanalicular insert product candidates, DEXTENZA and OTX-TP;
- conduct joint research and development under the strategic collaboration we entered into recently with Regeneron for the development and potential commercialization of products containing our sustained-release hydrogel depot in combination with Regeneron's large molecule 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 additional 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, in addition we expect to purchase \$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.

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 any 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 sustained-release 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 sustained-release 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;

Table of Contents

- 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.

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

Since our inception in 2006, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2015, we had federal net operating loss carryforwards of \$60.8 million, which begin to expire in 2026, and state net operating loss carryforwards of \$50.5 million, which begin to expire in 2029. As of December 31, 2015, we also had federal research and development tax credit carryforwards of \$3.0 million and state research and development tax credit carryforwards \$1.6 million, which begin to expire in 2026 and 2025, respectively. We have not completed a study to assess whether an ownership change, generally defined as a greater than 50% change (by value) in the equity ownership of our corporate entity over a three-year period, has occurred or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such studies. Accordingly, our ability to utilize our tax carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at September 30, 2016 and the effects such obligations are expected to have on our liquidity and cash flow in future periods:

	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
			(in thousands)		
Operating lease commitments	\$14,579	\$ 946	\$ 2,809	\$2,557	\$ 8,267
Purchase commitments	3,770	2,283	1,487	—	—
Manufacturing commitments	1,680	1,260	420	—	—
Debt obligations	18,522	5,096	11,523	1,903	—
Total	<u>\$38,551</u>	<u>\$ 9,585</u>	<u>\$16,239</u>	<u>\$4,460</u>	<u>\$ 8,267</u>

In the table above, we set forth our enforceable and legally binding obligations and future commitments at September 30, 2016, as well as obligations related to contracts that we are likely to continue, regardless of the fact that they may be cancelable at September 30, 2016. Some of the figures that we include in this table are based on management's estimates and assumptions about these obligations, including their duration, and other factors. Because these estimates and assumptions are necessarily subjective, the obligations we will actually pay in future periods may vary from those reflected in the table.

[Table of Contents](#)

Operating lease commitments represent payments due under our leases of office, laboratory and manufacturing space in Bedford, Massachusetts and certain office equipment under operating leases that expire in June 2017, June 2018 and July 2027.

On June 17, 2016, we entered into a lease agreement for approximately 70,712 square feet of general office, research and development and manufacturing space. The lease term will commence on February 1, 2017 and expire on July 31, 2027. No base rent will be due under the lease until August 1, 2017. The initial annual base rent is approximately \$1.2 million and will increase annually beginning on February 1 of each year. We are obligated to pay all real estate taxes and costs related to the premises, including costs of operations, maintenance, repair, and replacement and management of the new leased premises. We posted a customary letter of credit in the amount of \$1.5 million as a security deposit. We intend to relocate our corporate headquarters to the new leased premises beginning in 2017 and expect to relocate all of our operations to the new leased premises by 2018. The lease agreement allows for a construction allowance not to exceed approximately \$2.8 million to be applied to the total construction costs of the new leased premises. The construction allowance must be used on or before December 31, 2017, or it will be deemed forfeited with no further obligation by the landlord of the new leased premises.

Purchase commitments represent non-cancelable contractual commitments associated with certain clinical trial activities with our CROs and design fees for our future corporate headquarters.

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

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

We have an amended credit facility with an aggregate principal amount of \$15.6 million that provides for monthly, interest-only payments on outstanding borrowings through December 2016. Thereafter, we are required to pay thirty-six consecutive, equal monthly installments of principal and interest through December 1, 2019. There are no financial covenants associated with the credit facility. There are negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions; encumbering our intellectual property; incurring indebtedness or liens; paying dividends; making investments; and engaging in certain other business transactions. The obligations under the credit facility are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition. The credit facility is secured by substantially all of our assets except for our intellectual property, which is subject to a negative pledge.

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

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

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

[Table of Contents](#)

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), or ASU 2014-09. ASU 2014-09 outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model will require revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration a company expects to receive in exchange for those goods or services. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of Effective Date. The amendments in ASU 2015-14 defer the effective date of ASU 2014-09 for all entities by one year. The standard will be effective for public entities for annual reporting periods beginning after December 15, 2017 and interim periods within those periods. Early adoption is permitted, but it cannot be any earlier than 2017 for calendar year-end entities. Companies may use either a full retrospective or a modified retrospective approach to adopt ASU 2014-09. We are currently assessing the impact that adopting this new accounting guidance will have on our financial statements and footnote disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases (ASC 842), or ASU 2016-02. ASU 2016-02 requires lessees to recognize most leases on the balance sheet. This is expected to increase both reported assets and liabilities. The new lease standard does not substantially change lessor accounting. For public companies, the standard will be effective for the first interim reporting period within annual periods beginning after December 15, 2018, although early adoption is permitted. Lessees and lessors will be required to apply the new standard at the beginning of the earliest period presented in the financial statements in which they first apply the new guidance, using a modified retrospective transition method. The requirements of this standard include a significant increase in required disclosures. We are currently assessing the impact that adopting this new accounting guidance will have on our financial statements and footnote disclosures.

In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers: Principal versus Agent Considerations (Reporting Revenue Gross versus Net), or ASU 2016-08. ASU 2016-08 clarifies the implementation guidance on principal versus agent considerations. The guidance includes indicators to assist an entity in determining whether it controls a specified good or service before it is transferred to the customers. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements for ASU 2014-09. We are currently assessing the impact that adopting this new accounting guidance will have on our financial statements and footnote disclosures.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation, or ASU 2016-09. ASU 2016-09 identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. The amendments in this update will be effective for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. We are currently assessing the impact that adopting this new accounting guidance will have on our financial statements and footnote disclosures.

In April 2016, the FASB issued ASU No. 2016-10, Identifying Performance Obligations and Licensing (Topic 606), or ASU 2016-10, which amends certain aspects of the FASB's new revenue standard, ASU 2014-09. ASU 2016-10 identifies performance obligations and provides licensing implementation guidance. The effective date for ASU 2016-10 is the same as the effective date of ASU No. 2014-09. The standard will be effective for public entities for annual reporting periods beginning after December 15, 2017 and interim periods within those periods. We are currently assessing the impact that adopting this new accounting guidance will have on our financial statements and footnote disclosures.

In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients. ASU 2016-12 provides for amendments to ASU No. 2014-09, Revenue from Contracts with Customers, amending the guidance on transition, collectability, noncash consideration and the presentation of sales and other similar taxes. Specifically, ASU 2016-12 clarifies that, for a contract to be considered completed at transition, all (or substantially all) of the revenue must have been recognized under legacy GAAP. In addition, ASU 2016-12 clarifies how an entity should evaluate the collectability threshold and when an entity can recognize nonrefundable consideration received as revenue if an arrangement does not meet the standard's contract criteria. We are currently assessing the impact of ASU 2016-12, but it does not expect the adoption of ASU 2016-12 to have a material impact on its financial statements.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, Classification of Certain Cash Receipts and Cash Payments (ASU 2016-15). ASU 2016-15 is intended to add or clarify guidance on the classification of certain cash receipts and

[Table of Contents](#)

payments in the statement of cash flows and to eliminate the diversity in practice related to such classifications. The guidance in ASU 2016-15 is required for annual reporting periods beginning after December 15, 2017, with early adoption permitted. We are currently assessing the potential impact of the adoption of ASU 2016-15 on our statement of cash flows.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of September 30, 2016, we had cash and cash equivalents and marketable securities of \$75.7 million, which consisted of money market funds, United States treasury notes and government agency notes. We have policies requiring us to invest in high-quality issuers, limit our exposure to any individual issuer, and ensure adequate liquidity. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a 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 SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a 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 and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2016, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. 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. Please see page 1 of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. 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 insert 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 sustained-release 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 additional 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, in addition we expect to purchase \$2.0 to \$2.5 million in manufacturing and research and development capital equipment for our new facility;

Table of Contents

- 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 in February 2016 that were documented on FDA Form 483. More recently, we received a letter from the FDA New England District Office, or District Office, providing additional details pertaining to the manufacturing facility inspection observations. We refer to this letter as the FDA District Office Letter. 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 possibility 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 their review of our resubmission. We anticipate the close-out of corrective actions to address the FDA District Office letter and the resubmission of the NDA in the fourth quarter of 2016. Adequate resolution of the outstanding Form 483 manufacturing deficiencies 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 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 of the NDA as a class 2, or major review, and would take up to 6 months to complete. If no re-inspection is needed, we expect the FDA to classify the NDA resubmission as a type 2, or minor review, and take approximately 2 months to complete. While the FDA has indicated to us it intends to classify the resubmission of 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.

[Table of Contents](#)

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 sustained-release 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 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 any 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 sustained-release 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 sustained-release 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.

[Table of Contents](#)

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 and MidCap Financial SBIC, LP. 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:

- completing preclinical studies and clinical trials successfully;
- 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;
- competing effectively 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;

[Table of Contents](#)

- 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 two completed Phase 3 clinical trials of DEXTENZA at day 14. In the first of these two 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 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 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 have completed enrollment in a third Phase 3 clinical trial of DEXTENZA for post-surgical ocular inflammation and pain to support the potential labeling expansion of DEXTENZA's indications for use to include inflammation. We have modified the design of this third Phase 3 clinical trial compared to our two completed Phase 3 clinical trials of DEXTENZA based on our learnings from these prior trials. However, these modifications may not have the intended effect or yield favorable trial results. If the results of our third Phase 3 clinical trial of DEXTENZA are favorable 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

[Table of Contents](#)

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 favorable results from the third Phase 3 clinical trial on both primary efficacy endpoints, or at all. If we complete the third Phase 3 clinical trial prior to a final decision by the FDA with respect to approval of our NDA upon resubmission and we do not obtain favorable results in the third Phase 3 clinical trial, in particular with respect to the primary efficacy endpoint for pain, the FDA could refuse to grant marketing approval of DEXTENZA for the pain indication.

Post-hoc analyses that we performed on the results of our two completed Phase 3 clinical trials of DEXTENZA for post-surgical ocular inflammation and pain may not be predictive of success in our third Phase 3 clinical trial. Although we believe that the collective data from these trials, including the post-hoc analyses, provide support for our decision to conduct a third Phase 3 clinical trial and provide additional information regarding our platform technology, post-hoc analyses performed 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.

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.

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 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.

[Table of Contents](#)

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 sustained-release 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.

[Table of Contents](#)

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 sustained-release 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 or collaborators 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.

[Table of Contents](#)

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 sustained-release 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 by us, or third-party contractors or our collaborators;
- 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 sustained-release 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 sustained-release 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 our two completed 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 in each of our two trials, none of which were ocular in nature or considered by the investigator to be related to the study treatment. There was one ocular serious adverse event in the vehicle control group in the two completed Phase 3 clinical trials, which was hypopyon, or inflammatory cells in the anterior chamber. In our earlier Phase 2 clinical trial of 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 dacryocanalculitis, 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 sustained delivery of therapeutic agents to the eye using active pharmaceutical ingredients that are currently used in FDA-approved ophthalmic drugs. We have a number of product candidates at various stages of development based on our bioresorbable hydrogel technology platform and are exploring the potential use of our 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 sustained-release 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

[Table of Contents](#)

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. Subsequently, we received the FDA District Office Letter which provided additional details pertaining to the manufacturing facility inspection observations and which stated that the corrective actions included in our prior responses as a whole appear to adequately address the ten inspectional observations raised in the Form 483 letter we received in February 2016 from the FDA, with one exception which relates to the proposed process for identity testing of an incoming inert gas component used in our manufacturing process. The FDA District Office Letter also requested evidence (e.g., a final report) when the planned migration of analytical testing from manual to an automatic integration is complete. There were no other issues identified in the FDA District Office Letter. In October 2016, we met with the FDA to discuss plans for resubmission to the NDA and to attempt to gain clarity on the possibility 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 their review of our resubmission. We anticipate the close-out of corrective actions to address the FDA District Office Letter and the resubmission of the NDA in the fourth quarter of 2016. Adequate resolution of the outstanding Form 483 manufacturing deficiencies 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 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.

[Table of Contents](#)

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 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 and product labelling 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

[Table of Contents](#)

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 sustained-release 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.

[Table of Contents](#)

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, sustained-release 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 a sustained-release fashion to the back of the eye.

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

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

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

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

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

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs and devices, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws

Table of Contents

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 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.

[Table of Contents](#)

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 sustained-release 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 the Collaboration Agreement with Regeneron for the development and potential commercialization of products containing our sustained-release 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 sustained-release 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-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.

[Table of Contents](#)

Our current collaboration poses, and any future collaborations that we enter into may pose, a number of risks, including the following:

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

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report on Form 10-Q 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.

[Table of Contents](#)

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.

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.

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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;

Table of Contents

- 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.

[Table of Contents](#)

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;

[Table of Contents](#)

- 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 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.

[Table of Contents](#)

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.

[Table of Contents](#)

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

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

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

Risks Related to Our Common Stock

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 stockholders who own more than 5% of our outstanding common stock, in the aggregate, 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;

Table of Contents

- 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;

Table of Contents

- 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.

[Table of Contents](#)

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.

[Table of Contents](#)

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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Securities

We did not sell any shares of our common stock, shares of our preferred stock or warrants to purchase shares of our stock, or grant any stock options or restricted stock awards, during the period covered by this Quarterly Report on Form 10-Q that were not registered under the Securities Act of 1933, as amended, or the Securities Act, and that have not otherwise been described in a Current Report on Form 8-K.

Purchase of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Quarterly Report on Form 10-Q.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

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 thereunto duly authorized.

Date: November 9, 2016

OCULAR THERAPEUTIX, INC.

By: /s/ W. Bradford Smith
W. Bradford Smith
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
10.1†*	Collaboration, Option and License Agreement between Ocular Therapeutix, Inc. and Regeneron Pharmaceuticals, Inc. dated October 10, 2016
10.2*	Employment Agreement, dated January 5, 2016, by and between the Company and Jonathan H. Talamo, M.D.
10.3*	Employment Agreement, dated October 10, 2016, by and between the Company and Andrew Hurley
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Database
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

* Filed herewith.

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

COLLABORATION, OPTION AND LICENSE AGREEMENT

BETWEEN

OCULAR THERAPEUTIX, INC.

AND

REGENERON PHARMACEUTICALS, INC.

TABLE OF CONTENTS

ARTICLE 1	Definitions	1
ARTICLE 2	Research and Development	14
2.1	Performance	14
2.2	Costs	14
2.3	Collaboration Plan	14
2.4	Alternative Licensed Products	14
2.5	Use of Materials; Technology and Information	15
2.6	Results and Reporting	15
2.7	Records; Inspection	15
ARTICLE 3	Governance	16
3.1	Joint Research Committee	16
3.2	Responsibilities	16
3.3	Membership	16
3.4	Replacements	16
3.5	Meetings	16
3.6	Decision Making	16
3.7	Minutes	17
3.8	Expenses	17
3.9	Disbanding	18
ARTICLE 4	Manufacturing	18
4.1	Manufacturing Support; Collaboration Supply	18
4.2	Clinical and Commercial Supply	18
4.3	Technology Transfer	18
ARTICLE 5	Regulatory Affairs	19
5.1	Regulatory Matters	19
5.2	Regulatory Cooperation; Right of Reference	19
ARTICLE 6	Performance Standards	20
6.1	Affiliates	20
6.2	Subcontracts	20
ARTICLE 7	Option And Licenses; Exclusivity And Diligence	20
7.1	Research License Grant by Regeneron	20
7.2	Research License Grant by Collaborator	21
7.3	Pre-Option Exclusivity	21
7.4	Option	21
7.5	Commercial License	21
7.6	Post-Option Period Exclusivity	21

7.7	Diligence	22
7.8	Sublicensing by Regeneron	22
ARTICLE 8	Financial Terms	23
8.1	Option Exercise Fee	23
8.2	Milestone Payments	23
8.3	Royalties	24
8.4	Royalty Reductions & Adjustments	25
8.5	Royalty Reports and Payments	25
8.6	Regeneron Reimbursable Cost Reporting and Reimbursement	26
8.7	Audit Rights	26
8.8	Payments	27
8.9	Late Payments	27
8.10	Tax	27
ARTICLE 9	Intellectual Property	27
9.1	Ownership of Newly Created Intellectual Property	27
9.2	Prosecution and Maintenance of Patents	29
9.3	Administrative Patent Proceedings	30
9.4	Third Party Infringement	30
9.5	Incept Agreement	31
ARTICLE 10	Confidentiality	31
10.1	Non-use and Non-disclosure of Confidential Information	31
10.2	Exclusions Regarding Confidential Information	32
10.3	Authorized Disclosures of Confidential Information	32
10.4	Terms of this Agreement	34
10.5	Research Results	34
10.6	No License	34
ARTICLE 11	Publicity; Publications	34
11.1	Publicity	34
11.2	Publications	35
11.3	No Right to Use Names	36
ARTICLE 12	REPRESENTATIONS, Warranties And Covenants	36
12.1	Mutual Representations and Warranties	36
12.2	Knowledge of Pending or Threatened Litigation	37
12.3	Additional Representations of Collaborator	37
12.4	Disclaimers	38
12.5	Non-Reliance	38
12.6	Mutual Covenants	39
12.7	Debarment	39

12.8	Additional Representations, Warranties and Covenants Regarding the Upstream Agreement	39
12.9	No Challenge	40
ARTICLE 13	Indemnification; Liability	40
13.1	Indemnification	40
13.2	Procedure	41
13.3	Insurance	42
13.4	Limitation of Damages	42
ARTICLE 14	Term And Termination	42
14.1	Term	42
14.2	Termination	42
14.3	Effect of Expiration or Termination	44
ARTICLE 15	Force Majeure	45
ARTICLE 16	Miscellaneous	46
16.1	Governing Law; Submission to Jurisdiction	46
16.2	Waiver	46
16.3	Notices	46
16.4	Entire Agreement	47
16.5	Amendments	48
16.6	Interpretation	48
16.7	Construction	48
16.8	Severability	48
16.9	Assignment	48
16.10	Successors and Assigns	49
16.11	Signatures	49
16.12	Third Party Beneficiaries	49
16.13	Relationship of the Parties	49
16.14	Injunctive or Other Equity Relief	50
16.15	Non-Exclusive Remedies	50

Collaborator Patents Appendix
Collaboration Plan Appendix
Royalty Calculation Appendix
Upstream Agreement Appendix
Initial Press Release Appendix
Incept Agreement Appendix

THIS COLLABORATION, OPTION AND LICENSE AGREEMENT (this "Agreement") is made and entered into, effective as of October 10, 2016 (the "Effective Date"), by and between Ocular Therapeutix, Inc., a corporation organized under the laws of Delaware and having an address at 36 Crosby Drive, Suite 101, Bedford, Massachusetts 01730 ("Collaborator"), and Regeneron Pharmaceuticals, Inc., a corporation organized under the laws of New York and having an address at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron"). Collaborator and Regeneron are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

BACKGROUND

WHEREAS, Collaborator has proprietary readily injectable bioresorbable hydrogel technology;

WHEREAS, Regeneron has expertise in ophthalmology drug discovery, development and commercialization and protein formulation;

WHEREAS, Regeneron wishes to license such technology from Collaborator for, and the Parties wish to collaborate in, the research and development of co-formulated products consisting of Regeneron's products formulated in Collaborator's technology; and

WHEREAS, Regeneron desires to obtain an option for a commercial license to Collaborator's technology for the development and commercialization of such co-formulated products.

NOW THEREFORE, the Parties, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, agree as follows:

ARTICLE 1 **DEFINITIONS**

Capitalized terms used in this Agreement, whether used in the singular or plural, shall have the meanings set forth below, unless otherwise specifically indicated herein.

1.1 "Acquirer Competing Product" has the meaning set forth in Section 7.6.

1.2 "Acquiring Party" has the meaning set forth in Section 7.6.

1.3 "Additional Amounts" has the meaning set forth in Section 1.34.

1.4 "Additional Unforeseen Activities" means activities performed under the Collaboration Plan that were not included in the Collaboration Plan as of the Effective Date and that [**].

1.5 “Affiliate” means, with respect to any Party, any person that, directly or indirectly (through one or more intermediaries) controls, is controlled by, or is under common control with such Party. For purposes of this Section 1.5, “control” and cognates thereof with respect to any Person means the power, direct or indirect, to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract, or otherwise, including through (a) the direct or indirect ownership of greater than fifty percent (50%) of the voting stock or other voting interests of such Person having the right to vote for the election of directors or the equivalent governing body, or (b) the ability to otherwise control or direct the decisions of the board of directors or equivalent governing body of such Person. For clarity, Incept shall not be considered an Affiliate of Collaborator hereunder.

1.6 “Agreement” has the meaning set forth in the preamble.

1.7 “Alternative Licensed Product” has the meaning set forth in Section 2.4.

1.8 “Applicable Laws” means all applicable laws, rules, regulations, guidelines, statutes, orders, judgments or ordinances of any Governmental Authority having effect from time to time in any country worldwide.

1.9 “BLA” a Biologics License Application and amendments thereto filed pursuant to the requirements of the FDA, as defined in 21 C.F.R. § 600 et seq., for FDA approval of a Licensed Product (or the equivalent application in any foreign jurisdiction).

1.10 “Bulk Product” means the Collaboration Therapeutic Molecule formulated and spray dried as required by the Collaboration Plan, such that it is in a form ready for formulation with Collaborator Technology to generate a Licensed Product.

1.11 “Business Day” means any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, the United States are authorized or required by Applicable Law to remain closed.

1.12 “Calendar Quarter” means each successive period of three (3) calendar months commencing on 1st January, 1st April, 1st July and 1st October.

1.13 “Change of Control” means, with respect to a Party, any of the following events: (a) any Third Party (or group of Third Parties acting in concert) acquires, directly or indirectly, shares of such Party representing at least a majority of the voting power (where voting refers to being entitled to vote for the election of directors) then outstanding of such Party; (b) such Party consolidates with or merges into another corporation or entity which is a Third Party, or any corporation or entity which is a Third Party consolidates with or merges into such Party, in either event pursuant to a transaction in which at least a majority of the voting power of the acquiring or resulting entity outstanding immediately after such consolidation or merger is not held by the holders of the outstanding voting power of such Party immediately preceding such consolidation or merger; or (c) such Party conveys, transfers, licenses or leases all or substantially all of its assets to a Third Party.

1.14 “Collaboration Clinical Trial” means the initial first-in-human clinical trial of a Licensed Product that is included in the Collaboration Plan. The Parties acknowledge that the Collaboration Clinical Trial may be a Phase I Clinical Trial or a combination Phase I Clinical Trial and Phase II Clinical Trial. An initial draft plan and budget for the Collaboration Clinical Trial are included in the Collaboration Plan.

1.15 “Collaboration Costs” shall mean costs incurred by a Party that are reasonably necessary to perform its activities within the Collaboration Plan and all Regulatory, Support and Analytical Activities, including all such Party’s Out-of-Pocket Costs, FTE Costs and any other costs or expenses specifically identified to such Party and included in the Collaboration Plan or included as such Party’s Collaboration Costs under this Agreement.

1.16 “Collaboration Invention” means an invention that is conceived or made by the Parties or their Affiliates, employees, sublicensees, independent contractors, agents or consultants, alone or working together, in the course of conducting the Collaboration Plan.

1.17 “Collaboration Plan” means the plan and budget for the research and development of Licensed Products attached hereto as the Collaboration Plan Appendix, as such plan may be updated from time to time in accordance with this Agreement.

1.18 “Collaboration Therapeutic Molecule” means any Regeneron Therapeutic Molecule that is the subject of the activities conducted pursuant to the Collaboration Plan. As of the Effective Date, Collaboration Therapeutic Molecule is Regeneron’s molecule known as aflibercept.

1.19 “Collaborator” has the meaning set forth in the preamble.

1.20 “Collaborator Intellectual Property” means Collaborator Patents, Collaborator Know-How and Collaborator’s interest in Joint Patents and Joint Know-How.

1.21 “Collaborator Know-How” means Know-How relating to the Collaborator Technology that is Controlled by Collaborator on the Effective Date or at any time during the Term that is necessary or useful [**]. Collaborator Know-How includes [**]. Collaborator Know-How excludes [**].

1.22 “Collaborator Material” means Collaborator Technology or any other materials, technology or information provided by or on behalf of Collaborator for use in the performance of the Collaboration Plan or any other activities under this Agreement.

1.23 “[**]” has the meaning set forth in Section [**].

1.24 “Collaborator Patents” means (a) those Patents set forth on the Collaborator Patents Appendix attached hereto and (b) any other Patents that, as of the Effective Date or at any time thereafter during the Term, are (i) Controlled by Collaborator and [**].

1.25 “Collaborator Sole Invention” has the meaning set forth in Section 9.1(c).

1.26 “Collaborator Technology” means technology Controlled by Collaborator as of the Effective Date or at any time during the Term that is [**].

1.27 “Collaborator Technology Invention” means a Collaboration Invention that is, [**].

1.28 “Combination Product” means any product containing a Licensed Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price).

1.29 “Commercial License” has the meaning set forth in Section 7.5.

1.30 “Commercially Reasonable Efforts” means, with respect to a Party and any research, development or commercial activities for any Licensed Product, the efforts and resources typically used by such Party in the conduct of such activities for other products with comparable market potential, considering all relevant factors, including, as applicable, stage of research or development, efficacy and safety relative to competitive products, actual or anticipated Regulatory Authority approved labeling, the nature and extent of market exclusivity (including Patent coverage and regulatory exclusivity) and the cost and likelihood of obtaining Regulatory Approval, but excluding from such consideration in the case of Regeneron the availability to Regeneron of technologies competitive to the Collaborator Technology and the obligation to make the payments set forth in this Agreement.

1.31 “Competing Product” means any product containing [**].

1.32 “Confidential Information” means proprietary or confidential information (of whatever kind and in whatever form or medium, including copies thereof) (a) disclosed by or on behalf of a Party in connection with this Agreement, whether prior to or during the Term and whether disclosed orally, electronically, by observation or in writing, or (b) created by, or on behalf of, a Party and provided to the other Party, or created jointly by the Parties, in the course of the performance of this Agreement. For the avoidance of doubt, “Confidential Information” includes Know-How regarding a Party’s research, development plans, clinical trial designs, preclinical and clinical data, technology, products, business information or objectives and other information of the type that is customarily considered to be confidential information by entities engaged in activities that are substantially similar to the activities being engaged in by the Parties pursuant to this Agreement.

1.33 “Conflicting Agreement” has the meaning set forth in Section 7.4.

1.34 “Control,” “Controls” or “Controlled by” means, with respect to any Party’s Patents, Know-How, technology or information, the possession by such Party or its Affiliates of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense, right of reference or other right to or under, such Patent, Know-How, technology or information, without violating the terms of any agreement with any other Person and without requiring the consent of any other

Person. Notwithstanding the foregoing, for the purpose of determining whether any Patent or Know-How is Controlled by a Party, if such Patent or Know-How is first acquired, licensed or otherwise made available to such Party after the Effective Date and if the use, practice or exploitation thereof by or on behalf of the other Party, its Affiliates or sublicensees would require the first Party to pay any amounts to the Third Party from which the first Party acquired, licensed or otherwise obtained such Patent or Know-How (“Additional Amounts”), such Patent or Know-How shall be deemed to be Controlled by the first Party only if the other Party agrees to pay (if necessary) and does in fact pay all Additional Amounts with respect to such other Party’s use of or license to such Patent or Know-How. Prior to using such Patent or Know-How in connection with this Agreement in any manner that would result in any obligation to pay Additional Amounts, the first Party shall notify the other Party that Additional Amounts will apply to such other Party’s use of or license to such Patent or Know-How. If the first Party fails to provide such prior notification, the first Party shall still be deemed to Control the applicable Patents and Know-How for the purposes of the licenses granted under this Agreement and such first Party shall remain solely responsible for the payment of Additional Amounts in respect of the other Party’s use of or license to such Patent or Know-How as contemplated by this Agreement. Notwithstanding anything in this Agreement to the contrary, a Party and its Affiliates will be deemed to not Control any Patent or Know-How that is owned or controlled by a Third Party described in the definition of “Change of Control,” or such Third Party’s Affiliates (other than an Affiliate of such Party prior to the Change of Control), (a) prior to the closing of such Change of Control, or (b) after such Change of Control, except to the extent that such Patent or Know-How (i) is developed or conceived by such Third Party or its Affiliates (other than such Party or its Affiliates prior to a Change of Control) after such Change of Control and arises out of access by such Third Party or its Affiliates to Patents or Know-How Controlled by such Party or its Affiliates prior to the Change of Control or (ii) is used in the performance of the Collaboration Plan or incorporated into any Licensed Product. For purposes of this definition, Incept or its Affiliates shall not be considered to be a Third Party.

1.35 “Cover” means, with respect to a given product, process, method or service, that a claim would (absent a license thereunder or ownership thereof) be infringed by one or more of the making, using, selling, offering for sale, importation or other exploitation of such product, process, method or service. With respect to a claim of a pending patent application, “infringed” refers to activity that would infringe or be covered by such claim if it were contained in an issued patent.

1.36 “CPI” means (a) for personnel located in the United States, the Consumer Price Index – All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index), or (b) for personnel located in any other country, the applicable equivalent index published in such foreign country applicable to personnel in such country.

1.37 “Directed to” means that, with respect to any molecule and any biological target, such molecule specifically binds such target or functional portion thereof and modulates the activity of such target as its intended mechanism of action.

1.38 “Effective Date” has the meaning set forth in the preamble.

1.39 “[**]” means [**].

1.40 “[**]” means [**].

1.41 “[**]” means [**].

1.42 “[**]” means [**].

1.43 “[**]” means [**].

1.44 “Exclusive Option Period” means the period beginning on the Effective Date and expiring at the end of the twelve (12) month period immediately following the date that Regeneron receives Licensed Product consistent with the requirements of the Collaboration Plan; provided that, if Collaborator generates an Alternative Licensed Product under the circumstances described in Section 2.4, then the Exclusive Pre-Milestone Period shall remain in effect and not expire until the end of the twelve (12) month period immediately following the date that Regeneron receives such Alternative Licensed Product consistent with the requirements of the Collaboration Plan in quantities sufficient to perform the *in vitro* evaluation activities included under the Collaboration Plan.

1.45 “Executive Officers” means, for Regeneron, its Chief Executive Officer; and for Collaborator, its Chief Executive Officer.

1.46 “FDA” means the United States Food and Drug Administration.

1.47 [**].

1.48 [**].

1.49 “Field” means the field of products that are delivered by local administration to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to ophthalmic diseases or conditions.

1.50 “Finished Product” shall mean a Licensed Product in a formulation and delivery device that is in a form and package that is ready for use in clinical or pre-clinical trials or studies, as the case may be.

1.51 “First Commercial Sale” means the first sale of a Licensed Product for use by a Third Party end-user that is not a Sublicensee by Regeneron or an Affiliate or Sublicensee of Regeneron following the final Regulatory Approval of the marketing and, where required by Applicable Law, pricing, of the Product for a therapeutic or diagnostic indication by the relevant Regulatory Authorities in the country in which such sale occurred. Sales of commercially reasonable quantities of a Licensed Product in a country for clinical trial purposes or compassionate or similar use prior to Regulatory Approval shall not constitute a First Commercial Sale in such country.

1.52 “First Development Milestone” means the date that is [**]; provided that, [**], then the First Development Milestone will be [**].

1.53 “Force Majeure” has the meaning set forth in ARTICLE 15.

1.54 “Form 8-K” has the meaning set forth in Section 10.3(f).

1.55 “FTE Cost” means, for any activity, the product of (a) the number of FTEs performing such activity and (b) the FTE Rate.

1.56 “FTE Rate” means [**] Dollars (US\$ [**]) in the period from the Effective Date through December 31, 2017, such amount to be adjusted as of January 1, 2018 and annually thereafter by the percentage increase or decrease, if any, in the applicable CPI (determined based on the location of the applicable personnel) since the Effective Date or the latest adjustment date hereunder, whichever is later, through June 30 of the prior calendar year. The FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.

1.57 “Governmental Authority” means any court, tribunal, agency, authority, department, regulatory or legislative body or other office or instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

1.58 “[**]” has the meaning set forth in Section [**].

1.59 “[**]” has the meaning set forth in Section [**].

1.60 “Incept” means Incept, LLC.

1.61 “IND” means an investigational new drug application filed with the FDA, or the equivalent application in any foreign jurisdiction filed with another Regulatory Authority.

1.62 “IND Enabling GLP Toxicology Studies” means, with respect to a particular Licensed Product, the study or set of pre-clinical toxicology studies described in the Collaboration Plan performed under GLP conditions designed to support an IND for such Licensed Product. An initial draft plan and budget for the IND Enabling GLP Toxicology Studies are included in the Collaboration Plan.

1.63 “Indemnitee” has the meaning set forth in Section 13.2.

1.64 “Indemnitor” has the meaning set forth in Section 13.2.

1.65 “[**]” has the meaning set forth in Section [**].

1.66 “Joint Inventions” has the meaning set forth in Section 9.1(d).

- 1.67 “Joint Know-How” means Know-How comprising or within Joint Inventions.
- 1.68 “[**]” has the meaning set forth in Section [**].
- 1.69 “Joint Patents” means Patents claiming Joint Inventions.
- 1.70 “Joint Research Committee” or “JRC” has the meaning set forth in Section 3.1.
- 1.71 “Key Results Memorandum” means the data report containing final results from a clinical trial, in the form presented to Regeneron management following the completion of such clinical trial.
- 1.72 “Know-How” means any and all proprietary, non-public technical or scientific information, ideas, protocols, know-how, data, test results, processes, assays, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information (whether or not patentable or otherwise protected by trade secret law).
- 1.73 “Large Molecule” means [**].
- 1.74 “Licensed Product” means any product that contains a Regeneron Therapeutic Molecule and Collaborator Technology. [**].
- 1.75 “Licensed Target” means (a) VEGF-A, (b) VEGFR-1, (c) VEGFR-2, [**].
- 1.76 “Losses” has the meaning set forth in Section 13.1.
- 1.77 “Milestone Deduction” has the meaning set forth in Section 8.2.1.
- 1.78 “Net Sales” means the gross amounts invoiced by Regeneron, its Affiliates or its Sublicensees to Third Parties that are not Sublicensees for a bona fide arms’ length sale of Licensed Product, less the following deductions, determined in each case in accordance with Regeneron’s standard methods as generally and consistently applied by Regeneron:
- (a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of such Licensed Product;
 - (b) amounts repaid or credited with respect to such Licensed Product by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;
 - (c) chargebacks and other amounts paid on sale or dispensing of such Licensed Product;
 - (d) Third Party cash rebates and chargebacks related to sales of such Licensed Product, to the extent allowed;

(e) retroactive price reductions for such Licensed Product that are actually allowed or granted;

(f) compulsory refunds, credits and rebates directly related to the sale of such Licensed Product, accrued, paid or deducted pursuant to agreements (including managed care agreements) or governmental regulations;

(g) [**];

(h) freight, postage, shipment and insurance costs (or wholesaler fees in lieu of those costs) and customs duties incurred in delivering such Licensed Product that are separately identified on the invoice or other documentation;

(i) sales Taxes, duties, or other consumption Taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of such Licensed Product, which are separately identified on the invoice or other documentation;

(j) fees related to import, distribution or promotion of Licensed Products paid to Third Parties (specifically excluding any compensation paid to sales personnel, sales representatives and sales agents who are employees or consultants of Regeneron or its Affiliates or any Sublicensees and also any payments made to or in connection with contract sales forces);

(k) [**]; and

(l) any other specifically identifiable costs or charges included in the gross invoiced sales price of such Licensed Product falling within categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof.

In the event more than one of (a) to (l) applies to any given amount, such amount shall be deducted only once for purposes of calculating Net Sales. If Regeneron, its Affiliates or its Sublicensees receive non-cash consideration for any Licensed Product or in the case of any transfer of Licensed Product other than in a bona fide arms' length sale, Net Sales will be calculated based on the fair market value of such Licensed Product, assuming an arm's length transaction made in the ordinary course of business.

Solely for purposes of calculating Net Sales, if Regeneron or its Affiliate or Sublicensee sells any Combination Product, Net Sales of such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product, as determined in the first paragraph of this definition of "Net Sales", by the fraction $A/(A+B)$, where A is the invoice price of the Licensed Product, if sold separately, and B is the invoice price of the other active ingredient(s) in the combination, if sold separately. If, on a country-by-country basis, such other active ingredient(s) in the Combination Product is not sold separately in such country, but the Licensed Product component of the Combination Product is sold separately in such country, Net Sales for the Combination Product shall be calculated by multiplying actual Net Sales of the Combination Product by the fraction A/C , where A is the invoice price of the Licensed Product component, if sold separately, and C is the invoice price of the Combination Product. If, on a country-by-

country basis, the Licensed Product component is not sold separately in that country, Net Sales for the Combination Product shall be calculated by multiplying actual Net Sales of the Combination Product by the fraction $D/(D+E)$, where D is the fair market value of the portion of the Combination Product that contains the Licensed Product and E is the fair market value of the portion of the Combination Product containing the other active ingredient(s) included in such Combination Product, as such fair market values are determined by mutual agreement of the Parties.

1.79 “Non-Exclusive Option Period” means the six- (6-) month period immediately following the expiration of the Exclusive Option Period.

1.80 “Option” has the meaning set forth in Section 7.4.

1.81 “Option Period” means the entire period comprised of the Exclusive Option Period and the Non-Exclusive Option Period.

1.82 “Other Collaboration Invention” has the meaning set forth in Section 9.1(c).

1.83 “Out of Pocket Costs” shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP or IAS/IFRS) by either Party and/or its Affiliates in the performance of Collaboration Activities.

1.84 “Party” or “Parties” has the meaning set forth in the preamble.

1.85 “Patent(s)” means any and all patents and patent applications, including any patents issuing therefrom or claiming priority thereto, anywhere in the world, together with any extensions (including patent term extensions and supplementary protection certificates) and renewals thereof, reissues, reexaminations, revalidations, substitutions, confirmation patents, registration patents, invention certificates, patents of addition, renewals, divisionals, continuations, and continuations-in-part of any of the foregoing.

1.86 “Person” means and includes an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization, Governmental Authority, or any other entity or body.

1.87 “Personnel” has the meaning set forth in Section 9.1(c).

1.88 “Phase I Clinical Trial” means a clinical trial of a pharmaceutical product that meets the definition of a Phase 1 study for the United States as described in 21 C.F.R. §312.21(a), or a similar clinical study in a country other than the United States.

1.89 “Phase II Clinical Trial” means a human clinical study as described in 21 C.F.R. §312.21(b) to evaluate safety and effectiveness of a Licensed Product, or a similar clinical study in a country other than the United States.

1.90 “Phase III Clinical Trial” means a human clinical study, the principal purpose of which is to demonstrate clinically and statistically the efficacy and safety of a Licensed Product for one or more indications in order to support the Regulatory Approval of such Licensed Product for such indication as further described in 21 C.F.R. §312.21(c), or a similar clinical study in a country other than the United States.

- 1.91 “[**]” has the meaning set forth in Section [**].
- 1.92 “Prior Agreements” means [**].
- 1.93 “[**]” means [**].
- 1.94 “Publication” has the meaning set forth in Section 11.2.
- 1.95 “Regeneron” has the meaning set forth in the preamble.
- 1.96 “Regeneron Intellectual Property” means Regeneron Patents, Regeneron Know-How and Regeneron’s interest in Joint Patents and Joint Know-How.
- 1.97 “Regeneron Know-How” means Know-How Controlled by Regeneron on the Effective Date or at any time during the Term that is necessary or useful for the performance of the Collaboration Plan or the research or development of a Licensed Product in the Field. Regeneron Know-How includes Know-How Controlled by Regeneron comprising or within Therapeutic Inventions and Regeneron Sole Inventions.
- 1.98 “Regeneron Material” means any Collaboration Therapeutic Molecule or any other materials, technology or information provided by or on behalf of Regeneron for use in the performance of the Collaboration Plan or any other activities under this Agreement.
- 1.99 “Regeneron Patent” means any Patent that (a) as of the Effective Date or at any time thereafter during the performance of the Collaboration Plan, is Controlled by Regeneron and (b) claims inventions that are necessary or useful for the performance of the Collaboration Plan or the research or development of a Licensed Product in the Field. Regeneron Patents shall include Patents Controlled by Regeneron and claiming Therapeutic Inventions and Regeneron Sole Inventions.
- 1.100 “Regeneron Reimbursable Costs” means Collaboration Costs incurred by Regeneron in the conduct of [**]; provided that, Regeneron Reimbursable Costs shall not include [**].
- 1.101 “Regeneron Reimbursable Costs Cap” means Twenty Five Million Dollars (\$25,000,000); provided that, if the aggregate amount of Regeneron Reimbursable Costs incurred by Regeneron exceeds such amount due to Additional Unforeseen Activities, then the Regeneron Reimbursable Costs Cap shall be automatically increased by the amount of the Regeneron Reimbursable Costs incurred by Regeneron in the conduct of such Additional Unforeseen Activities; provided further that, in no event shall the Regeneron Reimbursable Costs Cap exceed Thirty Million Dollars (\$30,000,000).
- 1.102 “Regeneron Sole Invention” has the meaning set forth in Section 9.1(c).

1.103 “Regeneron Therapeutic Molecule” means a [**].

1.104 “Regulatory Approval” means the approval, registration, license, permit, or authorization issued by the appropriate Regulatory Authority necessary to market and commercialize a pharmaceutical or biological product in a country or jurisdiction.

1.105 “Regulatory Authority” means (a) the FDA or any successor thereto; (b) the European Medicines Agency or any successor agency thereto; or (c) any other supranational, national or local agency, authority, department, inspectorate, ministry official, parliament or public or statutory person of any government of any country having jurisdiction over any of the activities contemplated by the Agreement or the Parties, or any successor bodies thereto.

1.106 “Regulatory, Support and Analytical Activities” means those activities reasonably required to support the conduct of IND-Enabling GLP Toxicology Studies and the Collaboration Clinical Trial and the preparation and filing of the IND, including statistical analysis, data collection and management, drug safety surveillance, assay development, test method development, IND-enabling characterization studies and assays, medical and protocol writing, stability testing, quality assurance/quality control development, regulatory affairs, project management and other internal and external functions reasonably necessary to be performed to initiate, conduct and complete such study, trial and filing.

1.107 “Research License” has the meaning set forth in Section 7.2.

1.108 “Research Results” means any data and results that are generated or otherwise obtained pursuant to the performance of the Collaboration Plan. For clarity, data from development activities conducted by either Party outside of the Collaboration Plan shall not be included in Research Results.

1.109 “Royalty Term” means, with respect to a Licensed Product in any country in the Territory, the longer of (a) ten (10) years from the date of First Commercial Sale of such Licensed Product in such country; (b) the term for which a Valid Claim under the [**] remains in effect and would be infringed but for the licenses granted by this Agreement by the importing, offer for sale or sale of such Licensed Product in such country; or (c) the term for which a Valid Claim under the (i) [**] or (ii) [**].

1.110 “SEC Filing” has the meaning set forth in Section 10.3(f).

1.111 “SEC Filing Comment Period” has the meaning set forth in Section 10.3(f).

1.112 “Sole Invention” has the meaning set forth in Section 9.1(c).

1.113 “Sublicensee” means a Third Party to whom Regeneron or its Affiliate shall have granted a license or sublicense under Collaborator Intellectual Property pursuant to Section 7.8.

1.114 “Supply Requirements” means Finished Product and placebo, in form and quantities required by a Party or the Parties for activities under the Collaboration Plan and Regulatory, Support and Analytical Activities, including the conduct of research, pre-clinical studies, IND Enabling GLP Toxicology Studies and the Collaboration Clinical Trial.

1.115 “Tax” means any form of tax or taxation, levy, duty, charge, social security charge, contribution, or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax Authority.

1.116 “Tax Authority” means any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs, or excise authority, body or official anywhere in the world, authorized to levy Tax.

1.117 “Technology Transfer” has the meaning set forth in Section 4.3.

1.118 “Term” has the meaning set forth in Section 14.1.

1.119 “Territory” means all countries in the world except for those countries or [**].

1.120 “Therapeutic Invention” means a Collaboration Invention [**].

1.121 “Third Party” shall mean an entity or person that is not a Party or an Affiliate of a Party.

1.122 “Third Party Claims” has the meaning set forth in Section 13.1.

1.123 “Third Party Patent Licenses” has the meaning set forth in Section 8.4(b).

1.124 “Third Party Payment Reduction” has the meaning set forth in Section 8.4(b).

1.125 “Upstream Agreement Payments” has the meaning set forth in the Incept Agreement Appendix.

1.126 “Upstream Agreements” has the meaning set forth in Section 12.8(a).

1.127 “Valid Claim” means a claim of an issued patent that has not expired or been abandoned, or been revoked, held invalid or unenforceable by a patent office, court or other Governmental Authority of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period).

ARTICLE 2
RESEARCH AND DEVELOPMENT

2.1 Performance. Each Party shall use Commercially Reasonable Efforts to perform the obligations ascribed to it under the Collaboration Plan, which is incorporated herein by reference. Each Party shall allocate such Personnel, equipment, facilities and other resources as are necessary for the performance of such obligations.

2.2 Costs. Except as expressly set forth in this Agreement or the Collaboration Plan, each Party shall be solely responsible for all internal and external costs (including Collaboration Costs) incurred by such Party in connection with this Agreement (including, with respect to Regeneron, costs incurred by Regeneron for research and pre-clinical studies to evaluate the first candidate formulation for Licensed Products). Collaborator shall reimburse Regeneron for Regeneron Reimbursable Costs in accordance with Section 8.6. For clarity, as between the Parties, except as expressly set forth in this Agreement, including in ARTICLE 4 and ARTICLE 9, all costs (including internal and external costs) incurred by Regeneron in conducting the development and commercialization of Licensed Products outside of or following the conduct of the Collaboration Plan or after the Collaboration Clinical Trial shall be the sole responsibility of Regeneron.

2.3 Collaboration Plan.

(a) The initial Collaboration Plan contains research and evaluation activities prior to the initiation of any IND Enabling GLP Toxicology Studies, as well as a summary of the scope of the IND Enabling GLP Toxicology Studies and the Collaboration Clinical Trial and an estimated budget therefor. The Collaboration Plan may only be modified by the approval of the JRC.

(b) In the event Regeneron exercises the Option, Regeneron will generate and present to the JRC in writing the proposed protocols and design for, and each Party's designated responsibilities for the conduct of, IND Enabling GLP Toxicology Studies and the Collaboration Clinical Trial for any Licensed Products that were the subject of the activities previously conducted pursuant to the Collaboration Plan. Upon approval of the JRC, such protocols and designated responsibilities shall automatically and without further action of the Parties be deemed added to the Collaboration Plan. Regeneron will be solely responsible for conducting and funding the development and commercialization of Licensed Products following the Collaboration Clinical Trial.

2.4 Alternative Licensed Products. If the first candidate formulation of a Licensed Product provided by Collaborator under the Collaboration Plan fails to meet the applicable specifications or target criteria set forth in the Collaboration Plan, then, except as otherwise mutually agreed by the Parties, Collaborator shall generate and submit to the JRC a written plan to generate an alternative Licensed Product that meets such specifications and target criteria ("Alternative Licensed Product"). If Regeneron approves such plan, then Collaborator shall generate such Alternative Licensed Product. If the first Alternative Licensed Product fails to meet the applicable specifications or criteria set forth in the Collaboration Plan, then the research and development of other Alternative Licensed Products shall be subject to the mutual

agreement of the Parties. Upon delivery of any Alternative Licensed Product(s) to Regeneron, the Collaboration Plan shall be automatically modified to apply to such Alternative Licensed Product(s) instead of the previous Licensed Product.

2.5 Use of Materials; Technology and Information. Regeneron shall not use Collaborator Material for any purpose other than for the performance of the Collaboration Plan or as otherwise permitted under this Agreement. Collaborator shall not use any Regeneron Material for any purpose other than for the performance of the Collaboration Plan or as otherwise permitted under this Agreement; and, except as expressly set forth in the Collaboration Plan, Collaborator will not administer any Regeneron Material in any animal model or for human use. Collaborator shall not use any technology, information or materials for the performance of the Collaboration Plan nor incorporate any technology, information or materials into any Licensed Product unless (a) Collaborator Controls such technology, information or materials and such use or inclusion of such technology, information or materials will not result in any payments (including any Additional Amounts) owed to any Third Party other than Incept (which payments or Additional Amounts owed to Incept are the sole responsibility of Collaborator) or (b) Regeneron consents in writing to the incorporation of such technology, information or materials as proposed by Collaborator. Following the expiration of the Option Period or any earlier termination of this Agreement, if Regeneron has not exercised the Option, then Regeneron shall return or destroy any Collaborator Material remaining in its possession, which destruction shall include, for clarity, any Licensed Product remaining in its possession. Following completion of all activities under the Collaboration Plan or any earlier termination of this Agreement, Collaborator shall return or destroy any Regeneron Material (other than any Research Results that Collaborator is entitled to continue to use under Section 10.5) remaining in its possession, and shall destroy any Licensed Product remaining in its possession.

2.6 Results and Reporting. The Parties will share Research Results through the JRC at regular intervals during the conduct of the Collaboration Plan.

2.7 Records; Inspection. Each Party shall maintain records of its work conducted under the Collaboration Plan in sufficient detail and in good scientific manner as will properly reflect all work done, Research Results achieved, and any inventions disclosed, conceived or reduced to practice in the performance of the Collaboration Plan. Each Party shall maintain such records during the term of this Agreement and for a period of [**] years thereafter.

ARTICLE 3
GOVERNANCE

3.1 Joint Research Committee. The performance of the activities described in the Collaboration Plan shall be governed by the Parties through a joint research committee ("Joint Research Committee" or "JRC").

3.2 Responsibilities. The JRC shall have the responsibility to:

- (a) oversee, review and coordinate the performance of the Collaboration Plan;
- (b) agree on any modifications to the Collaboration Plan; and
- (c) make such other decisions as are expressly allocated to the JRC under this Agreement.

The JRC shall not have any authority beyond that set forth in this Section 3.2 and, in particular, shall not have any power to amend or modify the terms or provisions of this Agreement or to determine that a Party has fulfilled or breached any obligations under this Agreement.

3.3 Membership. The JRC shall be comprised of an equal number of representatives appointed from each Party. As of the Effective Date, the number of such representatives shall be three (3) from each Party. Each representative of a Party shall have relevant expertise (either individually or collectively) in the activities described in the Collaboration Plan. Any member of the JRC may designate a qualified substitute to attend and perform the functions of a member at any meeting of the JRC. Each Party may, in its reasonable discretion, invite non-member representatives of that Party to attend meetings of the JRC as non-voting participants, subject to the confidentiality obligations under this Agreement.

3.4 Replacements. Either Party may replace its respective JRC representatives with new persons (with appropriate expertise to replace the outgoing members) at any time, with prior written notice to the other Party.

3.5 Meetings. The JRC shall meet at least once every [**] months, unless otherwise agreed by the Parties. If possible, the meetings shall be held in person or where appropriate, by video or telephone conference. Unless otherwise agreed, the location of face-to-face meetings of the JRC shall alternate between the offices of Regeneron or its Affiliates and Collaborator or its Affiliates, with the first meeting to take place at [**] offices. The meetings of the JRC shall be chaired by each Party's selected chairperson in an alternating fashion between the Parties, with [**] selected chairperson to chair the first meeting.

3.6 Decision Making. Except as otherwise provided herein, all decisions of the JRC shall be made by unanimous agreement, with each Party having one (1) vote. If the JRC cannot agree on a decision within [**] days of

any matter being referred to it for action, at the written request of either Party, the issue shall be referred to the Executive Officers of Collaborator and Regeneron, who shall meet within [**] days (in person, by means of telephone conference, videoconference or other means of communication) and attempt in good faith to resolve such issue. If the Executive Officers cannot resolve any matter within [**] days after the date such matter is first referred to them, then the decision of Regeneron's Executive Officer shall control. Notwithstanding any other provision of this Agreement to the contrary, in exercising such casting vote, Regeneron's Executive Officer shall have no power to: (a) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement; (b) modify or amend the terms and conditions of this Agreement; (c) make any determination that Collaborator has breached or that Regeneron has fulfilled its obligations under this Agreement; (d) make any decision (including any change to the Collaboration Plan) that imposes or is reasonably likely to cause a material increase in Collaborator's costs or other obligations beyond those costs and obligations included in the then-effective Collaboration Plan and this Agreement; provided that, this Section 3.6(d) shall not apply to any decision (including any decision resulting in any change to the Collaboration Plan) that imposes or is reasonably likely to cause an increase in Regeneron Reimbursable Costs payable by Collaborator under Section 8.6, and subject to the limitations of Section 8.6, so long as such decision does not also impose or is not also reasonably likely to cause Collaborator's other costs and obligations to be materially increased; (e) increase the Regeneron Reimbursable Costs Cap; (f) negate any consent rights or other rights specifically allocated to Collaborator under this Agreement; (g) require Collaborator to perform any act that it reasonably believes to be inconsistent with any Applicable Law or any approval, order, policy, guidelines of a Regulatory Authority or ethical requirements or ethical guidelines; (h) allocate intellectual property rights; or (i) resolve any matter regarding the interpretation of this Agreement or any other legal dispute.

3.7 Minutes. The Parties shall alternate responsibility for preparing and circulating minutes of JRC meetings setting forth an overview of the discussions at the meeting and a list of any actions, decisions or determinations approved by the JRC and a list of any issues to be resolved by the Executive Officers pursuant to Section 3.6, and [**] shall have the responsibility for such matters as to the first meeting. Such minutes shall be effective only after approval by both Parties. The Parties shall promptly discuss any matters arising from the minutes and finalize the minutes no later than the date of the next meeting of the JRC.

3.8 Expenses. Collaborator and Regeneron shall each bear all expenses of its JRC members related to their participation in the JRC and attendance at JRC meetings.

3.9 Disbanding. The JRC shall be disbanded upon the completion of the activities set forth in the Collaboration Plan.

ARTICLE 4
MANUFACTURING

4.1 Manufacturing Support; Collaboration Supply. Collaborator shall be responsible for the production and supply to Regeneron, using Bulk Product supplied to Collaborator by Regeneron, of the Supply Requirements. Within [**] days following the Effective Date (or such other mutually agreed timeframe), the Parties shall execute a definitive supply agreement and GMP quality agreement in connection with the manufacture and supply of the Supply Requirements. Supply Requirements shall meet the specifications set forth in such agreements. Collaboration Costs for the manufacture and supply of the Supply Requirements shall be borne solely by Collaborator; provided that Regeneron shall be responsible for Collaboration Costs for the manufacture of Bulk Product in sufficient quantities for Collaborator to generate Supply Requirements.

4.2 Clinical and Commercial Supply. Regeneron shall in good faith discuss with Collaborator the possibility of engaging Collaborator for the manufacture and supply of Licensed Product for clinical development and commercial use outside of the Collaboration Plan; provided that Collaborator's manufacturing capabilities, processes and quality meet Regeneron's clinical, regulatory, commercial and quality requirements for the clinical and commercial supply of Licensed Product.

4.3 Technology Transfer. Upon Regeneron's request, Collaborator shall, at Regeneron's expense, provide a second-source manufacturer selected by Regeneron and reasonably acceptable to Collaborator with all Collaborator Know-How and materials, as well as, at Regeneron's expense, reasonable and timely assistance, as reasonably necessary to enable such second-source manufacturer to manufacture Collaborator Technology and to formulate Collaboration Therapeutic Molecule drug product with Collaborator Technology (the "Technology Transfer"), in each case, in order to complete clinical and commercial process development and engage in commercial manufacture and supply of Licensed Products that contain a Collaboration Therapeutic Molecule to Regeneron, its Affiliates or its or their Sublicensees. Notwithstanding the foregoing, if such a Technology Transfer is necessary due to any failure of Collaborator to manufacture or supply such Licensed Product in accordance with mutually agreed clinical, regulatory, commercial and quality requirements under a binding manufacture or supply agreement between the Parties, then the Technology Transfer shall be performed at Collaborator's sole cost and may be performed directly to Regeneron. After the Technology Transfer to Regeneron or any second-source manufacturer, Regeneron shall be responsible, at its sole expense, for the manufacture and supply of such Licensed Products.

ARTICLE 5
REGULATORY AFFAIRS

5.1 Regulatory Matters. Regeneron shall be responsible for, and shall have the decision-making authority in respect of, preparing, prosecuting and maintaining in its name, all filings, applications, submissions, correspondence and other communications with Regulatory Authorities, INDs, BLAs and any Regulatory Approvals for Licensed Products in the Field. As between Regeneron and Collaborator, Regeneron shall own, in their entirety, (a) all clinical data and reports related to any Licensed Product, including those arising from clinical trials conducted for any Licensed Product, and (b) all Regulatory Approvals and applications therefor, including INDs, BLAs, approvals and applications. Notwithstanding the foregoing, Regeneron shall not undertake any of the activities described in this Section 5.1 prior to its exercise of the Option, without Collaborator's prior written consent, such consent not to be unreasonably withheld.

5.2 Regulatory Cooperation; Right of Reference. Collaborator shall reasonably cooperate with Regeneron or its Affiliates (including for the benefit of Regeneron's or any of its Affiliate's Sublicensees), at Regeneron's expense, in the responsibilities described above in Section 5.1, including filing drug master files Controlled by Collaborator or its Affiliates relating to Collaborator Technology with Regulatory Authorities in the Territory. Collaborator agrees to provide a letter of authorization to permit Regeneron, its Affiliates or, upon Regeneron's request, its or their Sublicensees, to access and utilize such drug master files for use solely in connection with the development, manufacture or commercialization of Licensed Products. Collaborator shall provide Regeneron or its Affiliates (including for the benefit of Regeneron's or any of its Affiliate's Sublicensees) with such other information (or, to the extent the access and utilization of a drug master file is not legally permitted in any jurisdiction in the Territory, all information) reasonably available to Collaborator specifically relating to Collaborator Technology that is reasonably requested by Regeneron or its Affiliates (including for the benefit of Regeneron's or any of its Affiliate's Sublicensees) in connection with any regulatory submission for Regulatory Approval of any Licensed Product, including to the extent necessary to resolve issues or answer questions raised by the applicable Regulatory Authority. Collaborator hereby grants Regeneron and its Affiliates a non-exclusive, sublicensable "right of reference" (as defined in 21 C.F.R. § 314.3(b)) to any of Collaborator's filings with any Regulatory Authority in order for any of Regeneron, its Affiliates or its or their Sublicensees to prepare, submit and maintain its own filings with any Regulatory Authority for any Licensed Product. Notwithstanding the foregoing, Regeneron agrees to (i) limit disclosed information relating to Collaborator Technology to only information that Regeneron (or such Affiliate or Sublicensee), in its reasonable discretion, deems to be required by the applicable Regulatory

Authority for such submissions, issues or questions or to obtain or maintain Regulatory Approvals, and (ii) to inform Collaborator prior to making any such disclosures and seek, and cooperate with Collaborator in seeking, a protective order, confidential treatment or other appropriate remedy (including redaction) to avoid and minimize public disclosure of such information relating to Collaborator Technology that is not then publicly available.

ARTICLE 6
PERFORMANCE STANDARDS

6.1 Affiliates. Each Party may carry out its obligations under this Agreement through its Affiliates and absolutely, unconditionally and irrevocably guarantees to the other Party prompt performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, neither Party shall cause or permit any Affiliate of such Party to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly and each Party shall be responsible under this Agreement for the acts, omissions and performance of its Affiliates performing work under this Agreement to the same extent it would if it had done such work itself.

6.2 Subcontracts. Each Party may perform any of its obligations under this Agreement through one or more subcontractors, provided that (a) the subcontracting Party remains responsible for the work allocated to, and payment to, such subcontractors as it selects to the same extent it would if it had done such work itself; (b) the subcontractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information, that are substantially the same as those undertaken by the Parties pursuant to ARTICLE 10 hereof; and (c) the subcontractor agrees in writing to assign all inventions and intellectual property developed in the course of performing any such work under the Collaboration Plan or otherwise under this Agreement to the Party retaining such subcontractor, or as otherwise required under this Agreement and upon request to sign any documents to confirm or perfect such assignment and to cooperate in the preparation and prosecution of any such inventions. A Party may also subcontract work on terms other than those set forth in this Section 6.2, with the prior written approval of the other Party.

ARTICLE 7
OPTION AND LICENSES; EXCLUSIVITY AND DILIGENCE

7.1 Research License Grant by Regeneron. Regeneron grants to Collaborator a non-exclusive, worldwide, sublicensable (solely to subcontractors retained in accordance with Section 6.2), royalty-free license during the Term, under and to the Regeneron Intellectual Property, solely for the purpose of the performance of Collaborator's obligations under the Collaboration Plan. The foregoing license shall expire upon completion of all activities under the Collaboration Plan.

7.2 Research License Grant by Collaborator. Collaborator grants to Regeneron a non-exclusive, worldwide, royalty-free, sublicensable (in accordance with Section 7.8), license during the Term, under and to the Collaborator Intellectual Property, solely for the purpose of the performance of Regeneron's activities included under the Collaboration Plan (or necessary to perform such activities) and Regulatory, Support and Analytical Activities (the "Research License"). The Research License shall expire upon expiration of the Option Period.

7.3 Pre-Option Exclusivity. During the Exclusive Option Period, neither Collaborator nor any of its Affiliates shall, [**].

7.4 Option. Collaborator hereby grants to Regeneron an option (the "Option") to enter into the Commercial License. The Option shall be exercisable by Regeneron at any time during the Option Period, by notifying Collaborator of such exercise in writing and paying the fee set forth in Section 8.1. During the Exclusive Option Period, the Option shall be exclusive, meaning that Regeneron shall have the sole right to exercise the Option and enter into the Commercial License and Collaborator shall not grant to any Third Party during such period any option, license or other rights that would limit or prohibit Collaborator's ability to grant the Commercial License to Regeneron. During the Non-Exclusive Option Period, the Option shall be non-exclusive, meaning that the Option shall terminate and not be available for exercise upon Collaborator entering into an agreement with a Third Party during the Non-Exclusive Option Period that would prevent it from granting the Commercial License to Regeneron (a "Conflicting Agreement"). During the Non-Exclusive Option Period, if Collaborator receives any good faith, bona-fide written proposal for a Conflicting Agreement (whether set forth in a term sheet, letter of intent, memorandum of understanding, or similar document) from any Third Party, then Collaborator shall notify Regeneron of such events in writing and Regeneron shall have the opportunity (which shall be no less than [**] days) to exercise the Option.

7.5 Commercial License. Upon exercise of the Option, Collaborator grants to Regeneron an exclusive (even as to Collaborator), sublicensable (through multiple tiers and in accordance with Section 7.8) license under the Collaborator Intellectual Property to research, develop, make (and have made), use, sell, offer for sale, and import Licensed Products in the Field in the Territory (the "Commercial License"). [**].

7.6 Post-Option Period Exclusivity. In the event Regeneron exercises the Option, neither Collaborator nor any of its Affiliates will, [**]; provided that, Collaborator shall [**] of this Section 7.6 [**]. In the event of any Change of Control of Collaborator, the foregoing covenant by Collaborator

and its Affiliates will not apply to a Competing Product that is in advanced pre-clinical development (i.e., at least at the state where a lead clinical candidate has been identified), clinical development, subject to an IND filing, under review for Regulatory Approval or being commercialized by a Third Party described in the definition of “Change of Control,” or such Third Party’s Affiliates (other than an Affiliate of Collaborator prior to the Change of Control), prior to the closing of such Change of Control (such Competing Product, an “Acquirer Competing Product”); provided that (i) Collaborator[**] in connection with this Agreement and [**] pursuant to this Agreement. [**] this Section 7.6[**] of this Section 7.6.

7.7 Diligence. Following the exercise of the Option, Regeneron shall use Commercially Reasonable Efforts to research, develop and commercialize at least one Licensed Product. For purposes of this Section 7.7, Commercially Reasonable Efforts shall be deemed not to have been met by Regeneron if the first dose of a Licensed Product in the first clinical trial after the Collaboration Clinical Trial has not occurred by the earlier of (a) [**] after completion of the Collaboration Clinical Trial for such Licensed Product or (b) [**] after the initiation of IND Enabling GLP Toxicology Studies for such Licensed Product; provided that, the time periods in subclauses (a) and (b) above shall be (i) extended and shall not expire if and for so long as Regeneron has not ceased research and development of all Licensed Products without plans to resume such activities with respect to at least one Licensed Product within the succeeding [**] and (ii) tolled during any period of time that any clinical trial for a Licensed Product is ceased or delayed due to (1) communications from a Regulatory Authority or (2) development of a delivery device intended for commercial Licensed Product that is to be used to in a clinical trial for such Licensed Product; provided that Regeneron is using commercially reasonable efforts to resume such clinical trial or develop such device, as applicable. Commercially Reasonable Efforts shall apply on a Territory-wide basis and not on a country-by-country or jurisdiction-by-jurisdiction basis, meaning that the failure to use Commercially Reasonable Efforts to develop or commercialize a Licensed Product in a particular country shall not be deemed a breach of this Section 7.7, unless such failure amounts to a failure to use Commercially Reasonable Efforts in the Territory as a whole. Within [**] days after filing of a BLA for a Licensed Product, and at least [**] thereafter, the Parties shall meet and Regeneron shall provide Collaborator with a summary and update of commercialization activities and plans.

7.8 Sublicensing by Regeneron. Regeneron shall have the right, in its reasonable discretion, to sublicense the Research License to its wholly-owned Affiliates and the Commercial License to its Affiliates and any Third Party, through multiple tiers. Regeneron shall remain liable for any breach of this Agreement by its Sublicensees and Affiliates.

ARTICLE 8
FINANCIAL TERMS

8.1 Option Exercise Fee. Within [**] days of the exercise of the Option, Regeneron shall pay to Collaborator Ten Million Dollars (\$10,000,000).

8.2 Milestone Payments. Regeneron shall notify Collaborator of the achievement by Regeneron, its Affiliate or Sublicensee of each milestone event set forth in Section 8.2.1 or 8.2.2 below and shall pay Collaborator the corresponding milestone payment within [**] days after such achievement; provided that, if the First Development Milestone is achieved, but not pursuant to the proviso in the definition of "First Development Milestone" (i.e., [**]), then Regeneron, in its sole discretion, may elect either to pay or not to pay the First Development Milestone, and the notice described in this Section 8.2 shall include such election. If Regeneron elects not to pay the First Development Milestone, then Collaborator shall have the right to terminate this Agreement pursuant to Section 14.2.4.

8.2.1 Development Milestones. Subject to the proviso in Section 8.2, Regeneron shall pay to Collaborator the milestone payments described in this Section 8.2.1 upon achievement (first occurrence) of the corresponding milestone event on a Licensed Product-by-Licensed Product basis (i.e., payable for each Licensed Product that achieves such milestone).

<u>Development Milestone Event</u>	<u>Milestone Payment</u>
First Development Milestone	[**] Dollars (\$[**])
[**]	[**] Dollars (\$[**])
[**]	[**] Dollars (\$[**])
The First Commercial Sale of a Licensed Product	One Hundred Million Dollars (\$100,000,000)

Each milestone payment payable by Regeneron pursuant to this Section 8.2.1 shall be payable only once for each Licensed Product; provided that, if any Licensed Product achieves any development milestone event and the development or commercialization of such Licensed Product is subsequently ceased and another Licensed Product Directed to the same Licensed Target as the ceased Licensed Product is substituted for such ceased Licensed Product, then, with respect to the substitute Licensed Product, payments for the achievement of the same milestone events that were achieved by such ceased Licensed Product and paid by Regeneron shall not be payable. In addition, if for any reason a milestone event corresponding to a milestone payment in the table above does not occur prior to the occurrence of the next sequential milestone event in the table above (e.g., [**]), then such prior non-occurring milestone event shall be deemed to occur concurrently with the occurrence of such next sequential milestone event.

[**].

8.2.2 Sales Milestones. Regeneron shall pay to Collaborator the milestone payments described in this Section 8.2.2 upon achievement (first occurrence) of the corresponding sales milestone event.

<u>Sales Milestone Event</u>	<u>Milestone Payment</u>
The first occasion that aggregate annual Net Sales of all Licensed Products in a calendar year in the Territory exceed [**] Dollars (\$[**])	[**] Dollars (\$[**])
The first occasion that aggregate annual Net Sales of all Licensed Products in a calendar year in the Territory exceed [**] Dollars (\$[**])	[**] Dollars (\$[**])

Each milestone payment payable by Regeneron pursuant to this Section 8.2.2 shall be payable only once for all Licensed Products. If for any reason a sales milestone event corresponding to a milestone payment in the table above does not occur prior to the occurrence of the next sequential milestone event in the table above (e.g., aggregate annual Net Sales for all Licensed Products in a calendar year exceeds \$[**], but the milestone for annual Net Sales exceeding \$[**] was not previously paid), then such prior non-occurring milestone event shall be deemed to occur concurrently with the occurrence of such next sequential milestone event.

8.3 Royalties. Regeneron shall pay to Collaborator, on a Licensed Product-by-Licensed Product basis, a royalty on the Net Sales of each Licensed Product in the Territory as described in this Section 8.3. A royalty shall only be payable on Net Sales of a Licensed Product in any country in the Territory that occur during the Royalty Term for such Licensed Product in such country.

(a) A royalty in the amount of [**] percent ([**]%) on the portion of Net Sales that occur in the Territory less than or equal to [**] Dollars (\$[**]) within a calendar year.

(b) A royalty in the amount of [**] percent ([**]%) on the portion of Net Sales that occur in the Territory over [**] Dollars (\$[**]) but less than or equal to [**] Dollars (\$[**]) within a calendar year.

(c) A royalty in the amount of [**] percent ([**]%) on the portion of Net Sales that occur in the Territory over [**] Dollars (\$[**]) but less than or equal to [**] Dollars (\$[**]) within a calendar year.

(d) A royalty in the amount of [**] percent ([**]%) on the portion of Net Sales that occur in the Territory over [**] U.S. Dollars (\$[**]) within a calendar year.

8.4 Royalty Reductions & Adjustments.

(a) In the event that Net Sales of a Licensed Product occur in any country during the Royalty Term, but in a period when no Valid Claim exists in such country under (i) the [**] that, but for the licenses granted by this Agreement, would be infringed by the importing, selling or offering for sale of such Licensed Product in such country or (ii) [**] that remains in effect and Covers the importing, offer for sale or sale of such Licensed Product in such country, then the royalty rate for royalties payable to Collaborator under Section 8.3 with respect to such Net Sales shall be reduced by [**] percent ([**]%).

(b) In the event that Regeneron enters into one or more Patent licenses from any Third Party in order to make, use, sell, offer for sale or import a Licensed Product in any country in the Territory and such license is [**] (hereinafter "Third Party Patent Licenses"), then [**] percent ([**]%) of [**] ("Third Party Payment Reduction") shall be creditable against the royalty payments due to Collaborator based on Net Sales of such Licensed Product in such country under Section 8.3; provided, however, that no such credit may reduce any royalty payment by more than [**] percent ([**]%) of the royalty payment that would have been due absent this Section 8.4(b).

(c) In the event that any Third Party sells a Competing Product to any Licensed Product in any country in the Territory without the approval of, or the grant of a license from, Regeneron: (i) at the time of [**], then the royalty rate for royalties payable to Collaborator under Section 8.3 for Net Sales of the applicable Licensed Product shall be reduced by [**]%; or (ii) at any subsequent time and, following the first commercial sale of such Competing Product in such country, [**], the royalty rate for royalties payable to Collaborator under Section 8.3 for Net Sales of the applicable Licensed Product in such country shall be reduced by [**] percent ([**]%).

(d) If, in any Calendar Quarter any of the royalty reductions described in Sections 8.4(a), 8.4(b) or 8.4(c) apply in one or more but not all countries in the Territory and Net Sales in the Territory in such Calendar Quarter exceed one or more of the royalty percentage tiers described in Section 8.3, then such royalty reductions shall be applied to Net Sales in each such percentage tier in the same proportion as (i) the Net Sales to which such royalty reductions apply bear to (ii) the aggregate Net Sales subject to royalty payments in such Calendar Quarter.

(e) In no event shall the royalties paid by Regeneron to Collaborator in any Calendar Quarter be reduced pursuant to Sections 8.4(a), 8.4(b) and/or 8.4(c) to less than [**] percent ([**]%) of the amounts that would be owed in the absence of such reductions. [**].

8.5 Royalty Reports and Payments. Commencing with the Calendar Quarter in which the First Commercial Sale of a Licensed Product by Regeneron its Affiliates or Sublicensees occurs, until the Calendar Quarter in which the expiration of the Royalty Term for all Licensed Products in the Territory occurs, Regeneron shall make written reports to Collaborator within [**] days after the end of each such Calendar Quarter, stating in each such report the Net Sales in Dollars of each Licensed Product sold during such Calendar Quarter by Regeneron, its Affiliates or Sublicensees and the calculation of royalty payments due to Collaborator on such Net Sales. Regeneron shall pay to Collaborator the total royalties, if any, due for the

period of the report required in this Section 8.5, within [**] days following delivery of such report. If no royalties are due, Regeneron shall so report. An example of the report required by this Section 8.5, including examples of the calculation of royalties and royalty reductions, is set forth in the Royalty Calculation Appendix attached hereto.

8.6 Regeneron Reimbursable Cost Reporting and Reimbursement. For each Calendar Quarter commencing with the first Calendar Quarter in which Regeneron Reimbursable Costs are incurred by Regeneron, Regeneron shall provide to Collaborator within [**] days following the end of each such Calendar Quarter a written report (in electronic form) summarizing the material activities undertaken by Regeneron during such Calendar Quarter together with a statement of the corresponding Regeneron Reimbursable Costs incurred by Regeneron during such Calendar Quarter. Within [**] days following the delivery of the report required by this Section 8.6, Collaborator shall pay to Regeneron the total undisputed amount of Regeneron Reimbursable Costs specified in such report. Notwithstanding the foregoing, Collaborator shall not be obligated to pay Regeneron Reimbursable Costs if and to the extent such payment would result in the aggregate amount of Collaborator's payments under this Section 8.6 to exceed the Regeneron Reimbursable Costs Cap.

8.7 Audit Rights. Collaborator shall have the right to audit Regeneron's and its Affiliates' records relating to royalty reports and Regeneron Reimbursable Cost reports at Collaborator's own expense, but only to the extent such records are reasonably required to verify the royalties or Regeneron Reimbursable Costs payable under this Agreement. Collaborator shall have the right to engage an independent, certified, internationally-recognized public accounting firm reasonably acceptable to Regeneron to inspect Regeneron's relevant records; provided, however, that such auditor shall not disclose Regeneron's Confidential Information to Collaborator, except to the extent such disclosure is necessary to verify the amount of royalties or Regeneron Reimbursable Costs due under this Agreement. Collaborator may exercise such inspection right upon reasonable advance notice to Regeneron and only during normal business hours during the term of this Agreement and within [**] years after its termination or expiration. Such inspections may be exercised [**], within [**] years after the applicable payment was made to which such records relate, and any data and information relating to any particular payment shall be audited only once. Any amounts shown to be owing by any such audit by one Party to the other shall be paid promptly, together with interest calculated as set forth in Section 8.9. If any audit reveals an underpayment or overcharge by Regeneron that exceeds [**] percent ([**]%) of the amount actually due to or payable by Collaborator in respect of any Calendar Quarter, then Regeneron shall pay Collaborator's expenses for the audit in addition to the underpaid or overcharged amount.

8.8 Payments. All payments under this Agreement shall be made in U.S. Dollars by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. In those cases where the amount due in U.S. Dollars is calculated based upon one or more currencies other than U.S. Dollars, such amounts shall be converted to U.S. Dollars at the average rate of exchange for the Calendar Quarter to which such payment relates using the arithmetic mean of the daily rate of exchange (Mid Price Close), as reported in *Thomson Reuters Eikon*, or any other source as agreed to by the Parties.

8.9 Late Payments. The paying Party shall pay interest to the other Party on the aggregate amount of any payment that is not paid on or before the date such payment is due under this Agreement at a rate equal to the one month London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted on *Thomson Reuters Eikon*, or any other source as agreed to by the Parties, effective from the date on which the payment was due, [**] unless such payments are disputed in good faith. The Parties agree that if there is a good faith dispute regarding any payment amount, (a) only the disputed amount shall be withheld from the payment and the undisputed amount shall be paid within the timeframes set forth in this ARTICLE 8 and (b) this provision shall not apply to such disputed amount during the pendency of such dispute.

8.10 Tax. Regeneron will make all payments to Collaborator under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding for Taxes is required by Applicable Laws. Any Tax required to be withheld under Applicable Laws on amounts payable to Collaborator under this Agreement will promptly be paid by Regeneron on behalf of Collaborator to the appropriate Governmental Authority, and Regeneron will furnish Collaborator with proof of payment of such Tax as soon as practicable. Any such Tax required to be withheld will be an expense of and borne by Collaborator. The Parties will cooperate to secure a reduction in the rate of applicable Taxes withheld. Regeneron will make payments to Collaborator under this Agreement from an entity domiciled in the United States, Ireland, or any jurisdiction that does not require withholding for payments to the United States.

ARTICLE 9 INTELLECTUAL PROPERTY

9.1 Ownership of Newly Created Intellectual Property. Collaboration Inventions shall be owned as set forth in this Section 9.1.

- (a) Collaborator shall solely own all Collaborator Technology Inventions, regardless of inventorship.
- (b) Regeneron shall solely own all Therapeutic Inventions, regardless of inventorship.

(c) With regards to Collaboration Inventions that are neither Collaborator Technology Inventions nor Therapeutic Inventions (“Other Collaboration Inventions”), as between the Parties, each Party shall solely own all such Other Collaboration Inventions and intellectual property rights therein (including Know-How, Patents and copyrights) that are conceived or made solely by employees, sublicensees, independent contractors, agents or consultants of such Party or its Affiliates, or other individuals having an obligation to assign such Other Collaboration Inventions solely to such Party or its Affiliates or for which ownership vests in such Party or its Affiliates by operation of law (such employees, sublicensees, independent contractors, agents, consultants or other individuals, “Personnel,” and such Other Collaboration Inventions, “Sole Inventions”). Sole Inventions conceived or made solely by Personnel of Collaborator or its Affiliates or for which ownership vests in Collaborator or its Affiliates by operation of law are referred to herein as “Collaborator Sole Inventions.” Sole Inventions made solely by Personnel of Regeneron or its Affiliates or for which ownership vests in Regeneron or its Affiliates by operation of law are referred to herein as “Regeneron Sole Inventions.”

(d) With regards to Other Collaboration Inventions that are conceived or made jointly by Personnel of Collaborator or its Affiliates or for which ownership vests in Collaborator or its Affiliates by operation of law, on the one hand, and by Personnel of Regeneron or its Affiliates or for which ownership vests in Regeneron or its Affiliates by operation of law, on the other hand, the Parties shall jointly own all such inventions and intellectual property rights therein (including Know-How, Patents and copyrights), with each Party having an equal, undivided interest therein (“Joint Inventions”).

(e) Inventorship of Collaboration Inventions shall be determined in accordance with United States patent laws.

(f) To the extent that (i) any right, title or interest in or to any Collaboration Invention vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement or (ii) [**], then such Party (or its Affiliate) shall, and hereby does, irrevocably assign to the other Party such of its right, title and interest in and to such Collaboration Invention or [**], and all intellectual property rights therein and thereto, to the other Party to the extent required to effect the foregoing ownership principles without the need for any further action by any Party.

(g) Each Party shall have an equal, undivided interest in Joint Inventions, which may be sublicensed to Third Parties, and any ownership rights therein may be transferred, in whole or in part, by each Party without consent of the other Party, unless otherwise prohibited by this Agreement and subject to any licenses thereunder granted under this Agreement; provided, however, that [**] nothing in this ARTICLE 9 shall relieve a Party or its Affiliates of their obligations under ARTICLE 10 with respect to Confidential Information of any Party provided by the other Party or such other Party’s Affiliates. Neither Party hereto shall have the duty to account to the other Party for any revenues, profits or rights obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, a Joint Invention outside the scope of this Agreement. To the extent necessary to effect the intent of this Section 9.1(g), each Party grants to the other Party a nonexclusive, royalty-free, worldwide, sublicensable license under such Party’s interest in Joint Inventions, and all intellectual property rights therein, to make, use, sell, offer for sale and import the relevant Joint Invention, for all purposes.

9.2 Prosecution and Maintenance of Patents.

(a) Subject to this Section 9.2, (i) Collaborator, at its own expense, shall have the right to prepare, file, prosecute and maintain Patents claiming Collaborator Technology Inventions and Collaborator Sole Inventions, (ii) Regeneron, at its own expense, shall have the right to prepare, file, prosecute and maintain Patents claiming Therapeutic Inventions and Regeneron Sole Inventions and (iii) Regeneron, [**], shall have the right to prepare, file, prosecute and maintain the Joint Patents.

(b) Subject to Section 9.2(c), Collaborator, by counsel it selects, shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain the Collaborator Patents in the countries mutually agreed upon by the Parties. Collaborator shall keep Regeneron reasonably informed regarding the status of such activities. Collaborator shall have the sole right to make any final decisions regarding the filing, prosecution and maintenance of the Collaborator Patents, subject to Section 9.2(c). [**].

(c) In the event that Collaborator desires to abandon, withdraw or otherwise discontinue the maintenance or prosecution of any Collaborator Patent in the Territory, Collaborator shall provide reasonable prior written notice to Regeneron of such intention (which notice shall, in any event, be given no later than [**] days prior to the next deadline for any action that may be taken with respect to such Patent with the applicable patent office). Regeneron shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Collaborator's name [**].

(d) Subject to Section 9.2(e), Regeneron, [**], in consultation with Collaborator, shall be responsible for the preparation, filing, prosecution and maintenance of the Joint Patents. Regeneron shall provide Collaborator with [**]. Regeneron shall [**]. Collaborator and Regeneron shall [**]; provided if they do [**], Regeneron shall have [**]. Regeneron shall [**]; provided that Regeneron shall not amend or cancel any claim that would materially affect the scope of any Joint Patents (including substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent, abandoning any such Joint Patent, withdrawing any such Joint Patent, disclaiming any term of such Joint Patent, or not filing or perfecting the filing of any such Joint Patent in any country) without the prior written consent of Collaborator (provided that, if Collaborator [**], Collaborator shall [**], except that Regeneron [**] pursuant to this Section 9.2(d).

(e) In the event that Regeneron desires to abandon, withdraw or otherwise discontinue the maintenance or prosecution of any Joint Patent in the Territory, Regeneron shall provide reasonable prior written notice to Collaborator of such intention (which notice shall, in any event, be given no later than [**] days prior to the next deadline for any action that may be taken with respect to such Patents with the applicable patent office) and Collaborator shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in the Parties' names [**].

(f) If Collaborator desires to file a patent application that includes the [**], then Collaborator shall [**] Regeneron, at least [**] days prior to the anticipated filing date, [**].

- (i) In the event Collaborator desires to file a patent application, in accordance with Collaborator's rights under this Agreement, [**], Collaborator shall [**] Regeneron, at least [**] days prior to the anticipated filing date, [**]. In the event that, during such [**] day period, Regeneron [**] Collaborator that such patent application [**], then Collaborator shall, [**], and Collaborator and Regeneron shall [**]. For clarity, Collaborator shall [**].
- (ii) In the event Regeneron desires to file a patent application, in accordance with Regeneron's rights under this Agreement, [**], Regeneron shall [**] Collaborator, at least [**] days prior to the anticipated filing date, [**]. In the event that, during such [**] day period, Collaborator [**] Regeneron that such patent application [**], then Regeneron shall, [**], and Collaborator and Regeneron shall [**]. For clarity, Regeneron shall [**].

(g) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Patents pursuant to this Section 9.2, including the execution of all such documents and instruments and the performance of such acts (and causing its relevant Personnel to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Patents, including those Patents either Party has elected not to pursue as provided for in Sections 9.2(c) and (e).

9.3 Administrative Patent Proceedings.

(a) Each Party shall notify the other within [**] days of receipt by such Party of information concerning the request for, or filing or declaration of, any reissue, re-examination, post-grant review, inter partes review, interference, opposition, derivation proceeding or supplemental examination or other administrative proceeding relating to [**]. The Parties shall thereafter [**]. Subject to Section [**], as applicable, and [**], by Collaborator [**]. Collaborator and Regeneron shall [**], in which case the [**]. In the [**]. Collaborator shall [**]. Neither Party shall [**].

(b) When any proceeding under Section 9.3(a) involves Patents involved in an Infringement Action under Section 9.4, any decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding shall be made by the Party controlling such Infringement Action, in consultation with the other Party[**].

9.4 Third Party Infringement.

(a) Each Party shall promptly report in writing to the other Party during the Term any known or suspected infringement by a Third Party of [**] in the Field, in each case of which such Party becomes aware and shall provide the other Party with all evidence supporting or relating to such infringement in its possession. In the event either Party initiates a proceeding pursuant to this Section 9.4, the other Party shall cooperate fully and provide all assistance reasonably requested by the initiating Party, including [**]

- (b) [**].
- (c) Each of the Parties [**].
- (d) Except as set forth in Section 9.4(d), Collaborator shall have [**] as Collaborator, [**].
- (e) If Collaborator [**], or if Collaborator [**], then Regeneron may [**]. Regeneron shall thereafter [**]; provided, however, that Regeneron shall [**]. Notwithstanding the foregoing, if a Regeneron [**], then (i) the Parties will [**], Regeneron shall [**].
- (f) Subject to Section 9.4(f), Regeneron shall [**]. The Parties shall [**].
- (g) If Regeneron [**], or if Regeneron otherwise [**], then Collaborator may thereafter [**]. Collaborator shall thereafter have [**].
- (h) The Party [**] in accordance with this Section 9.4, then, after [**].
- (i) In the event a Party [**] in accordance with this Section 9.4, the other Party shall [**].
- (j) Notwithstanding anything in this Section 9.4 to the contrary, [**] in accordance with this Section 9.4 shall [**].

9.5 Incept Agreement. Within [**] days following the Effective Date (or within such other timeframe mutually agreed to by the Parties), Regeneron and Incept shall enter into a separate agreement that includes provisions described in the Incept Agreement Appendix.

ARTICLE 10 CONFIDENTIALITY

10.1 Non-use and Non-disclosure of Confidential Information. During the Term, and for a period of [**] years thereafter, a Party shall (a) except to the extent permitted by this Agreement or for the exercise of rights permitted by this Agreement or otherwise agreed to in writing with the other Party, keep confidential and not disclose to any Third Party any Confidential Information of the other Party; (b) except in connection with activities contemplated by this Agreement or the exercise of rights permitted by this Agreement or in order to further the purposes of this Agreement or as otherwise agreed to in writing with the other Party, not use for any purpose any Confidential Information of the other Party; and (c) take all reasonable precautions to protect the Confidential Information of the other Party (including precautions consistent with those a Party employs with respect to its own confidential information of a similar nature and in no event less than reasonable precautions to assure that no unauthorized use or disclosure is made by others to whom access to the Confidential Information of the Party is granted). Confidential Information includes “Confidential Information” under

the Prior Agreements and, beginning on the Effective Date, this ARTICLE 10 shall govern such information and shall supersede the confidentiality and non-use provisions of the Prior Agreements.

10.2 Exclusions Regarding Confidential Information. Notwithstanding anything set forth in this ARTICLE 10 to the contrary, the obligations of Section 10.1 shall not apply to information to the extent that such information:

- (a) was already known to the receiving Party, other than under an obligation of confidentiality to the other Party or its Affiliates, at the time of receipt by the receiving Party, as demonstrated by the receiving Party's written records;
- (b) was generally available to the public or otherwise part of the public domain at the time of its receipt by the receiving Party;
- (c) became generally available to the public or otherwise part of the public domain after its receipt by the receiving Party other than through any act or omission of the receiving Party in breach of this Agreement;
- (d) was received by the receiving Party from a Third Party who the receiving Party does not know to be under an obligation of confidentiality to the disclosing Party with respect to such information;
- (e) was independently developed by or for the receiving Party without use of or reference to the Confidential Information of the other Party, as demonstrated by the receiving Party's written records; or
- (f) was released from the restrictions set forth in this Agreement by express prior written consent of the disclosing Party.

10.3 Authorized Disclosures of Confidential Information. Notwithstanding the foregoing, a Party may use and disclose the Confidential Information of the other Party as follows:

- (a) to the extent required by law, rule, governmental regulation or request from a Governmental Authority, including as may be required in connection with any filings made with, or by the disclosure policies of, a major stock exchange; provided that the Party seeking to disclose the Confidential Information of the other Party shall (i) use all reasonable efforts to inform the other Party prior to making any such disclosures and cooperate with the other Party in seeking a protective order or other appropriate remedy (including redaction) and (ii) whenever possible, request confidential treatment of such information;
- (b) subject to Sections [**] and [**], to the extent such use and disclosure is reasonably required in the filing, prosecution, maintenance or publication of any patent application or patent on inventions;

(c) as reasonably necessary to obtain or maintain any Regulatory Approval, including to conduct preclinical studies and clinical trials and for pricing approvals, for Licensed Products, provided that the receiving Party shall take all reasonable steps to limit disclosure of the Confidential Information outside the applicable Regulatory Authority and to otherwise maintain the confidentiality of the Confidential Information in accordance with this Agreement;

(d) in a legal proceeding to enforce compliance with the terms and conditions of this Agreement;

(e) to the extent necessary, to Affiliates, employees, consultants, agents, professional advisors (including, attorneys, accountants and actual and prospective investment bankers), attorneys, contractors, and clinicians and to actual or potential Sublicensees, licensees, collaborators, vendors, acquirers, merger partners and sources of financing, in each case, under obligations of confidentiality at least as restrictive as those used by the receiving Party to protect its own proprietary or confidential information, but no less restrictive than standard practice in the biotechnology industry, in each case who have a need to know such information (i) in connection with such Party performing its obligations or exercising its rights under this Agreement or, (ii) with respect to actual or potential acquirers, merger partners and sources of financing only, for the purpose of evaluating and entering into a transaction with such party; or

(f) a Party may disclose the existence and terms of this Agreement where required, as reasonably determined by the legal counsel of the disclosing Party, by Applicable Law or by applicable stock exchange regulation, although, to the extent practicable, the other Party shall, subject to the next sentence of this Section 10.3(f), be given at least [**] Business Days' advance written notice of any such required disclosure to comment and the disclosing Party shall reasonably consider such comments provided by such other Party on the proposed disclosure. In case either Party is obliged to publicly disclose or file this Agreement as a "material agreement" in accordance with Applicable Law or applicable stock exchange regulations ("SEC Filing"), this Agreement shall be redacted by the filing Party to the extent permissible upon the advice of legal counsel, and the filing Party shall provide the other Party a copy of such redacted Agreement as soon as reasonably available prior to the date of filing, but in no event later than [**] Business Days in advance of such SEC Filing to enable the other Party to review and comment on the scope of such redaction (such [**] Business Day period, the "SEC Filing Comment Period"). The filing Party shall consider the comments of the reviewing Party in good faith. The filing Party shall not be obligated to accept comments contrary to the advice of its legal counsel. With respect to any comments of the reviewing Party made prior to the expiration of the first [**] days of the SEC Filing Comment Period, (a) the filing Party shall promptly notify the reviewing Party of any unaccepted comments and (b) the filing Party shall make a member of its senior management (senior vice president or above, and having decision-making authority over the content of the SEC Filing) and securities counsel available for a discussion with the reviewing Party's senior management and securities counsel to resolve such comments no later than [**] days prior to the expiration of the SEC Filing Comment Period. Notwithstanding the foregoing, neither Party shall be required to again provide to the other Party for comment and review any proposed redacted Agreement in connection with an SEC Filing where such redactions have previously been publicly disclosed or filed in accordance with this Section 10.3(f). The Parties acknowledge that Collaborator intends to file a Current Report on Form 8-K pursuant to the Securities Exchange Act of 1934 in connection with the entry into this Agreement (the "Form 8-K"). Collaborator agrees that the Form 8-K shall be in the form set forth on the 8-K Exhibit to this Agreement.

10.4 Terms of this Agreement. The Parties agree that this Agreement and the terms hereof will be considered Confidential Information of both Parties but can be disclosed as provided under Section 10.3.

10.5 Research Results. Research Results are the Confidential Information of Regeneron. Regeneron hereby consents to Collaborator's use and disclosure of Research Results solely as described in this Section 10.5. Collaborator may use Research Results for (a) conducting its activities related to this Agreement, (b) [**], and, (c) subject to Section 9.2(f) and Section 9.2(g), the filing and prosecution of Patents claiming Collaborator Technology Inventions or Collaborator Sole Inventions or, subject to Section 9.2(d) and Section 9.2(e), Joint Patents. Collaborator may disclose Research Results [**] to Third Parties; provided that, (x) such disclosure is subject to confidentiality restrictions at least as restrictive as those contained herein and any Publication of such Research Results is subject to the same consent and review rights as set forth in Section 11.2 (to the same extent as if Collaborator were making such Publication), (y) the identity of any Licensed Target, Collaboration Therapeutic Molecule, or Licensed Product has been removed and (z) any mention of Regeneron in relation to such Research Results has been removed.

10.6 No License. As between the Parties, Confidential Information disclosed hereunder shall remain the property of the disclosing Party. Disclosure of Confidential Information to the other Party shall not constitute any grant, option or license to the other Party, beyond those licenses expressly granted hereunder, under any Patent, trade secret or other rights now or hereinafter held by the disclosing Party.

ARTICLE 11 PUBLICITY; PUBLICATIONS

11.1 Publicity. Except as permitted in ARTICLE 10 or this Section 11.1, neither Party shall issue any press release or other public announcement concerning this Agreement without the prior written approval of the other Party.

11.1.1 By Regeneron. Regeneron may issue any press release or other public announcement concerning any Licensed Product following its exercise of the Option and payment of the Option Exercise Fee, provided that Regeneron shall use reasonable efforts to give Collaborator a reasonable opportunity to review and comment on the contents of each such press release prior to its issuance and Regeneron shall give good faith consideration to Collaborator's comments that are submitted to Regeneron within [**] Business Days of Regeneron's provision of the draft press release or other public announcement, or such shorter period as Regeneron has been advised by legal counsel, otherwise Collaborator's review and comment rights shall be deemed waived with respect to such press release or public announcement.

11.1.2 By Collaborator. Collaborator may issue the press release set forth in the Initial Press Release Appendix attached hereto following the Effective Date. Collaborator may issue additional press releases regarding Regeneron's exercise of the Option, achievement of any development or sales milestone event hereunder, or receipt of any Regulatory Approval of any Licensed Product, provided that Collaborator gives Regeneron a reasonable opportunity to review and comment on the contents of each such press release prior to its issuance and Collaborator shall give good faith consideration to Regeneron's comments that are submitted to Collaborator within [**] Business Days of Collaborator's provision of the draft press release or other public announcement, or such shorter period as Collaborator has been advised by legal counsel, otherwise Regeneron's review and comment rights shall be deemed waived with respect to such press release or public announcement. Notwithstanding the foregoing, Collaborator shall not be permitted to make any press release or other public disclosure that includes non-public information relating to a Licensed Product (other than the achievement of any development or sales milestone event hereunder) without Regeneron's prior written consent.

11.2 Publications. Neither Party shall disclose to Third Parties any papers, presentations, posters, slides, abstracts, manuscripts, marketing materials, or make any other similar disclosure to Third Parties ("Publication") that (a) includes Research Results, identifies the other Party or any Licensed Product or, in the case of Collaborator, discloses the fact that Regeneron is pursuing any Licensed Product or (b) otherwise concerns any aspect of this Agreement or the activities performed hereunder (except to the extent expressly permitted by the terms of this Agreement), in each case, without the express written consent of the other Party. Regeneron shall be permitted to make any Publication concerning any Licensed Product following its exercise of the Option without restriction except as to Confidential Information of Collaborator as provided below. With respect to any Publication proposed by Regeneron which utilizes Research Results, Collaborator shall have the right to review any such Publication. Regeneron shall submit to Collaborator the proposed Publication at least [**] calendar days prior to the date of submission for publication or the date of presentation, whichever is earlier. Collaborator shall review such submitted materials and respond to Regeneron within a reasonable time, but in any case within [**] calendar days of receipt thereof. At the option of Collaborator, Regeneron shall (i) delete from such proposed publication or presentation any Confidential Information of Collaborator or (ii) delay the date of submission or presentation for a period of time sufficiently long (but in no event longer than [**] calendar days) to permit Collaborator to seek appropriate patent protection. Once a Publication has been approved by Collaborator (or to the extent information in any proposed Publication is then available to the public), either Party may make subsequent public disclosure of the contents of such Publication (or other public information) without the further approval of the other Party; provided such content is not presented with any new data or information or conclusions or in a form or manner that materially alters the subject matter therein. For clarity, this Section 11.2 shall not prohibit Collaborator's disclosure of [**] to a Third Party under the conditions described in Section 10.5.

11.3 No Right to Use Names. Except as expressly provided herein, no right, express or implied, is granted by this Agreement to any Party to use in any manner the name of the other Party or its Affiliates or any other trade name, symbol, logo or trademark of the other Party or its Affiliates in connection with the performance of this Agreement; provided that, without Collaborator's consent, Regeneron may state that Regeneron is licensed by Collaborator under the Collaborator Intellectual Property.

ARTICLE 12
REPRESENTATIONS, WARRANTIES AND COVENANTS

12.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date:

- (a) it is duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation;
- (b) it has obtained all necessary consents, approvals and authorizations of all Governmental Authorities and other persons or entities required to be obtained by it in connection with this Agreement;
- (c) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on its part;
- (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to Applicable Laws of bankruptcy and moratorium);
- (e) it has the legal and corporate right and power to enter into this Agreement and to fully perform its obligations hereunder;
- (f) such Party is not prohibited by the terms of any agreement to which it is a party from granting the licenses granted to the other Party under ARTICLE 7 hereof and it has not granted any right to any Third Party relating to any intellectual property or proprietary right licensed, granted or assigned by it to the other Party hereunder that conflicts with the rights licensed, granted or assigned to the other Party hereunder;
- (g) neither the execution and delivery of this Agreement nor the performance hereof by such Party requires such Party to obtain any permits, authorizations or consents from any Governmental Authority or from any other Person; and
- (h) it follows reasonable commercial practices common in the industry to protect its proprietary and confidential information and intellectual property, including requiring its employees, consultants and agents to be bound in writing by obligations of confidentiality and non-disclosure, and requiring its employees, consultants and agents to assign to it any and all

inventions and discoveries discovered by such employees, consultants or agents made within the scope of, and during their employment, and only disclosing proprietary and confidential information to Third Parties pursuant to written confidentiality and non-disclosure agreements.

12.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any Governmental Authority or arbitrator that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or materially alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.

12.3 Additional Representations of Collaborator. As of the Effective Date, Collaborator represents and warrants to, and agrees with, Regeneron that:

(a) any Collaborator Intellectual Property purported to be provided under this Agreement (including each Patent listed on the Collaborator Patents Appendix) is Controlled (without any requirement to pay Additional Amounts) by Collaborator and Collaborator has the right to provide and license such Collaborator Intellectual Property to Regeneron and enforce (or have enforced) such Collaborator Intellectual Property against Third Parties pursuant to the terms of this Agreement;

(b) no Third Party has the right to practice the Collaborator Patents in the Field in the Territory in connection with any product containing a Large Molecule Directed to a Licensed Target;

(c) the Collaborator Intellectual Property is not subject to any lien or other encumbrance in favor of any Third Party that conflicts with the rights or licenses granted to Regeneron hereunder;

(d) Collaborator owns or possesses sufficient legal rights to all Collaborator Intellectual Property as of the Effective Date, without any known infringement of the rights of others, and Collaborator has no knowledge that any Third Party is infringing or misappropriating any of the Collaborator Intellectual Property as of the Effective Date;

(e) to Collaborator's knowledge, the conception, development or reduction to practice of any Collaborator Intellectual Property has not constituted or involved the misappropriation of trade secrets or other rights of any Person;

(f) to Collaborator's knowledge, the issued Patents included in the Collaborator Patents are not invalid or unenforceable, in whole or part;

(g) no Collaborator Patent is currently the subject of any reissue, post-grant review, inter partes review, derivation proceeding, supplemental examination, interference, opposition, reexamination or other administrative proceeding;

(h) neither Collaborator nor any of its Affiliates has entered into any agreement with any Third Party in which Collaborator or such Affiliate has granted or will grant license rights to a Third Party that prevent Regeneron from exercising the rights granted in this Agreement;

(i) the execution, delivery and performance of this Agreement shall not breach, violate or conflict with any instrument or agreement concerning Collaborator Intellectual Property; and shall not cause the forfeiture or termination or give rise to a right of forfeiture or termination of any of Collaborator Intellectual Property (or of any rights in, to or under any Collaborator Intellectual Property);

(j) Collaborator has not received any written notice from any Third Party asserting or alleging that the manufacture, use, sale, offer for sale, supply or importation by Collaborator (or its Affiliates) of products employing the Collaborator Technology infringes any claim of an issued Patent of any Third Party, or, if and when issued, any claim within any published Patent existing as of the Effective Date of any Third Party, in the Territory in the Field;

(k) neither Collaborator nor any of its Affiliates (i) has been debarred by a Regulatory Authority, (ii) is subject to debarment by a Regulatory Authority;

(l) notwithstanding any representation or warranty set forth herein, Regeneron acknowledges that US Patent No. [***], and any other US and foreign patent applications that claim priority thereto, are the subject of a prior, nonexclusive license grant from [***] without any restriction as to field of use.

12.4 Disclaimers. EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO PATENTS, KNOW-HOW, MATERIALS OR CONFIDENTIAL INFORMATION SUPPLIED BY IT TO THE OTHER PARTY HEREUNDER, AND EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT.

12.5 Non-Reliance. NOTWITHSTANDING ANYTHING CONTAINED IN THIS AGREEMENT TO THE CONTRARY, REGENERON ACKNOWLEDGES AND AGREES THAT EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES EXPRESSLY MADE BY COLLABORATOR IN THIS AGREEMENT, (INCLUDING IN THIS ARTICLE 12), COLLABORATOR IS NOT MAKING ANY REPRESENTATIONS AND DOES NOT EXTEND ANY WARRANTIES

OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO ANY COLLABORATOR INTELLECTUAL PROPERTY, COLLABORATOR MATERIAL, COLLABORATOR TECHNOLOGY, COLLABORATION INVENTIONS OR CONFIDENTIAL INFORMATION SUPPLIED BY COLLABORATOR TO REGENERON, INCLUDING WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE. NOTWITHSTANDING ANYTHING CONTAINED IN THIS AGREEMENT TO THE CONTRARY, COLLABORATOR ACKNOWLEDGES AND AGREES THAT EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES EXPRESSLY MADE BY REGENERON IN THIS AGREEMENT, (INCLUDING IN THIS ARTICLE 12), REGENERON IS NOT MAKING ANY REPRESENTATIONS AND DOES NOT EXTEND ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO ANY REGENERON MATERIAL, REGENERON INTELLECTUAL PROPERTY, COLLABORATION INVENTIONS OR CONFIDENTIAL INFORMATION SUPPLIED BY REGENERON TO COLLABORATOR, INCLUDING WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

12.6 Mutual Covenants. Each Party hereby covenants to the other Party as of the Effective Date that it shall not, during the Term, grant any right or license to any Third Party in the Territory that would conflict with the rights granted to the other Party under this Agreement in any material respect, and shall not take any action that would materially conflict with or adversely affect its obligations to the other Party under this Agreement.

12.7 Debarment. Neither Collaborator nor any of its Affiliates shall use, in any capacity, in connection with the activities to be performed under this Agreement, any Person who is or that has been debarred, or is the subject of debarment proceedings by any Regulatory Authority. If Collaborator learns that a Person performing on its behalf under this Agreement has been debarred by any Regulatory Authority, or has become the subject of debarment proceedings by any Regulatory Authority, Collaborator shall promptly notify Regeneron and shall prohibit such Person from performing on its behalf under this Agreement.

12.8 Additional Representations, Warranties and Covenants Regarding the Upstream Agreement. As of the Effective Date, Collaborator represents and warrants to, and agrees with, Regeneron that:

(a) any agreement with any Third Party pursuant to which (a) Collaborator Controls Collaborator Intellectual Property or (b) such Third Party has any interest in any Collaborator Intellectual Property (any such agreement, an "Upstream Agreement"), is listed on the Upstream Agreement Appendix;

(b) except for the Upstream Agreement, Collaborator is not party to any other Agreement with any Third Party providing for any fee or other payments that would result from this Agreement or the intellectual property licenses contemplated herein;

(c) Collaborator is not, and to Collaborator's knowledge, the other parties thereto are not, in material breach, violation or default under the Upstream Agreement and there does not exist, to the knowledge of Collaborator, any event that, with the giving of notice or the lapse of time or both, would constitute such a breach, violation or default;

(d) the Upstream Agreement (i) constitutes a valid and binding obligation of Collaborator, and (ii) to Collaborator's knowledge, is binding and enforceable against the other parties thereto;

(e) neither Collaborator nor any of its Affiliates has received or given any written notice, of an intention to terminate, not renew or challenge the validity or enforceability of the Upstream Agreement;

(f) Collaborator has provided to Regeneron, or allowed Regeneron access to review, a true and complete copy of the Upstream Agreement and the Upstream Agreement is, to Collaborator's knowledge, in full force and effect as of the Effective Date;

(g) Collaborator shall not, without the prior written approval of Regeneron, (i) amend any provision of the Upstream Agreement that would adversely impact Regeneron's rights under this Agreement or (ii) make any election or exercise any right or option to terminate in whole or in part the Upstream Agreement that would adversely impact Regeneron's rights under this Agreement; and

(h) Collaborator shall be responsible for the performance of all of its obligations under the Upstream Agreement in accordance with the terms thereof, including all payment obligations thereunder, and Collaborator shall devote Commercially Reasonable Efforts to maintain the Upstream Agreement in full force and effect, and to perform its obligations thereunder in all material respects, as necessary to preserve Regeneron's rights under this Agreement, and to keep Regeneron informed of any breach or alleged breach of the Upstream Agreement and any other material development pertaining thereto that would reasonably be expected to have an adverse effect on Regeneron's rights under this Agreement.

12.9 No Challenge. In the event Regeneron (itself or through an Affiliate or agent) commences legal action or otherwise challenges the validity or enforceability of the [**], Collaborator shall have the right, [**], to (a) terminate this Agreement and any licenses granted hereunder, or (b) [**].

ARTICLE 13 INDEMNIFICATION; LIABILITY

13.1 Indemnification. Subject to Section 13.2, each Party shall indemnify, defend and hold each of the other Party, its Affiliates and their respective directors, officers, employees, consultants, licensors, and agents

and the successors and assigns of any of the foregoing harmless from and against any and all liabilities, damages, settlements, penalties, fines, costs or expenses (including, without limitation, reasonable attorneys' or accountants' fees and other expenses of litigation) (collectively, "Losses") arising, directly or indirectly out of or in connection with any Third Party claims, suits, actions, demands or judgments ("Third Party Claims") to the extent resulting from (a) the gross negligence or willful misconduct of such Party in the performance of its obligations under this Agreement, (b) breach by such Party of the representations, warranties, or covenants made in this Agreement, (c) in the case of Regeneron's obligation as an Indemnitor, the development or commercialization of any Licensed Product sold by Regeneron or its Affiliates or Sublicensees, but excluding any such Third Party Claim to the extent such Third Party Claim concerns or arises from Collaborator Intellectual Property incorporated into any Licensed Product, including any claim of infringement of any intellectual property of any Third Party based upon such Collaborator Intellectual Property; provided neither Party shall be required to indemnify the other Party to the extent such Losses result from (i) the gross negligence or willful misconduct of the other Party under this Agreement, or (ii) breach by the other Party of the representations, warranties, or covenants made in this Agreement.

13.2 Procedure. If a Party intends to claim indemnification under this Agreement (the "Indemnitee"), it shall promptly notify the other Party (the "Indemnitor") in writing of the applicable Third Party Claim and potential Loss. The Indemnitor shall have the right to control the defense thereof with counsel of its choice as long as such counsel is reasonably acceptable to the Indemnitee. Any Indemnitee shall have the right to retain its own counsel at its own expense for any reason. The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any Third Party Claims covered by this Agreement. The Indemnitor shall obtain the written consent of the Indemnitee before settling any Third Party Claim; provided that, the Indemnitor shall not need the consent of the Indemnitee hereunder for any settlement that includes a complete and unconditional release of the Indemnitee from all liability with respect thereto and that imposes no liability or obligation on the Indemnitee (other than the obligation to pay money damages that are subject to payment by the Indemnitor). The failure to deliver timely written notice to the Indemnitor within a reasonable time after the commencement of any Third Party Claim shall not relieve the Indemnitor of its obligations to the Indemnitee under Section 13.1, except to the extent the Indemnitor is prejudiced by such delay or failure. It is understood that only Regeneron and Collaborator may claim indemnity under this Agreement (on its own behalf or on behalf of its Indemnitees), and other Indemnitees may not claim indemnity hereunder.

13.3 Insurance. Each Party will maintain, for the duration of this Agreement, insurance in an amount reasonably adequate to cover its obligations hereunder.

13.4 Limitation of Damages. NEITHER PARTY HERETO WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR EXEMPLARY DAMAGES ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT IN RESPECT OF ANY BREACH OF A PARTY'S CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 10, EXCLUSIVITY OBLIGATIONS UNDER SECTION 7.3 OR SECTION 7.6, OR INDEMNIFICATION OBLIGATIONS UNDER THIS ARTICLE 13 FOR THIRD PARTY CLAIMS OR EITHER PARTY'S, ITS AFFILIATES' OR ITS OR THEIR PERSONNELS' GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

ARTICLE 14 TERM AND TERMINATION

14.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date and, unless earlier terminated, will expire as set forth below:

(a) If Regeneron has exercised the Option, this Agreement will expire on a Licensed Product-by-Licensed Product and country-by-country basis, upon the expiration of the applicable Royalty Term for a Licensed Product in a country. Following such expiration of this Agreement, Collaborator hereby grants to Regeneron a perpetual, sublicensable, fully paid-up, non-exclusive license under the Collaborator Know-How to conduct research and to develop, make, have made, use, sell, offer for sale and import Licensed Products in the Field in the Territory.

(b) If Regeneron has not exercised the Option, this Agreement will expire upon the expiration of the Option Period.

14.2 Termination.

14.2.1 Termination for Convenience. Following the exercise of the Option, Regeneron may terminate this Agreement as to any or all Licensed Products at any time upon providing sixty (60) days' prior written notice to Collaborator.

14.2.2 Material Breach. Either Party may terminate this Agreement in the event of a material breach by the other Party of any of its obligations under this Agreement. The Party seeking to terminate must provide written notice of the material breach to the other Party, and termination will not become effective if the other Party cures such breach within [**] days' receipt of written notice thereof (or [**] days in the case of a payment breach, provided, however, that Collaborator shall have the additional cure period provided under Section 8.2.1 in the event of the circumstances described therein), or, if applicable, such longer period, but not to

exceed [**] days, as would be reasonably necessary to cure such material breach that is not a payment breach, provided the breaching Party has commenced and continues its Commercially Reasonable Efforts to cure during the initial [**]day period following the date on which the breach notice is provided and throughout the extended cure period). For purposes of this Section 14.2.2, the term “material breach” shall mean a breach by a Party that substantially undermines the benefits reasonably expected to be realized by the non-breaching Party from this Agreement, taken as a whole; provided that any failure of a Party to make undisputed payments to the other Party shall be deemed a “material breach”. In the event of any bona-fide, good-faith dispute as to whether a material breach has occurred, the Party seeking to terminate this Agreement shall not have the right to do so until the matter is finally, judicially determined (or, upon mutual agreement of the Parties, determined by arbitration or otherwise settled by the Parties).

14.2.3 Insolvency or Bankruptcy. Either Party may terminate this Agreement effective upon written notice to the other Party upon the liquidation, dissolution, winding up, insolvency, bankruptcy, or filing of any petition therefor, appointment of a receiver, custodian or trustee, or any other similar proceeding, by or of the other Party where such petition, appointment or similar proceeding is not dismissed or vacated within [**] calendar days and where such petition, appointment or similar proceeding is not a part of any *bona fide* reorganization of a Party or its Affiliates. All rights and licenses granted under or pursuant to this Agreement by a Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Regeneron, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any other provisions of Applicable Law outside the United States that provide similar protection for “intellectual property.” The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Collaborator under the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States, Regeneron shall be entitled to a complete duplicate of (or complete access to, as appropriate) any Collaborator Intellectual Property and all embodiments of such Collaborator Intellectual Property, which, if not already in Regeneron’s possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon Regeneron’s written request therefor, unless Collaborator elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of Collaborator upon written request therefor by Regeneron. Any agreements supplemental hereto will be deemed to be “agreements supplementary to” this Agreement for purposes of Section 365(n) of the Bankruptcy Code. Any payments (whether royalties or otherwise) which have become due or relate to any Net Sales made prior to the date of termination, shall remain due and owing following termination and become immediately payable upon termination.

14.2.4 Election Not to Pay First Development Milestone. If Regeneron elects not to pay the First Development Milestone pursuant to Section 8.2, then Collaborator may terminate this Agreement upon [**] days’ prior written notice; provided that, if Regeneron pays the First Development Milestone within such [**] day notice period, then this Agreement shall not terminate. For clarity, in the event Regeneron does not pay the First Development Milestone under the circumstances described in Section 8.2, then such milestone shall be deemed to not

have been achieved and the payment associated with such milestone shall be deemed to not have accrued, in each case, for all purposes under this Agreement (including for purposes of the survival of ARTICLE 8 under Section 14.3.5).

14.3 Effect of Expiration or Termination. In addition to any rights or obligations expressly provided in this Agreement to apply upon termination or expiration of this Agreement, the provisions set forth in this Section 14.3 shall apply to any expiration or termination of this Agreement.

14.3.1 Accrued Rights and Obligations. Expiration or termination of this Agreement for any reason shall not release either Party hereto from any liability which, as of the effective date of such expiration or termination, had already accrued to the other Party or which is attributable to a period prior to such termination, nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity which accrued, or are based upon any event occurring, prior to the effective date of such expiration or termination.

14.3.2 Termination by Collaborator for Material Breach, Insolvency or Election Not to Pay First Development Milestone; or by Regeneron for Convenience. Upon termination of this Agreement (i) by Collaborator for material breach pursuant to Section 14.2.2, bankruptcy or insolvency pursuant to Section 14.2.3 or Regeneron's election not to pay the First Development Milestone pursuant to Section 14.2.4 or (ii) by Regeneron for convenience pursuant to Section 14.2.1:

- (a) all rights and licenses granted to either Party by the other Party pursuant to this Agreement shall automatically and immediately terminate;
- (b) Collaborator shall return to Regeneron all Regeneron Material that is in the possession of Collaborator;
- (c) Regeneron shall return to Collaborator all Collaborator Material that is in the possession of Regeneron; and

(d) except in the case of a termination by Regeneron for convenience pursuant to Section 14.2.1 or by Collaborator for Regeneron's election not to pay the First Development Milestone pursuant to Section 14.2.4, any sublicense granted by Regeneron under the Commercial License, if granted prior to such termination in compliance with this Agreement, shall remain in full force and effect pursuant to the terms thereof, notwithstanding such termination; provided that the applicable Sublicensee is then in good standing and has not contributed to the breach or other circumstance that led to the termination of this Agreement, and all payments and other obligations due under any such sublicense to Regeneron shall become immediately due to Collaborator instead of Regeneron; further provided, however, that Collaborator shall have no obligation to perform any activities under such sublicense that extend beyond Collaborator's obligations under this Agreement.

14.3.3 Termination by Regeneron for Material Breach or Insolvency. Upon termination by Regeneron of this Agreement for material breach pursuant to Section 14.2.2 or insolvency or bankruptcy pursuant to Section 14.2.3:

- (a) all rights and licenses granted to Collaborator by Regeneron pursuant to this Agreement shall automatically and immediately terminate; and
- (b) Collaborator shall return to Regeneron all Regeneron Material (other than the Research Results) in the possession of Collaborator.

14.3.4 Return of Confidential Information. It is understood and agreed, that each Party shall have a continuing right to use Confidential Information of the other Party to the extent necessary to exercise any surviving rights, licenses or obligations under this Agreement. Subject to the foregoing, following expiry or any early termination of this Agreement, the Party that has Confidential Information of the other Party shall destroy (at such other Party's written request) all such Confidential Information in its possession as of the effective date of expiration or termination (with the exception of one copy of such Confidential Information, which may be retained by the legal department of the Party that received such Confidential Information to confirm compliance with the non-use and non-disclosure provisions of this Agreement).

14.3.5 Survival. In addition to any provisions that specify survival or non-survival in the event of expiration or termination of this Agreement, the provisions of Sections 2.5, 2.7, 4.3 (to the extent Regeneron retains the Commercial License or the perpetual license under Section 14.1(a) after such expiration or termination), 5.2 (to the extent Regeneron retains the Commercial License or the perpetual license under the second sentence of Section 14.1(a) after such expiration or termination), 8.7, 9.1, 9.2(a), 9.2(d), 9.2(e), 9.2(f), 9.2(g), 9.2(h) (solely with respect to other surviving provisions in ARTICLE 9), 9.3 (solely with respect to Joint Patents), 9.4(e), 9.4(h), 12.4, 12.5, 13.1, 13.2, 13.4, 14.1(a) (the second sentence) and 14.3 and, ARTICLE 1, ARTICLE 8 (with respect to payments accrued prior to the expiration or termination of this Agreement), ARTICLE 10 and ARTICLE 16, shall survive any termination or expiration of this Agreement.

14.3.6 Additional Remedy of Regeneron for Material Breach by Collaborator. In the event Regeneron has the right to terminate this Agreement for material breach pursuant to Section 14.2.2, then, instead of termination and in addition to any other rights and remedies of Regeneron in equity in respect of such material breach, upon Regeneron's election:

- (a) [**],
- (b) [**].

ARTICLE 15 FORCE MAJEURE

In this Agreement, "Force Majeure" means any act of God, strike, lock-out or other material industrial/labor disputes (whether involving the workforce of the Party so prevented or of any other Person), war, riot, civil commotion, terrorist act, epidemic, quarantine, fire, flood, storm, natural disaster or similar event which is beyond a Party's reasonable control and prevents such Party from performing its obligations under this Agreement. The Party affected by the Force Majeure shall, within [**] days after the occurrence of a Force Majeure event, give notice in writing to the other Party specifying the nature and extent of the event of Force Majeure, its

anticipated duration and any action being taken to avoid or minimize its effect. Subject to providing such notice and to such Party's other obligations under this ARTICLE 15, the Party invoking a Force Majeure event shall not be liable for delay in performance or for non-performance of its obligations under this Agreement (other than any payment obligation), in whole or in part, nor shall the other Party have the right to terminate this Agreement, except as otherwise provided in this Agreement, where non-performance or delay in performance has resulted from an event of Force Majeure. The suspension of performance allowed hereunder shall be of no greater scope and no longer duration than is reasonably required. The Party invoking a Force Majeure event shall use commercially reasonable efforts, to (a) bring the Force Majeure event to a close or (b) find a solution by which the Agreement may be performed despite the continuation of the event of Force Majeure.

ARTICLE 16
MISCELLANEOUS

16.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the conflict of laws principles thereof that would require the application of the law of any other jurisdiction. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the State of Delaware and United States federal courts of competent jurisdiction located in Wilmington, Delaware for the purposes of any action or proceeding arising out of or in connection with this Agreement. Each of the Parties hereby irrevocably and unconditionally agrees (a) to the extent such Party is not otherwise subject to service of process in the State of Delaware, to appoint and maintain an agent in the State of Delaware as such Party's agent for acceptance of legal process, and (b) that, to the fullest extent permitted by applicable law, service of process may also be made on such Party by prepaid certified mail with a proof of mailing receipt validated by post mail constituting evidence of valid service, and that service made pursuant to clause (a) or (b) above shall, to the fullest extent permitted by applicable law, have the same legal force and effect as if served upon such Party personally within the State of Delaware. Each of the Parties agrees (i) that this Agreement involves at least \$100,000.00, and (ii) that this Agreement has been entered into by the Parties in express reliance upon 6 Del. C. § 2708.

16.2 Waiver. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

16.3 Notices. All notices, instructions and other communications required or permitted hereunder or in connection herewith

shall be in writing, shall be sent to the address of the relevant Party set forth below in this Section 16.3 and shall be (a) delivered personally, (b) sent via a reputable nationwide overnight courier service or (c) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above. This Section 16.3 is not intended to govern the day-to-day business communications between the Parties in performing their obligations under the terms of this Agreement.

(a) If to Collaborator:

Ocular Therapeutix, Inc.
36 Crosby Drive, Suite 101
Bedford, Massachusetts 01730
Attention: CFO
Copy: General Counsel

With copy to:

Brian Johnson
WilmerHale
7 World Trade Center
250 Greenwich Street
New York, New York 10007

(b) If to Regeneron:

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
Attention: Senior Vice President, Strategy & Investor Relations
Copy: General Counsel

16.4 Entire Agreement. This Agreement contains the complete understanding of the Parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof. For clarity, this Agreement supersedes the Prior Agreements.

16.5 Amendments. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Collaborator and Regeneron.

16.6 Interpretation. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement: (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; (d) the words “herein” or “hereunder” relate to this Agreement; (e) the words “shall” and “will” have the same meaning; (f) references to a particular statute or regulation include all rules and regulations thereunder and any predecessor or successor statute, rules or regulation, in each case as amended or otherwise modified from time to time; (g) references to a particular person include such person’s successors and assigns to the extent not prohibited by this Agreement; (h) unless otherwise specified, “\$” is in reference to United States dollars; and (i) the word “or” has the inclusive meaning represented by the phrase “and/or”.

16.7 Construction. The Parties acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party will not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement will be construed fairly as to each Party and not in favor of or against either Party, regardless of which Party was generally responsible for the preparation of this Agreement.

16.8 Severability. To the fullest extent permitted by Applicable Law, the Parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then such provision will be given no effect by the Parties and shall not form part of this Agreement. To the fullest extent permitted by Applicable Law and if the rights or obligations of any Party will not be materially and adversely affected, all other provisions of this Agreement shall remain in full force and effect, and the Parties shall use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the Parties.

16.9 Assignment. Neither Party shall assign any of its rights and obligations hereunder without the prior written consent of the other Party, except (a) to a purchaser of all or substantially all of the assets or business of a Party to which this Agreement relates, or to the successor resulting from any

merger, acquisition, consolidation or similar transaction with such Party or (b) to an Affiliate; provided, however, that (i) such assignment to an Affiliate shall not relieve the assigning Party of any of its liability hereunder and, (ii) in each case, the assigning Party shall provide the other Party with written notice of such assignment. In the event of any assignment described in subsection (a), no intellectual property rights of the acquiring Person shall be included in the technology licensed to the other Party hereunder, unless such intellectual property rights arise as a result of the performance of this Agreement by or on behalf of such Person after such transaction becomes effective. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.9 shall be null and void.

16.10 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of each Party's Indemnitees.

16.11 Signatures. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument. An executed signature page of this Agreement delivered by facsimile transmission or by electronic mail in "portable document format" (".pdf") shall be as effective as an original executed signature page.

16.12 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, Section 13.1 is intended to benefit, in addition to the Parties, each Party's Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.

16.13 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as expressly provided in this Agreement. Neither Collaborator nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Collaborator, and Collaborator's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

16.14 Injunctive or Other Equity Relief. Nothing contained in this Agreement shall deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a *bona fide* emergency or prospective irreparable harm.

16.15 Non-Exclusive Remedies. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as and to the extent expressly set forth herein.

[Signature page follows – the rest of this page intentionally left blank.]

IN WITNESS WHEREOF, Collaborator and Regeneron have executed this Agreement by their respective officers hereunto duly authorized, as of the Effective Date.

Ocular Therapeutix, Inc.

By: /s/ Amarpreet S. Sawhney
Name: Amarpreet S. Sawhney
Title: Chairman, President & CEO

Regeneron Pharmaceuticals, Inc.

By: /s/ Michael Aberman
Name: Michael Aberman
Title: SVP, Strategy & IR

Collaborator Patents Appendix

Ref No.

Title

Serial No.
(Filing Date)

Pat. No.
(Issue Date)

[**]

[**]

[**]

[**]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of six pages were omitted. [**]

Collaboration Plan Appendix

In vitro Evaluation Activities:
[**] Program for Sustained Release of
VEGF Trap from PEG Hydrogel System

Summary

Regeneron Pharmaceuticals, Inc. and Ocular Therapeutix will work collaboratively to develop a long-acting formulation of VEGF Trap for intraocular delivery. [**].

Goal:

The goal of [**] is to [**].

Project outline:

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of one page was omitted. [**]

[] Activities**

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of two pages were omitted. [**]

Milestones

[**]

Deliverables

Regeneron

[**]

Ocular Therapeutix

[**]

Total Projected Duration: [].**

Note: [**].

Activity #1 :

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of one page was omitted. [**]

Section 1 Milestones/Deliverables:

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of one page was omitted. [**]

Section 2 Milestones/Deliverables:

[**]

Section 3 Milestones/Deliverables:

[**]

Collaboration Plan

IND-Enabling Toxicology Study

Study Design:

[**]

Study Analyses:

[**]

Collaboration Plan

IND- Enabling PK Study

Study Design & Analyses:

[**]

Collaboration Plan

Expanded Toxicology/ PK Study Options

[**]

Collaboration Plan

[] Clinical Trial**

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of one page was omitted. [**]

8-K Exhibit

[Please See Attached]

Incorporated by reference to the Current Report on Form 8-K filed by Ocular Therapeutix, Inc. with the Securities and Exchange Commission on October 13, 2016

Royalty Calculation Appendix

[Please See Attached]

Quarter

4

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

Notes:

- (1) Quarterly Exchange rates as obtained in accordance with Section 8.8.
- (2) For the Purposes of this illustration, this assumes that [**]

Upstream Agreement Appendix

Amended and Restated License Agreement between Incept LLC and Ocular Therapeutix, Inc., formerly Ocular, Inc., dated January 27, 2012.

Initial Press Release Appendix

[Please See Attached]

Ocular Therapeutix™ and Regeneron Enter Into Strategic Collaboration to Develop

Sustained Release Formulation of Aflibercept for the Treatment of Wet AMD and Other Serious Retinal Diseases

Sustained Release Formulation Has Potential to Significantly Advance Current Standard of Care by Reducing Injection Frequency in the Treatment of Wet AMD

Ocular Therapeutix Eligible to Receive up to \$305 Million in Milestone Payments in Addition to Royalties on Potential Future Net Sales

Company to host conference call today at 8:30am Eastern Time

BEDFORD, Mass, October X, 2016 – Ocular Therapeutix, Inc. (NASDAQ: OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced that it has entered into a strategic collaboration, option and license agreement with Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN). Ocular and Regeneron will collaborate on the development of a sustained release formulation of the vascular endothelial growth factor (VEGF) trap aflibercept for the treatment of wet age-related macular degeneration (wet AMD) and other serious retinal diseases. This formulation is currently in preclinical development. Regeneron's aflibercept is currently approved by the U.S. Food and Drug Administration for certain indications under the brand name EYLEA®.

Ocular Therapeutix is currently developing proprietary sustained-release hydrogel-based drug delivery depots for intravitreal injection that can be formulated with both small and large molecule pharmaceuticals, such as tyrosine kinase inhibitors (TKIs) and protein-based anti-VEGFs, respectively, with the goal of delivering sustained and therapeutic levels of drugs to targeted ocular tissues.

Under the terms of the agreement, Ocular Therapeutix and Regeneron will aim to develop a sustained release formulation of aflibercept that is suitable for advancement into clinical development. Regeneron has the option to obtain an exclusive license to use Ocular Therapeutix's hydrogel-based technology for the development and commercialization of a sustained release formulation of aflibercept and other biologics targeting VEGF for ophthalmic indications. Ocular Therapeutix will retain all rights to develop its sustained-release hydrogel-based drug delivery platform with all other non-VEGF targeting compounds as well as with small molecule pharmaceuticals, including TKIs, for other retinal diseases.

Upon exercising of the option, Ocular Therapeutix would receive a payment of \$10 million from Regeneron and Ocular Therapeutix would be responsible for funding development through Phase 1. Regeneron would be responsible for any subsequent development and commercialization costs. Ocular Therapeutix would be eligible to receive up to \$305 million in milestone payments from Regeneron for a sustained release version of aflibercept containing Ocular Therapeutix's sustained release hydrogel depot, comprised of up to \$155 million in development and regulatory milestone payments and up to \$150 million in commercial milestone payments. In addition, Ocular Therapeutix is eligible to receive tiered high single-digit to low-to-mid teen-digit royalties on potential future net sales.

“We have made considerable progress in developing our protein drug delivery platform at Ocular Therapeutix, so it is good to see an industry leader such as Regeneron recognizing the potential of this technology,” said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman of Ocular Therapeutix. “We are excited to partner with Regeneron to develop a potential first-in-class sustained release protein-based anti-VEGF hydrogel injection for wet AMD, DME, RVO, and other serious retinal diseases. This sustained release formulation could have the potential to significantly reduce dosing frequency and subsequently reduce doctor visits, thus reducing the burden of care for patients, caregivers and physicians, and may decrease the likelihood of certain side effects associated with frequent intravitreal injections.”

About Wet AMD and Other VEGF-Associated Retinal Diseases

Wet age-related macular degeneration (wet AMD) is characterized by loss of vision caused by degeneration of the central portion of the retina. Abnormal growth of blood vessels below the retina, and the leakage of fluid and protein from the vessels, causes retinal degeneration and can lead to severe and rapid loss of vision. Wet AMD is the leading cause of blindness in individuals aged 50 years or older.

Retinal vein occlusion (RVO) is a sight-threatening disorder resulting from the blockage of one of the veins carrying blood out of the retina. In RVO, the blockage of a retinal vein can lead to poor blood circulation, low oxygen and sometimes inflammation in the eye. A blocked vein will leak its contents of blood and fluid. Bleeding within the retina and swelling from the fluid can result in macular edema.

Diabetic macular edema (DME) is a complication of diabetes caused by fluid accumulation in the macula, or central portion of the eye. When the macula begins to fill with fluid, the ability of those cells to sense light is impaired, causing blurred vision that can be severe. Diabetic macular edema affects up to 30% of people who have had diabetes for 20 years or more, and if untreated, 20 to 30% of people who have it will experience moderate visual loss.

The global market for anti-VEGF drugs is over \$7.5 billion.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 8:30 am Eastern Time to discuss the collaboration with Regeneron as well as other recent progress made in the Company’s back of the eye programs.

The live webcast can be accessed by visiting the investor section of the Company’s website at investors.ocutx.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 844-464-3934 (U.S.) or 765-507-2620 (International) to listen to the conference call. The conference ID number for the live call will be XXXXXXXX. An archive of the webcast will be available until October 26, 2016 on the company’s website.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. (NASDAQ: OCUL) is a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology. Ocular Therapeutix has submitted an NDA for post-surgical pain for its lead product candidate, DEXTENZA™ (dexamethasone insert, extended release), which is in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis, and in Phase 2 clinical development for dry eye disease. OTX-TP (sustained release travoprost) is in Phase 3 clinical development for glaucoma and ocular hypertension. Ocular Therapeutix is also evaluating sustained-release injectable drug depots for back-of-the-eye diseases. Ocular Therapeutix's first product, ReSure® Sealant, is FDA-approved to seal corneal incisions following cataract surgery. For additional information about the Company, please visit www.ocutx.com.

Ocular Therapeutix Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the potential benefits and future operation of the collaboration with Regeneron, including any potential future payments thereunder, the ongoing development of the Company's sustained release hydrogel depot technology, the development and regulatory status of the Company's other product candidates, such as the Company's expectations and plans regarding regulatory submissions for and the timing and conduct of clinical trials of DEXTENZA™ for post-surgical ocular inflammation and pain, including our expectations regarding the NDA filed with the FDA, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the potential utility of any of the Company's product candidates, potential commercialization of the Company's product candidates, the sufficiency of the Company's cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the timing and costs involved in commercializing ReSure® Sealant or any product candidate that receives regulatory approval, the initiation and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's scientific approach and general development progress, the availability or commercial potential of the Company's product candidates, the sufficiency of cash resources and need for additional financing or other actions and other factors discussed in the "Risk Factors" section contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the

Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this release.

Ocular Therapeutix Contacts:

Investors

Ocular Therapeutix, Inc.
Brad Smith
Chief Financial Officer
bsmith@ocutx.com

or

Burns McClellan on behalf of Ocular Therapeutix
Steve Klass, 212-213-0006
sklass@burnsmc.com

or

Media

Ocular Therapeutix, Inc.
Scott Corning
Vice President of Sales and Marketing
scorning@ocutx.com

[**]

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (the "Agreement") is made as of January 5, 2016 by and between Ocular Therapeutix, Inc., a Delaware corporation (the "Company"), and Jon Talamo, M.D. ("Executive"). In consideration of the mutual covenants contained in this Agreement, the Company and Executive agree as follows:

1. Employment. The Company agrees to employ Executive and Executive agrees to be employed by the Company on the terms and conditions set forth in this Agreement.

(a) Capacity. Executive shall serve the Company as Chief Medical Officer, working an 80% (on average four (4) day per week) schedule (the "Reduced Schedule") and reporting to Amar Sawhney, President, Chief Executive Officer and Chairman (the "CEO"). During the Term (as defined below) of Executive's employment with the Company, Executive shall, subject to the direction of the CEO, have the responsibilities, duties and authority commensurate with the position of Chief Medical Officer (including, without limitation, those duties and responsibilities set forth on Exhibit A hereto) and shall perform such other duties as may from time to time be assigned to him by the Company. The Company may change Executive's position, duties, and work location as it deems necessary.

1. Devotion of Duties; Representations. During the Term of Executive's employment with the Company, Executive shall devote (during his Reduced Schedule or, if he ceases to work a Reduced Schedule, during his full-time employment with the Company) his best efforts and full business time and energies to the business and affairs of the Company, and shall endeavor to perform the duties and services contemplated hereunder to the reasonable satisfaction of the Company. Except as set forth below, during the Term of Executive's employment with the Company, Executive shall not engage in any other business activities without the prior written approval of the Company (by action of the Board), including undertaking any other employment from any person or entity or serving as a director of any other company; provided, however, that (i) the Company will entertain requests as to such other employment or directorships in good faith and (ii) Executive will be eligible to participate in any policy relating to outside activities that is applicable to the senior executives of the Company and approved by the Board after the date hereof, and provided further that in no event may any business activity be undertaken if it would (x) be in violation of any provision of this Agreement or other agreement between Executive and the Company, (y) interfere with the performance of Executive's duties for the Company, or (z) present a conflict of interest with the Company's business interests. The Company acknowledges that, while working the Reduced Schedule, (a) Executive may continue to practice medicine and may enter into business arrangements that allow him to do so, and (b) Executive may continue to serve as a consultant to Abbott Medical Optics, Aura Biosciences, Carl Zeiss Meditec, CXL Ophthalmics, Intersystems, Santen and Shire plc, unless the Company determines in its sole discretion that his continued services pursuant to (a) and/or (b) above (i) pose a conflict of interest with respect to his duties on behalf of the Company, (ii) would result in a violation of any provision of this Agreement or any other agreement between Executive and the Company, and/or (iii) would prevent Executive from fulfilling his duties hereunder to the Company, in which event continued services pursuant to (a) and/or (b) above would no longer be permitted. In the event that Executive ceases to

work the Reduced Schedule and becomes a full time employee of the Company, then the Company shall have the right, in its sole discretion, to review all of Executive's then-existing other business activities to determine whether the Company will continue to consent to Executive's participation in such activities.

2. Term of Employment.

(a) Executive's employment hereunder shall begin on January 8, 2016 (the "Effective Date"). Executive's employment hereunder shall be terminated upon the first to occur of the following:

(i) Immediately upon Executive's death;

(ii) By the Company, by written notice to Executive effective as of the date of such notice (or on such other date as specified in such notice):

(A) Following the Disability of Executive. "Disability" means that Executive (i) is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months or (ii) is, by reason of any medically determinable physical or mental impairment which can be expected to last for a continuous period of not less than twelve (12) months, receiving income replacement benefits for a period of not less than three (3) months under an accident and health plan covering employees of the Company. Such incapacity shall be determined by a physician chosen by the Company and reasonably satisfactory to Executive (or Executive's legal representative) upon examination requested by the Company (to which Executive hereby agrees to submit). Notwithstanding the foregoing, such Disability must result in Executive becoming "Disabled" within the meaning of Section 409A(a)(2)(C) of the Internal Revenue Code of 1986, as amended (the "Code") and the guidance issued thereunder. (In this Agreement we refer to Section 409A of the Code and any guidance issued thereunder as "Section 409A.")

(B) For Cause (as defined below); or

(C) Subject to Section 4 hereof, without Cause;

(iii) By Executive:

(A) At any time by written notice to the Company, effective thirty (30) days after the date of such notice; or

(B) By written notice to the Company for Good Reason (as defined below), effective on the date specified in such notice.

The term of Executive's employment by the Company under this Agreement is referred to herein as the "Term."

(b) Definition of “Cause”. For purposes of this Agreement, “Cause” shall, pursuant to the reasonable good faith determination by the Company as documented in writing, include: (i) the willful and continued failure by Executive to substantially perform Executive’s material duties or responsibilities under this Agreement (other than such a failure as a result of Disability); (ii) any action or omission by Executive involving willful misconduct or gross negligence with regard to the Company, which has a detrimental effect on the Company; (iii) Executive’s conviction of a felony, either in connection with the performance of Executive’s obligations to the Company or which otherwise shall adversely affect Executive’s ability to perform such obligations or shall materially adversely affect the business activities, reputation, goodwill or image of the Company; (iv) the material breach of a fiduciary duty to the Company; or (v) the material breach by Executive of any of the provisions of this Agreement, provided that any breach of Executive’s obligations with respect to Sections 5 or 6 of this Agreement, subject to the cure provision in the next sentence, shall be deemed “material.” In respect of the events described in clauses (i) and (v) above, the Company shall give Executive notice of the failure of performance or breach, reasonable as to time, place and manner in the circumstances, and a 30-day opportunity to cure, provided that such failure of performance or breach is reasonably amenable to cure as determined by the Company in its sole discretion.

(c) Definition of “Good Reason”. For purposes of this Agreement, a “Good Reason” shall mean any of the following, unless (i) the basis for such Good Reason is cured within a reasonable period of time (determined in the light of the cure appropriate to the basis of such Good Reason, but in no event less than thirty (30) nor more than ninety (90) days) after the Company receives written notice (which must be received from Executive within ninety (90) days of the initial existence of the condition giving rise to such Good Reason) specifying the basis for such Good Reason or (ii) Executive has consented to the condition that would otherwise be a basis for Good Reason:

(i) A change in the principal location at which Executive provides services to the Company to a location more than fifty (50) miles from such principal location (which change, the Company has reasonably determined as of the date hereof, would constitute a material change in the geographic location at which Executive provides services to the Company), provided that such a relocation shall not be deemed to occur under circumstances where Executive’s responsibilities require him to work at a location other than the corporate headquarters for a reasonable period of time;

(ii) A material adverse change by the Company in Executive’s duties, authority or responsibilities which causes Executive’s position with the Company to become of materially less responsibility or authority than Executive’s position immediately following the Effective Date where such change is not remedied within ten (10) business days after written notice thereof by Executive;

(iii) A material reduction in Executive’s base salary;

(iv) A material breach of this Agreement by the Company which has not been cured within thirty (30) days after written notice thereof by Executive; or

(v) Failure to obtain the assumption (assignment) of this Agreement by any successor to the Company.

(d) Definition of “Corporate Change”. For purposes of this Agreement, “Corporate Change” shall mean any circumstance in which (i) the Company is not the surviving entity in any merger, consolidation or other reorganization (or survives only as a subsidiary or affiliate of an entity other than a previously wholly-owned subsidiary of the Company); (ii) the Company sells, leases or exchanges all or substantially all of its assets to any other person or entity (other than a wholly-owned subsidiary of the Company); (iii) any person or entity, including a “group” as contemplated by Section 13(d)(3) of the Securities Exchange Act of 1934 (excluding, for this purpose, the Company or any subsidiary, or any employee benefit plan of the Company or any subsidiary, or any “group” in which all or substantially all of its members or its members’ affiliates are individuals or entities who are or were beneficial owners of the Company’s outstanding shares prior to the initial public offering of the Company’s common stock, if any, of the Company’s stock), acquires or gains ownership or control (including, without limitations, powers to vote) of more than 50% of the outstanding shares of the Company’s voting stock (based upon voting power); or (v) as a result of or in connection with a contested election of directors, the persons who were directors of the Company before such election shall cease to constitute a majority of the Board of Directors of the Company. Notwithstanding the foregoing, a “Corporate Change” shall not occur as a result of a merger, consolidation, reorganization or restructuring after which either (1) a majority of the Board of Directors of the controlling entity consists of persons who were directors of the Company prior to the merger, consolidation, reorganization or restructuring or (2) all or substantially all of the individuals or entities who were the beneficial owners of the Company’s outstanding shares immediately prior to such merger, consolidation, reorganization or restructuring beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in substantially the same proportions as their ownership of the Company’s outstanding shares immediately prior to the merger, consolidation, reorganization or restructuring. Notwithstanding the foregoing, for any payments or benefits hereunder (including pursuant to Section 4(b)(iii) hereof) or pursuant to any other agreement between the Company and Executive, in either case that are subject to Section 409A, the Corporate Change must constitute a “change in control event” within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i).

3. Compensation.

(a) Base Salary. Except as provided below, Executive’s minimum base salary during the Term shall be at the rate of \$300,000 per year based on Executive’s Reduced Schedule. If Executive ceases working the Reduced Schedule and converts to full time employment, Executive’s base salary shall be increased by 25%. Executive’s base salary shall be payable in substantially equal installments in accordance with the Company’s payroll practices as in effect from time to time, less any amounts required to be withheld under applicable law. The base salary will be subject to adjustment from time to time in the sole discretion of the Company; provided that, the Company covenants that (A) during the first twelve months of Executive’s employment, it shall not reduce Executive’s base salary and (B) following such twelve month period, it shall not reduce the base salary below the base salary then in effect immediately prior to the reduction unless (i) Executive consents to such reduction, or (ii) the reduction is in connection with a general reduction of not more than 20% in compensation of senior executives of the Company generally that occurs prior to the effective date of any Corporate Change.

(b) Bonus. In addition to the base salary, the Company may pay Executive an annual bonus (the “Bonus”) as determined by the Board, solely in its discretion (it being understood that Executive’s target annual bonus shall be thirty five percent (35%) of Executive’s base salary in effect for such year, but may be higher or lower in any year in the Board’s discretion). The Board’s decision to issue a Bonus to Executive in any particular year shall have no effect on the absolute discretion of the Board to grant or not to grant a Bonus in subsequent years. Any Bonus for a particular year shall be paid or provided to Executive in a lump sum no later than March 15th of the calendar year following the calendar year in which the Bonus was earned.

(c) Stock Option Program. Executive will be eligible to participate in the Company’s stock option program. Subject to approval by the Company’s Board of Directors, the Company will grant to Executive an option to purchase 72,000 shares of the Company’s Common Stock (the “New Hire Option”) and if, within the first year of Executive’s employment, Executive ceases working the Reduced Schedule and converts to a full time employee, the Company will grant to Executive an option to purchase an additional 18,000 shares of the Company’s Common Stock (the “Additional New Hire Option” and, together with the New Hire Option, the “Options”). Both Options are subject to adjustment for stock splits, combinations, or other recapitalizations. The stock option exercise price shall be equal to the closing price as quoted on the NASDAQ stock exchange on the date of approval of the New Hire Option and, if applicable, the date of approval of the Additional New Hire Option, in either case by the Board of Directors. Each Option shall be issued pursuant to the Company’s 2014 Equity Incentive Plan, as amended, and will be subject to all of the terms and conditions set forth in such plan and the Stock Option Agreement covering the Option.

(d) Vacation. While working the Reduced Schedule, Executive shall be entitled to take sixteen (16) days of paid vacation during each year of the Term to be taken at such time or times as shall be mutually convenient and consistent with his duties and obligations to the Company. If Executive ceases to work a Reduced Schedule and converts to full time employment status, Executive shall be entitled to take twenty (20) days of paid vacation on the same terms stated above. The number of vacation days for which Executive is eligible shall accrue at the rate of 1.33 days per month that he works the Reduced Schedule (or 1.66 days per month if he ceases to work the Reduced Schedule and converts to a full time employee). Vacation is at all times subject to the Company’s Time-Off Policy, which the Company may change periodically in its sole discretion.

(e) Fringe Benefits. Executive shall be entitled to participate in any employee benefit plans that the Company makes available to its executives (including, without limitation, group life, disability, medical, dental and other insurance, retirement, pension, profit-sharing and similar plans) (collectively, the “Fringe Benefits”), provided that the Fringe Benefits shall not include any stock option or similar plans relating to the grant of equity securities of the Company. These benefits may be modified or changed from time to time at the sole discretion of the Company. Where a particular benefit is subject to a formal plan (for example, medical or life insurance), eligibility to participate in and receive any particular benefit is governed solely by the applicable plan document, and eligibility to participate in such plan(s) may be dependent upon, among other things, a physical examination.

(f) Reimbursement of Expenses. Executive shall be entitled to reimbursement for all ordinary and reasonable out-of-pocket business expenses that are reasonably incurred by him in furtherance of the Company’s business in accordance with reasonable policies adopted from time to time by the Company for senior executives, subject to Section 4(d)(v).

(g) Withholdings. All compensation payable to Executive shall be subject to applicable taxes and withholdings.

4. Severance Compensation.

(a) In the event of any termination of Executive's employment for any reason, the Company shall pay Executive (or Executive's estate) such portions of Executive's base salary as have accrued prior to such termination and have not yet been paid, together with (i) amounts for accrued unused vacation days (as provided above), (ii) any amounts for expense reimbursement which have been properly incurred or the Company has become obligated to pay prior to termination and have not been paid as of the date of such termination and (iii) the amount of any Bonus previously granted to Executive by the Board but not yet paid, which amount shall not include any pro rata portion of any Bonus which would have been earned if such termination had not occurred (the "Accrued Obligations"). Such Accrued Obligations shall be paid as soon as possible after termination.

(b) In the event that Executive's employment hereunder is terminated (i) by Executive for a Good Reason or (ii) by the Company without Cause, the Company shall pay to Executive the Accrued Obligations. In addition, the Company shall pay to Executive the severance benefits set forth below for twelve (12) months, or for eighteen (18) months if such termination occurs during the twelve (12) month period following a Corporate Change (the "Protected Period"), following Executive's termination of employment (as applicable, the "Severance Period"). The receipt of any severance benefits provided in this Section shall be dependent upon Executive's execution and nonrevocation of a standard separation agreement and general release of claims, substantially in the form attached hereto as Exhibit B (the "Release"). The distribution of severance benefits in this Section 4 is subject to Section 4(d).

(i) The Company shall continue to pay Executive his base salary for the Severance Period in accordance with the Company's payroll practice, beginning on the Company's first regular payroll date that occurs on or after the 30th day following Executive's termination of employment, provided that the Release has been executed and any applicable revocation period has expired as of such date. Notwithstanding the foregoing, if Executive's termination of employment occurs during the Protected Period, the Company shall pay Executive his base salary for the Severance Period in a lump sum 30 days following Executive's termination of employment, provided that the Release has been executed and any applicable revocation period has expired as of such date.

(ii) Only if Executive's employment is terminated (A) by Executive for a Good Reason or (B) by the Company without Cause, in each case during the Protected Period, the Company shall pay Executive an amount equal to one and one-half times his target annual bonus, described in Section 3(b) hereof, for the year in which the termination of employment occurs, which total amount shall be payable in a lump sum 30 days following Executive's termination of employment, provided that the Release has been executed and any applicable revocation period has expired as of such date.

(iii) Only if Executive's employment is terminated (A) by Executive for a Good Reason or (B) by the Company without Cause, in each case during the Protected Period, one hundred percent (100%) of Executive's outstanding unvested equity awards granted under the Company's equity and long-term incentive plan(s) prior to his termination shall vest immediately.

(iv) The Company shall continue to provide Executive and his then-enrolled eligible dependents with group health insurance and shall continue to pay the amount of the premium as in effect on the date of such termination for the Severance Period commencing on the effective date of such termination, subject to applicable law and the terms of the respective policies; provided that the Company's obligation to provide the benefits contemplated herein shall terminate upon Executive's becoming eligible for coverage under the medical benefits program of a subsequent employer. The foregoing shall not be construed to extend any period of continuation coverage (e.g., COBRA) required by Federal law.

(c) In the event that Executive's employment hereunder is terminated (i) by Executive for other than a Good Reason, or (ii) by the Company for Cause, or (iii) as a result of Executive's death or Disability, then the Company will pay to Executive the Accrued Obligations. The Company shall have no obligation to pay Executive (or Executive's estate) any other compensation following such termination except as provided in Section 4(a).

(d) Compliance with Section 409A. Subject to the provisions in this Section 4(d), any severance payments or benefits under this Agreement shall begin only upon the date of Executive's "separation from service" (determined as set forth below) which occurs on or after the date of termination of Executive's employment. The following rules shall apply with respect to the distribution of the severance payments and benefits, if any, to be provided to Executive under this Agreement:

(i) It is intended that each installment of the severance payments and benefits provided under this Agreement shall be treated as a separate "payment" for purposes of Section 409A. Neither the Company nor Executive shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.

(ii) If, as of the date of Executive's "separation from service" from the Company, Executive is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments and benefits shall be made on the dates and terms set forth in this Agreement.

(iii) If, as of the date of Executive's "separation from service" from the Company, Executive is a "specified employee" (within the meaning of Section 409A), then:

(A) Each installment of the severance payments and benefits due under this Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and such payments and benefits shall be paid or provided on the dates and terms set forth in this Agreement; and

(B) Each installment of the severance payments and benefits due this Agreement that is not described in Section 4(d)(iii)(A) above and that would, absent this subsection (B), be paid within the six-month period following Executive's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, Executive's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following Executive's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of severance payments and benefits if and to the maximum extent that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of Executive's second taxable year following the taxable year in which the separation from service occurs.

(iv) The determination of whether and when Executive's separation from service from the Company has occurred shall be made in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Section 4(d)(iv), "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

(v) All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Sections 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during Executive's lifetime (or during a shorter period of time specified in this Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

(vi) Notwithstanding anything herein to the contrary, the Company shall have no liability to Executive or to any other person if the payments and benefits provided hereunder that are intended to be exempt from or compliant with Section 409A are not so exempt or compliant.

(e) Modified Section 280G Cutback.

(i) Notwithstanding any other provision of this Agreement, except as set forth in Section 4(e)(ii), in the event that the Company undergoes a “Change in Ownership or Control” (as defined below), the Company shall not be obligated to provide to Executive a portion of any “Contingent Compensation Payments” (as defined below) that Executive would otherwise be entitled to receive to the extent necessary to eliminate any “excess parachute payments” (as defined in Section 280G(b)(1) of the Code) for Executive. For purposes of this Section 4(e), the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Payments” and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Amount.”

(ii) Notwithstanding the provisions of Section 4(e)(i), no such reduction in Contingent Compensation Payments shall be made if (1) the Eliminated Amount (computed without regard to this sentence) exceeds (2) 100% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that would be incurred by Executive if the Eliminated Payments (determined without regard to this sentence) were paid to him (including federal and state income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of Executive’s “base amount” (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 4(e)(ii) shall be referred to as a “Section 4(e)(ii) Override.” For purpose of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

(iii) For purposes of this Section 4(e) the following terms shall have the following respective meanings:

(1) “Change in Ownership or Control” shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.

(2) “Contingent Compensation Payment” shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this Agreement or otherwise) to a “disqualified individual” (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.

(iv) Any payments or other benefits otherwise due to Executive following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the “Potential

Payments”) shall not be made until the dates provided for in this Section 4(e)(iv). Within 30 days after each date on which Executive first becomes entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify Executive (with reasonable detail regarding the basis for its determinations) (1) which Potential Payments constitute Contingent Compensation Payments, (2) the Eliminated Amount and (3) whether the Section 4(e)(ii) Override is applicable. Within 30 days after delivery of such notice to Executive, Executive shall deliver a response to the Company (the “Executive Response”) stating either (A) that he agrees with the Company’s determination pursuant to the preceding sentence or (B) that he disagrees with such determination, in which case he shall set forth (x) which Potential Payments should be characterized as Contingent Compensation Payments, (y) the Eliminated Amount, and (z) whether the Section 4(e)(ii) Override is applicable. In the event that Executive fails to deliver an Executive Response on or before the required date, the Company’s initial determination shall be final. If Executive states in the Executive Response that he agrees with the Company’s determination, the Company shall make the Potential Payments to Executive within three business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If Executive states in the Executive Response that he disagrees with the Company’s determination, then, for a period of 60 days following delivery of the Executive Response, Executive and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such 60-day period, such dispute shall be settled exclusively by arbitration in the greater Boston, Massachusetts area, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator’s award in any court having jurisdiction. The Company shall, within three business days following delivery to the Company of the Executive Response, make to Executive those Potential Payments as to which there is no dispute between the Company and Executive regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three business days following the resolution of such dispute.

(v) The Contingent Compensation Payments to be treated as Eliminated Payments shall be determined by the Company by determining the “Contingent Compensation Payment Ratio” (as defined below) for each Contingent Compensation Payment and then reducing the Contingent Compensation Payments in order beginning with the Contingent Compensation Payment with the highest Contingent Compensation Payment Ratio. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio, such Contingent Compensation Payment shall be reduced based on the time of payment of such Contingent Compensation Payments with amounts having later payment dates being reduced first. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio and the same time of payment, such Contingent Compensation Payments shall be reduced on a pro rata basis (but not below zero) prior to reducing Contingent Compensation Payments with a lower Contingent Compensation Payment Ratio. The term “Contingent Compensation Payment Ratio” shall mean a fraction the numerator of which is the value of the applicable Contingent Compensation Payment that must be taken into account by

Executive for purposes of Section 4999(a) of the Code, and the denominator of which is the actual amount to be received by Executive in respect of the applicable Contingent Compensation Payment. For example, in the case of an equity grant that is treated as contingent on the Change in Ownership or Control because the time at which the payment is made or the payment vests is accelerated, the denominator shall be determined by reference to the fair market value of the equity at the acceleration date, and not in accordance with the methodology for determining the value of accelerated payments set forth in Treasury Regulation Section 1.280G-1Q/A-24(b) or (c).

(vi) The provisions of this Section 4(e) are intended to apply to any and all payments or benefits available to Executive under this Agreement or any other agreement or plan of the Company under which Executive receives Contingent Compensation Payments.

5. Employee Covenants.

(a) Restrictive Covenant Agreement. As a condition of Executive's employment, he will be required to execute the Company's Proprietary Information and Inventions Agreement (the "Restrictive Covenant Agreement"), a copy of which is attached as Exhibit C hereto. Executive agrees that if there is a conflict between any provision in the Restrictive Covenant Agreement and any provision of this Agreement, then the provision that provides the most protection to the Company and/or its interests shall govern.

(b) Confidential Information. Executive recognizes and acknowledges the competitive and proprietary aspects of the business of the Company, and that as a result of Executive's employment, Executive recognizes and acknowledges that he has had and will continue to have access to, and has been and will continue to be involved in the development of, Confidential Information (as defined below) of the Company. As used herein, "Confidential Information" shall mean and include trade secrets, knowledge and other confidential information of the Company, which Executive has acquired, no matter from whom or on what matter such knowledge or information may have been acquired, heretofore or hereafter, concerning the content and details of the business of the Company, and which is not known to the general public, including but not limited to: confidential and proprietary information supplied to Executive with the legend "Confidential and Proprietary," or equivalent, the Company's marketing and customer support strategies, suppliers and customers, marketing and selling, business plans, licenses, the Company's financial information, including sales, costs, profits, prices, pricing methods, budgets and unpublished financial statements, the Company's internal organization, employee information, information regarding the skills and compensation of other employees of the Company and customer lists, the Company's technology, including products, discoveries, inventions, research, experimental and development efforts, clinical studies, processes, hardware/software design and maintenance tools, samples, media and/or molecular structures (and procedures and formulations for producing any such samples, media and/or molecular structures), formulas, methods, know-how and show-how, designs, prototypes, plans for research and new products, and all derivatives, improvements and enhancements of any of the above and information of third parties as to which the Company has an obligation of confidentiality.

(i) For as long as Executive is employed and at all times thereafter, Executive shall not, directly or indirectly, communicate, disclose or divulge to any person

or entity, or use for Executive's own benefit or the benefit of any person (other than the Company), any Confidential Information, except as permitted in subparagraph (iii) below. Upon termination of Executive's employment, or at any other time at the request of the Company, Executive agrees to deliver promptly to the Company all Confidential Information, including, but not limited to, customer and supplier lists, files and records, in Executive's possession or under Executive's control. Executive further agrees that he will not make or retain any copies of any of the foregoing and will so represent to the Company upon termination of Executive's employment.

(ii) Executive shall disclose immediately to the Company any trade secrets or other Confidential Information conceived or developed by Executive at any time during Executive's employment. Executive hereby assigns and agrees to assign to the Company Executive's entire right, title and interest in and to all Confidential Information. Such assignment shall include, without limitation, the rights to obtain patent or copyright protection thereon in the United States and foreign countries. Executive agrees to provide all reasonable assistance to enable the Company to prepare and prosecute any application before any governmental agency for patent or copyright protection or any similar application with respect to any Confidential Information. Executive further agrees to execute all documents and assignments and to make all oaths necessary to vest ownership of such intellectual property rights in the Company, as the Company may request. These obligations shall apply whether or not the subject thereof was conceived or developed at the suggestion of the Company, and whether or not developed during regular hours of work or while on the premises of the Company.

(iii) Executive shall at all times, both during and after termination of this Agreement by either Executive or the Company, maintain in confidence and shall not, without prior written consent of the Company, use, except in the course of performance of Executive's duties for the Company or as required by legal process (provided that Executive will promptly notify the Company of such legal process except with respect to any confidential government investigation), disclose or give to others any Confidential Information. In the event Executive is questioned by anyone not employed by the Company or by an employee of or a consultant to the Company not authorized to receive such information, in regard to any such information or any other secret or confidential work of the Company, or concerning any fact or circumstance relating thereto, Executive will promptly notify the Company.

(c) Non-Competition and Non-Solicitation. Executive recognizes that the Company is engaged in a competitive business and that the Company has a legitimate interest in protecting its trade secrets, confidential business information, and customer, business development partner, licensee, supplier, and credit and/or financial relationships. Accordingly, in exchange for valuable consideration, including without limitation Executive's access to confidential business information and employment, Executive agrees that, during the term hereof and for a period of twelve (12) months thereafter, Executive shall not:

(i) directly or indirectly, whether for himself or for any other person or entity, and whether as a proprietor, principal, shareholder, partner, agent, employee, consultant, independent contractor, or in any other capacity whatsoever, undertake or have any interest in (other than the passive ownership of publicly registered securities representing an ownership interest of less than 1%), engage in or assume any role

involving directly or indirectly any business activity which is directly or indirectly in competition with the products or services being developed, marketed, sold or otherwise provided by the Company or any other business in which the Company is engaged and for which Executive has rendered services while employed by the Company, or enter into any agreement to do any of the foregoing; or

(ii) initiate contact with (including without limitation phone calls, press releases and the sending or delivering of announcements), or in any manner solicit, directly or indirectly, any customers, business development partners, licensors, licensees, or creditors (including institutional lenders, bonding companies and trade creditors) of the Company in an attempt to induce or motivate them either to discontinue or modify their then prevailing or future relationship with the Company or to transfer any of their business with the Company to any person or entity other than the Company; or

(iii) initiate contact with, or in any manner solicit, directly or indirectly, any supplier of goods, services or materials to the Company in an attempt to induce or motivate them either to discontinue or modify their then prevailing or future relationship with the Company or to supply the same or similar inventory, goods, services or materials (except generally available inventory, goods, services or materials) to any person or entity other than the Company; or

(iv) directly or indirectly recruit, solicit or otherwise induce or influence any employee or independent contractor of the Company to discontinue or modify his or her employment or engagement with the Company, or employ or contract with any such employee or contractor for the provision of services.

(d) Definition of "Customer". The term "customer" or "customers" shall include any person or entity (a) that is a current customer of the Company, (b) that was a customer of the Company at any time during the preceding twenty-four (24) months or (c) to which the Company made a written presentation for the solicitation of business at any time during the preceding twenty-four (24) months.

(e) Reasonableness of Restrictions. Executive further recognizes and acknowledges that (i) the types of employment which are prohibited by this Section 5 are narrow and reasonable in relation to the skills which represent Executive's principal salable asset both to the Company and to Executive's other prospective employers, and (ii) the broad geographical scope of the provisions of this Section 5 is reasonable, legitimate and fair to Executive in light of the global nature of the Company's business, and in light of the limited restrictions on the type of employment prohibited herein compared to the types of employment for which Executive is qualified to earn Executive's livelihood.

(f) Remedies. Executive acknowledges that a breach of this Section 5 will cause great and irreparable injury and damage, which cannot be reasonably or adequately compensated by money damages. Accordingly, Executive acknowledges that the remedies of injunction and specific performance shall be available in the event of such a breach, in addition to money damages, costs and attorneys' fees, and other legal or equitable remedies, and that the Company shall be entitled as a matter of course to an injunction pending trial, without the posting of bond or other security. Any period of restriction set forth in this Section 5 shall be extended for a period of time equal to the duration of any breach or violation hereof.

(g) Notification. Any person employing Executive or evidencing any intention to employ Executive may be notified as to the existence and provisions of this Agreement.

(h) Modification of Covenants; Enforceability. In the event that any provision of this Section 5 is held to be in any respect an unreasonable restriction, then the court so holding may modify the terms thereof, including the period of time during which it operates or the geographic area to which it applies, or effect any other change to the extent necessary to render this section enforceable, it being acknowledged by the parties that the representations and covenants set forth herein are of the essence of this Agreement.

(i) Subsidiaries. For purposes of Sections 5 and 6 of this Agreement, "Company" shall include all direct and indirect subsidiaries of the Company. An entity shall be deemed to be a subsidiary of the Company if the Company directly or indirectly owns or controls 50% or more of the equity interest in such entity.

6. Ownership of Ideas, Copyrights and Patents.

(a) Property of the Company. Executive agrees that all ideas, inventions, original works of authorship, developments, concepts, know-how, improvements or trade secrets, whether patentable, copyrightable or not, which Executive may conceive, reduce to practice or develop, alone or in conjunction with another, or others, whether during or out of regular business hours, and whether at the request or upon the suggestion of the Company, or otherwise, in the course of performing services for the Company in any capacity, whether heretofore or hereafter, (collectively, "the Inventions") are and shall be the sole and exclusive property of the Company, and that Executive shall not publish any of the Inventions without the prior written consent of the Company. Executive hereby assigns to the Company all of Executive's right, title and interest in and to all of the foregoing. Executive further represents and agrees that to the best of Executive's knowledge and belief none of the Inventions will violate or infringe upon any right, patent, copyright, trademark or right of privacy, or constitute libel or slander against or violate any other rights of any person, firm or corporation and that Executive will use his best efforts to prevent any such violation.

(b) Cooperation. At any time during or after the Term, Executive agrees that he will fully cooperate with the Company, its attorneys and agents in the preparation and filing of all papers and other documents as may be required to perfect the Company's rights in and to any of such Inventions, including, but not limited to, executing any lawful document (including, but not limited to, applications, assignments, oaths, declarations and affidavits) and joining in any proceeding to obtain letters patent, copyrights, trademarks or other legal rights of the United States and of any and all other countries on such Inventions, provided that any patent or other legal right so issued to Executive, personally, shall be assigned by Executive to the Company without charge by Executive. Executive further designates the Company as his agent for, and grants to the Company a power of attorney with full power of substitution, which power of attorney shall be deemed coupled with an interest, for the purpose of effecting the foregoing assignments from Executive to the Company. Company will bear the reasonable expenses which it causes to be incurred in Executive's assisting and cooperating hereunder. Executive waives all claims to moral rights in any Inventions.

7. Disclosure to Future Employers. The Company may provide in its discretion, a copy of the covenants contained in Sections 5 and 6 of this Agreement to any business or enterprise which Executive may directly, or indirectly, own, manage, operate, finance, join, control or in which Executive participates in the ownership, management, operation, financing, or control, or with which Executive may be connected as an officer, director, employee, partner, principal, agent, representative, consultant or otherwise.

8. Records. Upon termination of Executive's relationship with the Company, Executive shall deliver to the Company any property of the Company which may be in Executive's possession including products, materials, memoranda, notes, records, reports, or other documents or photocopies of the same.

9. Insurance. The Company, in its sole discretion, may apply for and procure in its own name (whether or not for its own benefit) policies of insurance insuring Executive's life. Executive agrees to submit to reasonable medical or other examinations and to execute and deliver any applications or other instruments in writing that are reasonably necessary to effectuate such insurance. No adverse employment actions may be based upon the results of any such exam or the failure by the Company to obtain such insurance.

10. No Conflicting Agreements. Executive hereby represents and warrants that he has no commitments or obligations inconsistent with this Agreement. Executive further represents that he is not bound by any employment contract, restrictive covenant or other restriction preventing him from entering into employment with, or carrying out his responsibilities for, the Company, or which is in any way inconsistent with the terms of this Agreement.

11. "Market Stand-Off" Agreement. Executive agrees, if requested by the Company and an underwriter of common stock (or other securities) of the Company, not to sell or otherwise transfer or dispose of any common stock (or other securities) of the Company held by Executive during a period not to exceed one hundred and eighty (180) days following the effective date of an underwritten public offering of common stock of the Company, offered on a firm commitment basis pursuant to a registration statement filed with the Securities and Exchange Commission (or any successor agency of the Federal government administering the Securities Act of 1933, as amend, and the Securities Exchange Act of 1934, as amended) under the Securities Act of 1933, as amended, on Form S-1 or its then equivalent, and to enter into an agreement to such effect. The Company may impose stop-transfer instructions with respect to the shares (or securities) subject to the foregoing restriction until the end of said period.

12. General.

(a) Notices. All notices, requests, consents and other communications hereunder shall be in writing, shall be addressed to the receiving party's address as follows:

If to the Company: Ocular Therapeutix, Inc.
36 Crosby Drive, Suite 101
Bedford, MA 01730
USA
Attention: Chief Executive Officer
Telephone: (781) 357-4000

With an email copy to: ASawhney@ocutx.com

If to Executive: Jon Talamo, M.D.
81 Varick Road
Newton, MA 02468
USA
Telephone:

or to such other address as a party may designate by notice hereunder, and shall be either (i) delivered by hand, (ii) sent by overnight courier, or (iii) sent by registered or certified mail, return receipt requested, postage prepaid. All notices, requests, consents and other communications hereunder shall be deemed to have been given either (i) if by hand, at the time of the delivery thereof to the receiving party at the address of such party set forth above, (ii) if sent by overnight courier, on the next business day following the day such notice is delivered to the courier service, or (iii) if sent by registered or certified mail, on the fifth (5th) business day following the day such mailing is made.

(b) Entire Agreement. This Agreement embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof (including without limitation, the Offer Letter that the parties had been negotiating) but does not supersede the Restrictive Covenant Agreement. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in this Agreement shall affect, or be used to interpret, change or restrict, the express terms and provisions of this Agreement.

(c) Modifications and Amendments. The terms and provisions of this Agreement may be modified or amended only by written agreement executed by the parties hereto.

(d) Waivers and Consents. The terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given, and shall not constitute a continuing waiver or consent.

(e) Assignment. The Company shall assign its rights and obligations hereunder to any person or entity that succeeds to all or substantially all of the Company's business or that aspect of the Company's business in which Executive is principally involved. Executive may not assign Executive's rights and obligations under this Agreement without the prior written consent of the Company.

(f) Benefit. All statements, representations, warranties, covenants and agreements in this Agreement shall be binding on the parties hereto and shall inure to the benefit of the respective successors and permitted assigns of each party hereto. Nothing in this Agreement shall be construed to create any rights or obligations except among the parties hereto, and no person or entity shall be regarded as a third-party beneficiary of this Agreement.

(g) Governing Law. This Agreement and the rights and obligations of the parties hereunder shall be construed in accordance with and governed by the law of The Commonwealth of Massachusetts, without giving effect to the conflict of law principles thereof.

(h) Jurisdiction and Service of Process. Any legal action or proceeding with respect to this Agreement shall be brought in the courts of The Commonwealth of Massachusetts or of the United States of America for the District of Massachusetts. By execution and delivery of this Agreement, each of the parties hereto accepts for itself and in respect of its property, generally and unconditionally, the jurisdiction of the aforesaid courts. Each of the parties hereto irrevocably consents to the service of process of any of the aforementioned courts in any such action or proceeding by the mailing of copies thereof by certified mail, postage prepaid, to the party at its address set forth in Section 12(a) hereof. THE PARTIES IRREVOCABLY WAIVE ANY RIGHT TO TRIAL BY JURY AS TO ALL CLAIMS HEREUNDER.

(i) Severability. The parties intend this Agreement to be enforced as written. However, (i) if any portion or provision of this Agreement shall to any extent be declared illegal or unenforceable by a duly authorized court having jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law; and (ii) if any provision, or part thereof, is held to be unenforceable because of the duration of such provision or the geographic area covered thereby, the Company and Executive agrees that the court making such determination shall have the power to reduce the duration and/or geographic area of such provision, and/or to delete specific words and phrases (“blue-penciling”), and in its reduced or blue-penciled form such provision shall then be enforceable and shall be enforced.

(j) Headings and Captions; Interpretation. The headings and captions of the various subdivisions of this Agreement are for convenience of reference only and shall in no way modify, or affect the meaning or construction of any of the terms or provisions hereof. The provisions of the following Sections of this Agreement are in addition to, and do not limit, each other: Sections 6 and 5(a); Sections 7 and 5(g); Sections 12(k) and 5(f); and Sections 12(l) and 12(d).

(k) Injunctive Relief. Executive hereby expressly acknowledges that any breach or threatened breach of any of the terms and/or conditions set forth in Section 5 or 6 of this Agreement will result in substantial, continuing and irreparable injury to the Company. Therefore, Executive hereby agrees that, in addition to any other remedy that may be available to the Company, the Company shall be entitled to injunctive or other equitable relief by a court of appropriate jurisdiction.

(l) No Waiver of Rights, Powers and Remedies. No failure or delay by a party hereto in exercising any right, power or remedy under this Agreement, and no course of dealing between the parties hereto, shall operate as a waiver of any such right, power or remedy of the party. No single or partial exercise of any right, power or remedy under this Agreement by a party hereto, nor any abandonment or discontinuance of steps to enforce any such right,

power or remedy, shall preclude such party from any other or further exercise thereof or the exercise of any other right, power or remedy hereunder. The election of any remedy by a party hereto shall not constitute a waiver of the right of such party to pursue other available remedies. No notice to or demand on a party not expressly required under this Agreement shall entitle the party receiving such notice or demand to any other or further notice or demand in similar or other circumstances or constitute a waiver of the rights of the party giving such notice or demand to any other or further action in any circumstances without such notice or demand.

(m) Counterparts. This Agreement may be executed in one or more counterparts, and by different parties hereto on separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

(n) Survival. The provisions of Sections 4, 5, 6, 7, 8, 11 and 12 shall survive the termination of this Agreement and Executive's employment hereunder in accordance with their terms.

IN WITNESS THEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

Ocular Therapeutix, Inc.

/s/ W. Bradford Smith

Name: W. Bradford Smith
Title: Chief Financial Officer

Agreed and Accepted

/s/ Jonathan Talamo

Jon Talamo, M.D.

Exhibit A

- a. Acting as the spokesperson for the Company with key opinion leaders at scientific conferences and advisory boards
- b. Building and maintaining relationships consistent with commercial and development objectives
- c. Ensuring that clinical development programs meet quality and safety standards required by medical and regulatory agencies
- d. Providing leadership and oversight to Medical Affairs, drug safety/pharmacovigilance, and pharmacoeconomic activities.
- e. Providing leadership and oversight to Clinical Development.
- f. Interfacing with our product development leaders to help define target product profiles and successfully translate those into the clinical development phase.
- g. Working cross-functionally to define, plan and implement all phases of clinical trials.
- h. Representing the Company with regulatory and legislative agencies, globally addressing the scientific and medical/health aspects of our product portfolio.
- i. Having P&L and budgetary responsibility for Clinical Development and Medical Affairs and providing strategic input to the annual and long-range budgetary processes.
- j. Advocating for the health and well-being of our patients.
- k. Developing processes and procedures to ensure the safety and monitoring of our products including processes to address product issues, recalls and product complaints.
- l. Providing medical input into complaint and adverse event investigations.

EXHIBIT B

Sample Separation and Release Agreement General Release

[Insert Date]

[Insert Executive's address]

Dear [Executive]:

In connection with the termination of your employment with Ocular Therapeutix, Inc. (the "Company") on [Termination Date], you are eligible to receive the Severance Compensation as described in Section 4 of the Employment Agreement executed between you and the Company dated _____, 20__ (the "Employment Agreement") if you sign and return this letter agreement to me by [Return Date –21 days from date of receipt of this letter agreement] and it becomes binding between you and the Company. By signing and returning this letter agreement and not revoking your acceptance, you will be agreeing to the terms and conditions set forth in the numbered paragraphs below, including the release of claims set forth in paragraph 3. Therefore, you are advised to consult with an attorney before signing this letter agreement and you may take up to twenty-one (21) days to do so. If you sign this letter agreement, you may change your mind and revoke your agreement during the seven (7) day period after you have signed it by notifying me in writing. If you do not so revoke, this letter agreement will become a binding agreement between you and the Company upon the expiration of the seven (7) day period.

If you choose not to sign and return this letter agreement by [Return Date-Same as Above], or if you timely revoke your acceptance in writing, you shall not receive any Severance Compensation from the Company. You will, however, receive payment for your final wages and any unused vacation time accrued through the Termination Date, as defined below, on the Company's regular payroll date immediately following the Termination Date. Also, regardless of signing this letter agreement, you may elect to continue receiving group medical insurance pursuant to the federal "COBRA" law, 29 U.S.C. § 1161 et seq. If you so elect, you shall pay all premium costs on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation. You should consult the COBRA materials to be provided by the Company for details regarding these benefits. All other benefits will cease upon your Termination Date in accordance with the plan documents.

The following numbered paragraphs set forth the terms and conditions that will apply if you timely sign and return this letter agreement and do not revoke it in writing within the seven (7) day period.

1. **Termination Date** – Your effective date of termination from the Company is [Insert Date] (the "Termination Date").
2. **Release** – In consideration of the payment of the Severance Compensation, which you acknowledge you would not otherwise be entitled to receive, you hereby fully, forever, irrevocably and unconditionally release, remise and discharge the Company, its affiliates, subsidiaries, parent companies, predecessors, and successors, and all of their respective past and present officers, directors, stockholders, partners, members, employees, agents, representatives, plan administrators, attorneys, insurers and fiduciaries (each in their individual and corporate capacities) (collectively, the "Released Parties") from any and

all claims, charges, complaints, demands, actions, causes of action, suits, rights, debts, sums of money, costs, accounts, reckonings, covenants, contracts, agreements, promises, doings, omissions, damages, executions, obligations, liabilities, and expenses (including attorneys' fees and costs), of every kind and nature that you ever had or now have against any or all of the Released Parties, including, but not limited to, any and all claims arising out of or relating to your employment with and/or separation from the Company, including, but not limited to, all claims under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., the Americans With Disabilities Act of 1990, 42 U.S.C. § 12101 et seq., the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq., the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000ff et seq., the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq., the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101 et seq., the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq., Executive Order 11246, Executive Order 11141, the Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq., and the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq., all as amended; the Massachusetts Fair Employment Practices Act, M.G.L. c.151B, § 1 et seq., the Massachusetts Civil Rights Act, M.G.L. c.12, §§ 11H and 11I, the Massachusetts Equal Rights Act, M.G.L. c.93, § 102 and M.G.L. c.214, § 1C, the Massachusetts Labor and Industries Act, M.G.L. c.149, § 1 et seq., the Massachusetts Privacy Act, M.G.L. c.214, § 1B and the Massachusetts Maternity Leave Act, M.G.L. c.149, § 105(d), all as amended; all common law claims including, but not limited to, actions in defamation, intentional infliction of emotional distress, misrepresentation, fraud, wrongful discharge, and breach of contract, including without limitation, all claims arising from the Employment Agreement; all state and federal whistleblower claims to the maximum extent permitted by law; all claims to any non-vested ownership interest in the Company, contractual or otherwise; and any claim or damage arising out of your employment with and/or separation from the Company (including a claim for retaliation) under any common law theory or any federal, state or local statute or ordinance not expressly referenced above; provided, however, that nothing in this letter agreement shall (i) prevent you from filing a charge with, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission or a state fair employment practices agency (except that you acknowledge that you may not recover any monetary benefits in connection with any such claim, charge or proceeding); (ii) deprive you of any accrued benefits to which you have acquired a vested right under any employee benefit plan or policy, stock plan or deferred compensation arrangement, any health care continuation to the extent required by applicable law or any agreement, or any right to severance benefits or any other benefits due to you upon termination of employment or post-employment consulting arrangements that you may have under the Employment Agreement; or (iii) deprive you of any rights you may have to be indemnified by the Company as provided in the Employment Agreement, any other agreement between the Company and you or pursuant to the Company's Certificate of Incorporation or by-laws. This Release shall not extend to any claims you may have against any persons that are Released Parties to the extent such claims are (i) related solely to your ownership of the Company's stock and (ii) unrelated to your employment with the Company.

3. **Non-Disclosure, Non-Competition and Non-Solicitation** – You acknowledge and reaffirm your obligation to keep confidential and not disclose all non-public information concerning the Company and its clients that you acquired during the course of your employment with the Company, as stated more fully in Section 5 of the Employment Agreement, which remains in full force and effect.

4. **Return of Company Property** – You confirm that you have returned to the Company all keys, files, records (and copies thereof), equipment (including, but not limited to, computer hardware, software and printers, wireless handheld devices, cellular phones, smartphones, tablets, etc.), Company identification, and any other Company-owned property in your possession or control and have left intact all electronic Company documents, including but not limited to those which you developed or helped to develop during your employment. You further confirm that you have cancelled all accounts for your benefit, if any, in the Company’s name, including but not limited to, credit cards, telephone charge cards, cellular phone and/or wireless data accounts and computer accounts.
5. **Business Expenses and Final Compensation** – You acknowledge that you have been reimbursed by the Company for all business expenses incurred in conjunction with the performance of your employment and that no other reimbursements are owed to you. You further acknowledge that you have received payment in full for all services rendered in conjunction with your employment by the Company, including payment for all wages, bonuses and accrued, unused vacation time, and that no other compensation is owed to you except as provided herein.
6. **Non-Disparagement** – To the extent permitted by law, you understand and agree that as a condition for payment to you of the Severance Compensation herein described, for a period of five years following the date hereof you shall not make any false, disparaging or derogatory statements to any person or entity, including any media outlet, regarding the Company or any of its directors, officers, employees, agents or representatives or about the Company’s business affairs and financial condition. Further, for a period of five years following the date hereof, neither the Company, nor any of its executive officers or members of its Board will directly or indirectly make, or cause to be made, any false statement, observation or opinion, disparaging your reputation.
7. **Continued Assistance**—You agree that after the Termination Date you will provide all reasonable cooperation to the Company, taking into account any duties you then owe to any future employer, including but not limited to, assisting the Company transition your job duties, assisting the Company in defending against and/or prosecuting any litigation or threatened litigation, and performing any other tasks as reasonably requested by the Company.
8. **Cooperation** – To the extent permitted by law, you agree to cooperate fully with the Company in the defense or prosecution of any claims or actions which already have been brought, are currently pending, or which may be brought in the future against or on behalf of the Company, whether before a state or federal court, any state or federal government agency, or a mediator or arbitrator. Your full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare its claims or defenses, to prepare for trial or discovery or an administrative hearing or a mediation or arbitration and to act as a witness when

requested by the Company at reasonable times designated by the Company. You agree that you will notify the Company promptly in the event that you are served with a subpoena or in the event that you are asked to provide a third party with information concerning any actual or potential complaint or claim against the Company.

9. **Amendment and Waiver** – This letter agreement shall be binding upon the parties and may not be modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by duly authorized representatives of the parties hereto. This letter agreement is binding upon and shall inure to the benefit of the parties and their respective agents, assigns, heirs, executors, successors and administrators. No delay or omission by the Company in exercising any right under this letter agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.
10. **Validity** – Should any provision of this letter agreement be declared or be determined by any court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this letter agreement.
11. **Confidentiality** – To the extent permitted by law, you understand and agree that as a condition for payment to you of the Severance Compensation herein described, the terms and contents of this letter agreement, and the contents of the negotiations and discussions resulting in this letter agreement, shall be maintained as confidential by you and your agents and representatives and shall not be disclosed except to the extent required by federal or state law or as otherwise agreed to in writing by the Company.
12. **Nature of Agreement** – You understand and agree that this letter agreement is a severance agreement and does not constitute an admission of liability or wrongdoing on the part of the Company.
13. **Acknowledgments** – You acknowledge that you have been given at least twenty-one (21) days to consider this letter agreement, and that the Company advised you to consult with an attorney of your own choosing prior to signing this letter agreement. You understand that you may revoke this letter agreement for a period of seven (7) days after you sign this letter agreement by notifying me in writing, and the letter agreement shall not be effective or enforceable until the expiration of this seven (7) day revocation period. You understand and agree that by entering into this agreement, you are waiving any and all rights or claims you might have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefits Protection Act, and that you have received consideration beyond that to which you were previously entitled.
14. **Voluntary Assent** – You affirm that no other promises or agreements of any kind have been made to or with you by any person or entity whatsoever to cause you to sign this letter agreement, and that you fully understand the meaning and intent of this letter agreement. You state and represent that you have had an opportunity to fully discuss and review the terms of this letter agreement with an attorney. You further state and represent that you have carefully read this letter agreement, understand the contents herein, freely and voluntarily assent to all of the terms and conditions hereof and sign your name of your own free act.

15. **Applicable Law** – This letter agreement shall be interpreted and construed by the laws of the Commonwealth of Massachusetts, without regard to conflict of laws provisions. You hereby irrevocably submit to and acknowledge and recognize the jurisdiction of the courts of the Commonwealth of Massachusetts, or if appropriate, a federal court located in the Commonwealth of Massachusetts (which courts, for purposes of this letter agreement, are the only courts of competent jurisdiction), over any suit, action or other proceeding arising out of, under or in connection with this letter agreement or the subject matter hereof.
16. **Entire Agreement** – This letter agreement contains and constitutes the entire understanding and agreement between the parties hereto with respect to your Severance Compensation and the settlement of claims against the Company and cancels all previous oral and written negotiations, agreements and commitments in connection therewith. Nothing in this paragraph, however, shall modify, cancel or supersede your obligations set forth in paragraph 3 herein.
17. **Tax Acknowledgement** – In connection with the payments and consideration provided to you pursuant to this letter agreement, the Company shall withhold and remit to the tax authorities the amounts required under applicable law, and you shall be responsible for all applicable taxes with respect to such payments and consideration under applicable law. You acknowledge that you are not relying upon the advice or representation of the Company with respect to the tax treatment of any of the Severance Compensation set forth in Section 4 of the Employment Agreement.

If you have any questions about the matters covered in this letter agreement, please call me at **[Insert Phone Number]**.

Very truly yours,

By: _____
[Name]
[Title]

I hereby agree to the terms and conditions set forth above. I have been given at least twenty-one (21) days to consider this letter agreement and I have chosen to execute this on the date below. I intend that this letter agreement will become a binding agreement between me and the Company if I do not revoke my acceptance in seven (7) days.

[Executive]

Date

To be returned to me by **[Return Date – 21 days from date of receipt of this letter]**

Ocular Therapeutix, Inc.

PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT

As an employee of **OCULAR THERAPEUTIX, INC.**, its subsidiary or its affiliate (together, the "Company"), and as a condition of my employment by the Company and in consideration of the compensation now and hereafter paid to me, I agree to the following:

1. MAINTAINING CONFIDENTIAL INFORMATION.

- (a) **Company Information.** I agree at all times during the term of my employment and thereafter to hold in strictest confidence, and not to use, except for the benefit of the Company, or to disclose to any person, firm or corporation, without the written authorization of the Board of Directors of the Company, any trade secrets, confidential knowledge, data or other proprietary information of the Company. By way of illustration and not limitation, such shall include information relating to products, processes, know-how, designs, formulas, methods, samples, prototypes, developmental or experimental work, improvements, discoveries, plans for research, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, suppliers and customers, and information regarding the skills and compensation of other employees of the Company.
- (b) **Former Employer Information.** I agree that I will not, during my employment with the Company, improperly use or disclose any proprietary information or trade secrets of my former or concurrent employers or companies, if any, and that I will not bring onto the premises of the Company any unpublished documents or any property belonging to my former or concurrent employers or companies unless previously and specifically consented to in writing by said employers or companies.
- (c) **Third Party Information.** I recognize that the Company has received and in the future will receive confidential or proprietary information from third parties subject to a duty on the Company's part to maintain the confidentiality of such information and, in some cases, to use it only for certain limited purposes. I agree that I owe the Company and such third parties, both during the term of my employment and thereafter, a duty to hold all such confidential or proprietary information in the strictest confidence and not to disclose it to any person, firm or corporation (except in a manner that is consistent with the Company's agreement with the third party) or use it for the benefit of anyone other than the Company or such third party (consistent with the Company's agreement with the third party), unless expressly authorized to act otherwise by an officer of the Company.

2. ASSIGNMENT OF INVENTIONS AND ORIGINAL WORKS

- (a) **Inventions and Original Works Retained by Me.** I have attached hereto as Exhibit A, a complete disclosure of all inventions, original works of authorship, developments, improvements, and trade secrets that I have, alone or jointly with others, conceived, developed or reduced to practice or caused to be conceived, developed or reduced to practice prior to the commencement of my employment with the Company, that I consider to be my property or the property of third parties and that I wish to have excluded from the scope of this Agreement. If disclosure of an item on Exhibit A would cause me to violate any prior confidentiality agreement, I understand that I am not to disclose such on Exhibit A but in the applicable space on Exhibit A I am only to disclose a cursory name for each such invention, a listing of the party(ies) to whom it belongs and the fact that full disclosure as to such inventions have not been made for that reason. A space is provided on Exhibit A for such purpose. If no disclosure is attached, I represent that there are no such inventions.
- (b) **Inventions and Original Works Assigned to the Company.** I agree that I will make prompt written disclosure to the Company, will hold in trust for the sole right and benefit of the Company, and hereby assign, without further compensation, to the Company all my right, title and interest in and to any ideas, inventions, original works of authorship, developments, improvements or trade secrets which I may solely or jointly conceive or reduce to practice, or cause to be conceived or reduced to practice, during the period of my employment with the Company. I acknowledge that all original works of authorship which are made by me (solely or jointly with others) within the scope of my employment and which are protected by copyright are “works made for hire,” as that term is defined in the United States Copyright Act (17 U.S.C., Section 101). If the copyright to any such copyrightable work shall not be the property of the Company by operation of law, I will, without further consideration, assign to the Company all of my right, title and interest in such copyrightable work and will cooperate with the Company and its designees, at the Company’s expense, to secure, maintain and defend for the Company’s benefit copyrights and any extensions and renewals thereof on any and all such work. To the extent I cannot transfer and assign my entire right, title, and interest to the intellectual property, or any portion thereof, then I will assign and transfer all right, title, and interest in and to the intellectual property to the Company at the first opportunity to do so. To the extent that I cannot assign and transfer any of my full right, title, and interest in the intellectual property, then I hereby grant the Company an irrevocable, worldwide, fully paid-up, royalty-free, exclusive license, with the right to sublicense through multiple tiers, to make, use, sell, improve, reproduce, distribute, perform, display, transmit, manipulate in any manner, create derivative works based upon, and otherwise exploit or utilize in any manner the intellectual property.
- (c) **Obtaining Letters Patent, Copyright Registrations and Other Protections.** I will assist the Company in every proper way to obtain and enforce United States and foreign proprietary rights relating to any and all inventions, original works of

authorship, developments, improvements or trade secrets of the Company in any and all countries. To that end I will execute, verify and deliver such documents and perform such other acts (including appearing as a witness) the Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such proprietary rights and the assignment thereof. In addition, I will execute, verify and deliver assignments of such proprietary rights to the Company or its designee. My obligation to assist the Company with respect to proprietary rights in any and all countries shall continue beyond the termination of my employment, but the Company shall compensate me at a reasonable rate after my termination for the time actually spent by me at the Company's request on such assistance.

In the event the Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in the preceding paragraph, I hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as my agent and attorney-in-fact, to act for and in my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me. I hereby waive and quit claim to the Company any and all claims of any nature whatsoever which I now or may hereafter have for infringement of any proprietary rights assigned to the Company.

- (d) **Obligation to Keep the Company Informed.** In addition to my obligations under paragraph 2(b) above, during the period of my employment and for one (1) year after termination of my employment for any reason, I will promptly disclose to the Company fully and in writing all patent applications filed by me or on my behalf. At the time of each such disclosure, I will advise the Company in writing of any inventions that I believe are not required to be assigned to the company under Section (2b); and I will at that time provide to the Company in writing all evidence necessary to substantiate that belief. I understand that the Company will keep in confidence and will not disclose to third parties without my consent any proprietary information disclosed in writing to the Company pursuant to this Agreement relating to inventions that are not required to be assigned to the company under the provisions of Section 2(b). I will preserve the confidentiality of any such invention that is required to be assigned to the Company under Section 2(b). I agree to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that may be required by the Company) of all proprietary information developed by me and all inventions made by me during the period of my employment at the Company, which records shall be available to and remain the sole property of the Company at all times.

3. NO CONFLICTING EMPLOYMENT; NO INDUCEMENT OF OTHER EMPLOYEES OR SOLICITATION OF CUSTOMERS.

I agree that during the period of my employment by the Company I will not, without the Company's express written consent, engage in any other employment or business activity directly related to the business in which the Company is now involved or becomes

involved, nor will I engage in any other activities which conflict with my obligations to the Company. For a period of one (1) year after the termination or cessation of my employment with the Company for any reason, I agree that I will not, directly or indirectly, alone or as a partner, officer, director, employee, consultant, agent, independent contractor, or stockholder of any company or business organization, engage in any business activity which is directly or indirectly in competition with the products or services being developed, marketed, sold or otherwise provided by the Company, or which is directly or indirectly detrimental to the Company's business ("Competitive Activity"). I agree that, during my employment and for the one year period immediately following the cessation of my employment for any reason, I will not, and will not assist anyone else to, (a) hire or solicit for hiring any employee of the Company or seek to persuade or induce any employee of the Company to discontinue employment with the Company, or (b) solicit, encourage or induce any independent contractor providing services to the Company to terminate or diminish its relationship with the Company. For the purposes of this Agreement, an "employee" of the Company is any person who was such at any time within the preceding two years. I further agree that, for a period of one (1) year after the termination or cessation of my employment with the Company, I will not in any capacity, either separately, jointly or in association with others, directly or indirectly, solicit or contact in connection with, or in furtherance of, a Competitive Activity any of the Company's consultants, agents, suppliers, customers or prospects that were such with respect to the Company at any time during the one year immediately preceding the date of my termination of employment or that become such with respect to the Company at any time during the one year immediately following the date of my termination. My obligations under this Section 3 shall survive the termination or cessation of my employment.

If any restriction set forth in this Section is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or geographic area as to which it may be enforceable.

4. NO CONFLICTING OBLIGATIONS.

I represent that my performance of all the terms of this Agreement and as an employee of the Company does not and will not breach any agreement or obligation of mine relating to any time prior to my employment by the Company. I have not entered into, and I agree I will not enter into, any agreement either written or oral in conflict herewith.

5. RETURN OF COMPANY DOCUMENTS.

When I leave the employ of the Company, I will deliver to the Company (and will not keep in my possession, recreate or deliver to anyone else) any and all devices, records, data, notes, reports, proposals, lists, correspondence, specifications, drawings, blueprints, sketches, materials, equipment, other documents or property, together with all copies thereof (in whatever medium recorded) belonging to the Company, its successors or assigns whether kept at the Company, home or elsewhere. I further agree that any

property situated on the Company's premises and owned by the Company, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Company personnel at any time with or without notice. Prior to leaving, I will cooperate with the Company in completing and signing the Company's termination statement for technical and management personnel confirming the above and my obligations under this Agreement.

6. NOTIFICATION OF NEW EMPLOYER.

In the event that I leave the employ of the Company, I hereby consent to the notification of my new employer of my rights and obligations under this Agreement.

7. LEGAL AND EQUITABLE REMEDIES.

Because my services are personal and unique and because I may have access to and become acquainted with the proprietary information of the Company, the Company shall have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach of this Agreement.

8. GENERAL PROVISIONS.

- (a) **Not an Employment Contract.** I agree and understand that nothing in this Agreement shall confer any right with respect to continuation of my employment by the Company, nor shall it interfere in any way with my right or the Company's right to terminate my employment at any time, with or without cause.
- (b) **Governing Law; Consent to Personal Jurisdiction.** This Agreement will be governed by and construed according to the laws of the Commonwealth of Massachusetts, excluding conflicts of laws principles. I hereby expressly consent to the personal jurisdiction of the state and federal courts located in Massachusetts for any lawsuit filed there against me by the Company arising from or relating to this Agreement.
- (c) **Entire Agreement.** This Agreement, and Exhibit A attached hereto and hereby incorporated herein, sets forth the final, complete and exclusive agreement and understanding between the Company and me relating to the subject matter hereof and supersedes all prior and contemporaneous understandings and agreements relating to its subject matter. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in writing and signed by both the Company and me. Any subsequent change or changes in my duties, salary or compensation will not affect the validity or scope of this Agreement.
- (d) **Severability.** If one or more of the provisions in this Agreement are deemed unenforceable by law, then the remaining provisions will continue in full force and effect.

- (e) **Successors and Assigns.** This Agreement will be binding upon my heirs, executors, administrators and other legal representatives and will be for the benefit of the Company, its successors and its assigns.
- (f) **Survival.** The provisions of this Agreement shall survive the termination of my employment and the assignment of this Agreement by the Company to any successor in interest or other assignee.
- (g) **Waiver.** No waiver by the Company of any breach of this Agreement shall be a waiver of any preceding or succeeding breach. No waiver by the Company of any right under this Agreement shall be construed as a waiver of any other right. The Company shall not be required to give notice to enforce strict adherence to all terms of this Agreement.
- (h) **Notice.** Any notices required or permitted hereunder shall be given to the appropriate party at the address specified below or at such other address as the party shall specify in writing. Such notice shall be deemed given upon personal delivery, or sent by certified or registered mail, postage prepaid, three (3) days after the date of mailing.

This Agreement shall be effective as of the first day of my employment with the Company.

I UNDERSTAND THAT THIS AGREEMENT AFFECTS MY RIGHTS TO INVENTIONS I MAKE DURING MY EMPLOYMENT, AND RESTRICTS MY RIGHT TO DISCLOSE OR USE THE COMPANY'S PROPRIETARY INFORMATION DURING OR SUBSEQUENT TO MY EMPLOYMENT.

I HAVE READ THIS AGREEMENT CAREFULLY AND UNDERSTAND ITS TERMS. I HAVE COMPLETELY FILLED OUT EXHIBIT A TO THIS AGREEMENT.

Dated: January 5, 2016

/s/ Jonathan M. Talamo

SIGNATURE

ADDRESS

ACCEPTED AND AGREED TO:

BY: /S/ W. BRADFORD SMITH

BRAD SMITH
CHIEF FINANCIAL OFFICER

OCULAR THERAPEUTIX, INC.
34 CROSBY DRIVE, SUITE 105
BEDFORD, MA 01730

EXHIBIT A

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

To whom it may concern:

1. Except as listed in Section 2 below the following is a complete disclosure of all inventions or improvements relevant to the subject matter of my employment by Ocular Therapeutix, Inc. (the "Company") that have been made or conceived or first reduced to practice by me alone or jointly with others prior to my engagement by the Company:

No inventions or improvements.

X See below. Probably not relevant but have included anyways.

— Additional sheets attached.

2. Due to a prior confidentiality agreement, I cannot complete the disclosure under Section 1 above with respect to inventions or improvements generally listed below, the proprietary rights and duty of confidentiality with respect to which I owe to the following party(ies):

Invention or Improvement	Party(ies)	Relationship
---------------------------------	-------------------	---------------------

U.S. Patents #20100208200 & #2010024483. Intraocular lens alignment using corneal center. A method for generating a radial alignment guide for an eye that includes collecting preoperative corneal topography data. Acquired by Alcon, Inc and incorporated into the Verion™ Image Guided System.

U.S. Patent # 8,863,749 B2; Patient Interface for ophthalmologic diagnostic and interventional procedures. Acquired by Abbott Medical Optics.

3. I propose to bring to my employment the following devices, materials and documents of a former employer or other person to whom I have an obligation of confidentiality that are not generally available to the public, which materials and documents may be used in my employment pursuant to the express written authorization of my former employer or such other person (a copy of which is attached hereto):

X No inventions or improvements.

— See below

— Additional sheets attached.

Date: January 5, 2016

Very truly yours,

/S/ JONATHAN TALAMO

SIGNATURE

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (the "Agreement") is made as of October 10, 2016 (the "Effective Date"), by and between Ocular Therapeutix, Inc., a Delaware corporation (the "Company"), and Andy Hurley ("Executive"). In consideration of the mutual covenants contained in this Agreement, the Company and Executive agree as follows:

1. Employment. The Company agrees to employ Executive and Executive agrees to be employed by the Company on the terms and conditions set forth in this Agreement.

(a) Capacity. Executive shall serve the Company as Chief Commercial Officer reporting to Amar Sawhney, President, Chief Executive Officer and Chairman (the "CEO"). During the Term (as defined below) of Executive's employment with the Company, Executive shall, subject to the direction of the CEO, have the responsibilities, duties and authority commensurate with the position of Chief Commercial Officer and shall perform such other duties as may from time to time be assigned to him by the Company. The Company may change Executive's position, duties, and work location as it deems necessary.

(b) Devotion of Duties; Representations. During the Term of Executive's employment with the Company, and as set forth in the Offer Letter between the Executive and the Company dated September 26, 2016 (the "Offer Letter"), Executive shall devote 100% of his best efforts and full business time and energies to the business and affairs of the Company, and shall endeavor to perform the duties and services contemplated hereunder to the reasonable satisfaction of the Company. Except as set forth in the Offer Letter, during the Term of Executive's employment with the Company, Executive shall not, without the prior written approval of the Company (by action of the Board), undertake any other employment from any person or entity or serve as a director of any other company; provided, however, that (i) the Company will entertain requests as to such other employment or directorships in good faith and (ii) Executive will be eligible to participate in any policy relating to outside activities that is applicable to the senior executives of the Company and approved by the Board after the date hereof. As set forth in the Offer Letter, Executive may transition to full-time employment and the terms applicable to such full time employment are set forth in the Offer Letter and are incorporated herein by reference when and if such terms become applicable.

2. Term of Employment.

(a) Executive's employment hereunder shall begin on the Effective Date. Executive's employment hereunder shall be terminated upon the first to occur of the following:

(i) Immediately upon Executive's death;

(ii) By the Company, by written notice to Executive effective as of the date of such notice (or on such other date as specified in such notice):

(A) Following the Disability of Executive. "Disability" means that Executive (i) is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months or (ii) is, by reason of any medically determinable physical or mental impairment which can be expected to last for a continuous period of not less than twelve (12) months, receiving income replacement benefits for a period of not less than three (3) months under an accident and health plan covering employees of the Company. Such incapacity shall be determined by a physician chosen by the Company and reasonably satisfactory to Executive (or Executive's legal representative) upon examination requested by the Company (to which Executive hereby agrees to submit). Notwithstanding the foregoing, such Disability must result in Executive becoming "Disabled" within the meaning of Section 409A(a)(2)(C) of the Internal Revenue Code of 1986, as amended (the "Code") and the guidance issued thereunder. (In this Agreement we refer to Section 409A of the Code and any guidance issued thereunder as "Section 409A.")

(B) For Cause (as defined below); or

(C) Subject to Section 4 hereof, without Cause;

(iii) By Executive:

(A) At any time by written notice to the Company, effective thirty (30) days after the date of such notice; or

(B) By written notice to the Company for Good Reason (as defined below), effective on the date specified in such notice.

The term of Executive's employment by the Company under this Agreement is referred to herein as the "Term."

(b) Definition of "Cause". For purposes of this Agreement, "Cause" shall, pursuant to the reasonable good faith determination by the Company as documented in writing, include: (i) the willful and continued failure by Executive to substantially perform Executive's material duties or responsibilities under this Agreement (other than such a failure as a result of Disability); (ii) any action or omission by Executive involving willful misconduct or gross negligence with regard to the Company, which has a detrimental effect on the Company; (iii) Executive's conviction of a felony, either in connection with the performance of Executive's obligations to the Company or which otherwise shall adversely affect Executive's ability to perform such obligations or shall materially adversely affect the business activities, reputation, goodwill or image of the Company; (iv) the material breach of a fiduciary duty to the Company; or (v) the material breach by Executive of any of the provisions of this Agreement, provided that any breach of Executive's obligations with respect to Sections 5 or 6 of this Agreement, subject to the cure provision in the next sentence, shall be deemed "material." In respect of the events described in clauses (i) and (v) above, the Company shall give Executive notice of the failure of performance or breach, reasonable as to time, place and manner in the circumstances, and a 30-day opportunity to cure, provided that such failure of performance or breach is reasonably amenable to cure as determined by the Company in its sole discretion.

(c) Definition of "Good Reason". For purposes of this Agreement, a "Good Reason" shall mean any of the following, unless (i) the basis for such Good Reason is cured within a reasonable period of time (determined in the light of the cure appropriate to the basis of such Good

Reason, but in no event less than thirty (30) nor more than ninety (90) days) after the Company receives written notice (which must be received from Executive within ninety (90) days of the initial existence of the condition giving rise to such Good Reason) specifying the basis for such Good Reason or (ii) Executive has consented to the condition that would otherwise be a basis for Good Reason:

(i) A change in the principal location at which Executive provides services to the Company to a location more than fifty (50) miles from such principal location (which change, the Company has reasonably determined as of the date hereof, would constitute a material change in the geographic location at which Executive provides services to the Company), provided that such a relocation shall not be deemed to occur under circumstances where Executive's responsibilities require him to work at a location other than the corporate headquarters for a reasonable period of time;

(ii) A material adverse change by the Company in Executive's duties, authority or responsibilities which causes Executive's position with the Company to become of materially less responsibility or authority than Executive's position immediately following the Effective Date where such change is not remedied within ten (10) business days after written notice thereof by Executive;

(iii) A material reduction in Executive's base salary;

(iv) A material breach of this Agreement by the Company which has not been cured within thirty (30) days after written notice thereof by Executive; or

(v) Failure to obtain the assumption (assignment) of this Agreement by any successor to the Company.

(d) Definition of "Corporate Change". For purposes of this Agreement, "Corporate Change" shall mean any circumstance in which (i) the Company is not the surviving entity in any merger, consolidation or other reorganization (or survives only as a subsidiary or affiliate of an entity other than a previously wholly-owned subsidiary of the Company); (ii) the Company sells, leases or exchanges all or substantially all of its assets to any other person or entity (other than a wholly-owned subsidiary of the Company); (iii) any person or entity, including a "group" as contemplated by Section 13(d)(3) of the Securities Exchange Act of 1934 (excluding, for this purpose, the Company or any subsidiary, or any employee benefit plan of the Company or any subsidiary, or any "group" in which all or substantially all of its members or its members' affiliates are individuals or entities who are or were beneficial owners of the Company's outstanding shares prior to the initial public offering of the Company's common stock, if any, of the Company's stock), acquires or gains ownership or control (including, without limitations, powers to vote) of more than 50% of the outstanding shares of the Company's voting stock (based upon voting power); or (v) as a result of or in connection with a contested election of directors, the persons who were directors of the Company before such election shall cease to constitute a majority of the Board of Directors of the Company. Notwithstanding the foregoing, a "Corporate Change" shall not occur as a result of a merger, consolidation, reorganization or restructuring after which either (1) a majority of the Board of Directors of the controlling entity consists of persons who were directors of the Company prior to the merger, consolidation, reorganization or restructuring or (2) all or substantially all of the individuals or entities who were the beneficial owners of the Company's outstanding shares

immediately prior to such merger, consolidation, reorganization or restructuring beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in substantially the same proportions as their ownership of the Company's outstanding shares immediately prior to the merger, consolidation, reorganization or restructuring. Notwithstanding the foregoing, for any payments or benefits hereunder (including pursuant to Section 4(b)(iii) hereof) or pursuant to any other agreement between the Company and Executive, in either case that are subject to Section 409A, the Corporate Change must constitute a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i).

3. Compensation.

(a) Base Salary. Executive's minimum base salary during the Term shall be at the rate of \$335,000. Executive's base salary shall be payable in substantially equal installments in accordance with the Company's payroll practices as in effect from time to time, less any amounts required to be withheld under applicable law. The base salary will be subject to adjustment from time to time in the sole discretion of the Company; provided that, the Company covenants that (A) during the first twelve months of Executive's employment, it shall not reduce Executive's base salary and (B) following such twelve month period, it shall not reduce the base salary below the base salary then in effect immediately prior to the reduction unless (i) Executive consents to such reduction, or (ii) the reduction is in connection with a general reduction of not more than 20% in compensation of senior executives of the Company generally that occurs prior to the effective date of any Corporate Change.

(b) Bonus. In addition to the base salary, the Company may pay Executive an annual bonus (the "Bonus") as determined by the Board, solely in its discretion (it being understood that Executive's target annual bonus shall be forty percent (40%) of Executive's base salary in effect for such year, but may be higher or lower in any year in the Board's discretion). The Board's decision to issue a Bonus to Executive in any particular year shall have no effect on the absolute discretion of the Board to grant or not to grant a Bonus in subsequent years. Any Bonus for a particular year shall be paid or provided to Executive in a lump sum no later than March 15th of the calendar year following the calendar year in which the Bonus was earned.

(c) Vacation. Executive shall be entitled to take four (4) weeks of paid vacation during each year of the Term to be taken at such time or times as shall be mutually convenient and consistent with his duties and obligations to the Company.

(d) Fringe Benefits. Executive shall be entitled to participate in any employee benefit plans that the Company makes available to its executives (including, without limitation, group life, disability, medical, dental and other insurance, retirement, pension, profit-sharing and similar plans) (collectively, the "Fringe Benefits"), provided that the Fringe Benefits shall not include any stock option or similar plans relating to the grant of equity securities of the Company. These benefits may be modified or changed from time to time at the sole discretion of the Company. Where a particular benefit is subject to a formal plan (for example, medical or life insurance), eligibility to participate in and receive any particular benefit is governed solely by the applicable plan document, and eligibility to participate in such plan(s) may be dependent upon, among other things, a physical examination.

(e) Reimbursement of Expenses. Executive shall be entitled to reimbursement for all ordinary and reasonable out-of-pocket business expenses that are reasonably incurred by him in furtherance of the Company's business in accordance with reasonable policies adopted from time to time by the Company for senior executives, subject to Section 4(d)(v).

4. Severance Compensation.

(a) In the event of any termination of Executive's employment for any reason, the Company shall pay Executive (or Executive's estate) such portions of Executive's base salary as have accrued prior to such termination and have not yet been paid, together with (i) amounts for accrued unused vacation days (as provided above), (ii) any amounts for expense reimbursement which have been properly incurred or the Company has become obligated to pay prior to termination and have not been paid as of the date of such termination and (iii) the amount of any Bonus previously granted to Executive by the Board but not yet paid, which amount shall not include any pro rata portion of any Bonus which would have been earned if such termination had not occurred (the "Accrued Obligations"). Such Accrued Obligations shall be paid as soon as possible after termination.

(b) In the event that Executive's employment hereunder is terminated (i) by Executive for a Good Reason or (ii) by the Company without Cause, the Company shall pay to Executive the Accrued Obligations. In addition, the Company shall pay to Executive the severance benefits set forth below for twelve (12) months, or for eighteen (18) months if such termination occurs during the twelve (12) month period following a Corporate Change (the "Protected Period"), following Executive's termination of employment (as applicable, the "Severance Period"). The receipt of any severance benefits provided in this Section shall be dependent upon Executive's execution and non-revocation of a standard separation agreement and general release of claims, substantially in the form attached hereto as Exhibit A (the "Release"). The distribution of severance benefits in this Section 4 is subject to Section 4(d).

(i) The Company shall continue to pay Executive his base salary for the Severance Period in accordance with the Company's payroll practice, beginning on the Company's first regular payroll date that occurs on or after the 30th day following Executive's termination of employment, provided that the Release has been executed and any applicable revocation period has expired as of such date. Notwithstanding the foregoing, if Executive's termination of employment occurs during the Protected Period, the Company shall pay Executive his base salary for the Severance Period in a lump sum 30 days following Executive's termination of employment, provided that the Release has been executed and any applicable revocation period has expired as of such date.

(ii) Only if Executive's employment is terminated (A) by Executive for a Good Reason or (B) by the Company without Cause, in each case during the Protected Period, the Company shall pay Executive an amount equal to one and one-half times his target annual bonus, described in Section 3(b) hereof, for the year in which the termination of employment occurs, which total amount shall be payable in a lump sum 30 days following Executive's termination of employment, provided that the Release has been executed and any applicable revocation period has expired as of such date.

(iii) Only if Executive's employment is terminated (A) by Executive for a Good Reason or (B) by the Company without Cause, in each case during the Protected Period, one hundred percent (100%) of Executive's outstanding unvested equity awards granted under the Company's equity and long-term incentive plan(s) prior to his termination shall vest immediately.

(iv) The Company shall continue to provide Executive and his then-enrolled eligible dependents with group health insurance and shall continue to pay the amount of the premium as in effect on the date of such termination for the Severance Period commencing on the effective date of such termination, subject to applicable law and the terms of the respective policies; provided that the Company's obligation to provide the benefits contemplated herein shall terminate upon Executive's becoming eligible for coverage under the medical benefits program of a subsequent employer. The foregoing shall not be construed to extend any period of continuation coverage (e.g., COBRA) required by Federal law.

(c) In the event that Executive's employment hereunder is terminated (i) by Executive for other than a Good Reason, or (ii) by the Company for Cause, or (iii) as a result of Executive's death or Disability, then the Company will pay to Executive the Accrued Obligations. The Company shall have no obligation to pay Executive (or Executive's estate) any other compensation following such termination except as provided in Section 4(a).

(d) Compliance with Section 409A. Subject to the provisions in this Section 4(d), any severance payments or benefits under this Agreement shall begin only upon the date of Executive's "separation from service" (determined as set forth below) which occurs on or after the date of termination of Executive's employment. The following rules shall apply with respect to the distribution of the severance payments and benefits, if any, to be provided to Executive under this Agreement:

(i) It is intended that each installment of the severance payments and benefits provided under this Agreement shall be treated as a separate "payment" for purposes of Section 409A. Neither the Company nor Executive shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.

(ii) If, as of the date of Executive's "separation from service" from the Company, Executive is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments and benefits shall be made on the dates and terms set forth in this Agreement.

(iii) If, as of the date of Executive's "separation from service" from the Company, Executive is a "specified employee" (within the meaning of Section 409A), then:

(A) Each installment of the severance payments and benefits due under this Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and such payments and benefits shall be paid or provided on the dates and terms set forth in this Agreement; and

(B) Each installment of the severance payments and benefits due this Agreement that is not described in Section 4(d)(iii)(A) above and that would, absent this subsection (B), be paid within the six-month period following Executive's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, Executive's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following Executive's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of severance payments and benefits if and to the maximum extent that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of Executive's second taxable year following the taxable year in which the separation from service occurs.

(iv) The determination of whether and when Executive's separation from service from the Company has occurred shall be made in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Section 4(d)(iv), "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

(v) All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Sections 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during Executive's lifetime (or during a shorter period of time specified in this Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

(vi) Notwithstanding anything herein to the contrary, the Company shall have no liability to Executive or to any other person if the payments and benefits provided hereunder that are intended to be exempt from or compliant with Section 409A are not so exempt or compliant.

(e) Modified Section 280G Cutback.

(i) Notwithstanding any other provision of this Agreement, except as set forth in Section 4(e)(ii), in the event that the Company undergoes a “Change in Ownership or Control” (as defined below), the Company shall not be obligated to provide to Executive a portion of any “Contingent Compensation Payments” (as defined below) that Executive would otherwise be entitled to receive to the extent necessary to eliminate any “excess parachute payments” (as defined in Section 280G(b)(1) of the Code) for Executive. For purposes of this Section 4(e), the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Payments” and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Amount.”

(ii) Notwithstanding the provisions of Section 4(e)(i), no such reduction in Contingent Compensation Payments shall be made if (1) the Eliminated Amount (computed without regard to this sentence) exceeds (2) 100% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that would be incurred by Executive if the Eliminated Payments (determined without regard to this sentence) were paid to him (including federal and state income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of Executive’s “base amount” (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 4(e)(ii) shall be referred to as a “Section 4(e)(ii) Override.” For purpose of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

(iii) For purposes of this Section 4(e) the following terms shall have the following respective meanings:

(1) “Change in Ownership or Control” shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.

(2) “Contingent Compensation Payment” shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this Agreement or otherwise) to a “disqualified individual” (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.

(iv) Any payments or other benefits otherwise due to Executive following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the “Potential

Payments”) shall not be made until the dates provided for in this Section 4(e)(iv). Within 30 days after each date on which Executive first becomes entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify Executive (with reasonable detail regarding the basis for its determinations) (1) which Potential Payments constitute Contingent Compensation Payments, (2) the Eliminated Amount and (3) whether the Section 4(e)(ii) Override is applicable. Within 30 days after delivery of such notice to Executive, Executive shall deliver a response to the Company (the “Executive Response”) stating either (A) that he agrees with the Company’s determination pursuant to the preceding sentence or (B) that he disagrees with such determination, in which case he shall set forth (x) which Potential Payments should be characterized as Contingent Compensation Payments, (y) the Eliminated Amount, and (z) whether the Section 4(e)(ii) Override is applicable. In the event that Executive fails to deliver an Executive Response on or before the required date, the Company’s initial determination shall be final. If Executive states in the Executive Response that he agrees with the Company’s determination, the Company shall make the Potential Payments to Executive within three business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If Executive states in the Executive Response that he disagrees with the Company’s determination, then, for a period of 60 days following delivery of the Executive Response, Executive and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such 60-day period, such dispute shall be settled exclusively by arbitration in the greater Boston, Massachusetts area, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator’s award in any court having jurisdiction. The Company shall, within three business days following delivery to the Company of the Executive Response, make to Executive those Potential Payments as to which there is no dispute between the Company and Executive regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three business days following the resolution of such dispute.

(v) The Contingent Compensation Payments to be treated as Eliminated Payments shall be determined by the Company by determining the “Contingent Compensation Payment Ratio” (as defined below) for each Contingent Compensation Payment and then reducing the Contingent Compensation Payments in order beginning with the Contingent Compensation Payment with the highest Contingent Compensation Payment Ratio. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio, such Contingent Compensation Payment shall be reduced based on the time of payment of such Contingent Compensation Payments with amounts having later payment dates being reduced first. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio and the same time of payment, such Contingent Compensation Payments shall be reduced on a pro rata basis (but not below zero) prior to reducing Contingent Compensation Payments with a lower Contingent Compensation Payment Ratio. The term “Contingent Compensation Payment Ratio” shall mean a fraction the numerator of which is the value of the applicable Contingent Compensation Payment that must be taken into account by

Executive for purposes of Section 4999(a) of the Code, and the denominator of which is the actual amount to be received by Executive in respect of the applicable Contingent Compensation Payment. For example, in the case of an equity grant that is treated as contingent on the Change in Ownership or Control because the time at which the payment is made or the payment vests is accelerated, the denominator shall be determined by reference to the fair market value of the equity at the acceleration date, and not in accordance with the methodology for determining the value of accelerated payments set forth in Treasury Regulation Section 1.280G-1Q/A-24(b) or (c)).

(vi) The provisions of this Section 4(e) are intended to apply to any and all payments or benefits available to Executive under this Agreement or any other agreement or plan of the Company under which Executive receives Contingent Compensation Payments.

5. Employee Covenants.

(a) Confidential Information. Executive recognizes and acknowledges the competitive and proprietary aspects of the business of the Company, and that as a result of Executive's employment, Executive recognizes and acknowledges that he has had and will continue to have access to, and has been and will continue to be involved in the development of, Confidential Information (as defined below) of the Company. As used herein, "Confidential Information" shall mean and include trade secrets, knowledge and other confidential information of the Company, which Executive has acquired, no matter from whom or on what matter such knowledge or information may have been acquired, heretofore or hereafter, concerning the content and details of the business of the Company, and which is not known to the general public, including but not limited to: confidential and proprietary information supplied to Executive with the legend "Confidential and Proprietary," or equivalent, the Company's marketing and customer support strategies, suppliers and customers, marketing and selling, business plans, licenses, the Company's financial information, including sales, costs, profits, prices, pricing methods, budgets and unpublished financial statements, the Company's internal organization, employee information, information regarding the skills and compensation of other employees of the Company and customer lists, the Company's technology, including products, discoveries, inventions, research, experimental and development efforts, clinical studies, processes, hardware/software design and maintenance tools, samples, media and/or molecular structures (and procedures and formulations for producing any such samples, media and/or molecular structures), formulas, methods, know-how and show-how, designs, prototypes, plans for research and new products, and all derivatives, improvements and enhancements of any of the above and information of third parties as to which the Company has an obligation of confidentiality.

(i) For as long as Executive is employed and at all times thereafter, Executive shall not, directly or indirectly, communicate, disclose or divulge to any person or entity, or use for Executive's own benefit or the benefit of any person (other than the Company), any Confidential Information, except as permitted in subparagraph (iii) below. Upon termination of Executive's employment, or at any other time at the request of the Company, Executive agrees to deliver promptly to the Company all Confidential Information, including, but not limited to, customer and supplier lists, files and records, in Executive's possession or under Executive's control. Executive further agrees that he will not make or retain any copies of any of the foregoing and will so represent to the Company upon termination of Executive's employment.

(ii) Executive shall disclose immediately to the Company any trade secrets or other Confidential Information conceived or developed by Executive at any time during Executive's employment. Executive hereby assigns and agrees to assign to the Company Executive's entire right, title and interest in and to all Confidential Information. Such assignment shall include, without limitation, the rights to obtain patent or copyright protection thereon in the United States and foreign countries. Executive agrees to provide all reasonable assistance to enable the Company to prepare and prosecute any application before any governmental agency for patent or copyright protection or any similar application with respect to any Confidential Information. Executive further agrees to execute all documents and assignments and to make all oaths necessary to vest ownership of such intellectual property rights in the Company, as the Company may request. These obligations shall apply whether or not the subject thereof was conceived or developed at the suggestion of the Company, and whether or not developed during regular hours of work or while on the premises of the Company.

(iii) Executive shall at all times, both during and after termination of this Agreement by either Executive or the Company, maintain in confidence and shall not, without prior written consent of the Company, use, except in the course of performance of Executive's duties for the Company or as required by legal process (provided that Executive will promptly notify the Company of such legal process except with respect to any confidential government investigation), disclose or give to others any Confidential Information. In the event Executive is questioned by anyone not employed by the Company or by an employee of or a consultant to the Company not authorized to receive such information, in regard to any such information or any other secret or confidential work of the Company, or concerning any fact or circumstance relating thereto, Executive will promptly notify the Company.

(b) Non-Competition and Non-Solicitation. Executive recognizes that the Company is engaged in a competitive business and that the Company has a legitimate interest in protecting its trade secrets, confidential business information, and customer, business development partner, licensee, supplier, and credit and/or financial relationships. Accordingly, in exchange for valuable consideration, including without limitation Executive's access to confidential business information and continued at-will employment, Executive agrees that, during the term hereof and for a period of twelve (12) months thereafter, Executive shall not:

(i) directly or indirectly, whether for himself or for any other person or entity, and whether as a proprietor, principal, shareholder, partner, agent, employee, consultant, independent contractor, or in any other capacity whatsoever, undertake or have any interest in (other than the passive ownership of publicly registered securities representing an ownership interest of less than 1%), engage in or assume any role involving directly or indirectly any business activity which is directly or indirectly in competition with the products or services being developed, marketed, sold or otherwise provided by the Company or any other business in which the Company is engaged and for which Executive has rendered services while employed by the Company, or enter into any agreement to do any of the foregoing; or

(ii) initiate contact with (including without limitation phone calls, press releases and the sending or delivering of announcements), or in any manner solicit, directly or indirectly, any customers, business development partners, licensors, licensees, or creditors (including institutional lenders, bonding companies and trade creditors) of the Company in an attempt to induce or motivate them either to discontinue or modify their then prevailing or future relationship with the Company or to transfer any of their business with the Company to any person or entity other than the Company; or

(iii) initiate contact with, or in any manner solicit, directly or indirectly, any supplier of goods, services or materials to the Company in an attempt to induce or motivate them either to discontinue or modify their then prevailing or future relationship with the Company or to supply the same or similar inventory, goods, services or materials (except generally available inventory, goods, services or materials) to any person or entity other than the Company; or

(iv) directly or indirectly recruit, solicit or otherwise induce or influence any employee or independent contractor of the Company to discontinue or modify his or her employment or engagement with the Company, or employ or contract with any such employee or contractor for the provision of services.

(c) Definition of "Customer". The term "customer" or "customers" shall include any person or entity (a) that is a current customer of the Company, (b) that was a customer of the Company at any time during the preceding twenty-four (24) months or (c) to which the Company made a written presentation for the solicitation of business at any time during the preceding twenty-four (24) months.

(d) Reasonableness of Restrictions. Executive further recognizes and acknowledges that (i) the types of employment which are prohibited by this Section 5 are narrow and reasonable in relation to the skills which represent Executive's principal salable asset both to the Company and to Executive's other prospective employers, and (ii) the broad geographical scope of the provisions of this Section 5 is reasonable, legitimate and fair to Executive in light of the global nature of the Company's business, and in light of the limited restrictions on the type of employment prohibited herein compared to the types of employment for which Executive is qualified to earn Executive's livelihood.

(e) Remedies. Executive acknowledges that a breach of this Section 5 will cause great and irreparable injury and damage, which cannot be reasonably or adequately compensated by money damages. Accordingly, Executive acknowledges that the remedies of injunction and specific performance shall be available in the event of such a breach, in addition to money damages, costs and attorneys' fees, and other legal or equitable remedies, and that the Company shall be entitled as a matter of course to an injunction pending trial, without the posting of bond or other security. Any period of restriction set forth in this Section 5 shall be extended for a period of time equal to the duration of any breach or violation hereof.

(f) Notification. Any person employing Executive or evidencing any intention to employ Executive may be notified as to the existence and provisions of this Agreement.

(g) Modification of Covenants; Enforceability. In the event that any provision of this Section 5 is held to be in any respect an unreasonable restriction, then the court so holding may modify the terms thereof, including the period of time during which it operates or the geographic area to which it applies, or effect any other change to the extent necessary to render this section enforceable, it being acknowledged by the parties that the representations and covenants set forth herein are of the essence of this Agreement.

(h) Subsidiaries. For purposes of Sections 5 and 6 of this Agreement, "Company" shall include all direct and indirect subsidiaries of the Company. An entity shall be deemed to be a subsidiary of the Company if the Company directly or indirectly owns or controls 50% or more of the equity interest in such entity.

6. Ownership of Ideas, Copyrights and Patents.

(a) Property of the Company. Executive agrees that all ideas, inventions, original works of authorship, developments, concepts, know-how, improvements or trade secrets, whether patentable, copyrightable or not, which Executive may conceive, reduce to practice or develop, alone or in conjunction with another, or others, whether during or out of regular business hours, and whether at the request or upon the suggestion of the Company, or otherwise, in the course of performing services for the Company in any capacity, whether heretofore or hereafter, (collectively, "the Inventions") are and shall be the sole and exclusive property of the Company, and that Executive shall not publish any of the Inventions without the prior written consent of the Company. Executive hereby assigns to the Company all of Executive's right, title and interest in and to all of the foregoing. Executive further represents and agrees that to the best of Executive's knowledge and belief none of the Inventions will violate or infringe upon any right, patent, copyright, trademark or right of privacy, or constitute libel or slander against or violate any other rights of any person, firm or corporation and that Executive will use his best efforts to prevent any such violation.

(b) Cooperation. At any time during or after the Term, Executive agrees that he will fully cooperate with the Company, its attorneys and agents in the preparation and filing of all papers and other documents as may be required to perfect the Company's rights in and to any of such Inventions, including, but not limited to, executing any lawful document (including, but not limited to, applications, assignments, oaths, declarations and affidavits) and joining in any proceeding to obtain letters patent, copyrights, trademarks or other legal rights of the United States and of any and all other countries on such Inventions, provided that any patent or other legal right so issued to Executive, personally, shall be assigned by Executive to the Company without charge by Executive. Executive further designates the Company as his agent for, and grants to the Company a power of attorney with full power of substitution, which power of attorney shall be deemed coupled with an interest, for the purpose of effecting the foregoing assignments from Executive to the Company. Company will bear the reasonable expenses which it causes to be incurred in Executive's assisting and cooperating hereunder. Executive waives all claims to moral rights in any Inventions.

7. Disclosure to Future Employers. The Company may provide in its discretion, a copy of the covenants contained in Sections 5 and 6 of this Agreement to any business or enterprise which Executive may directly, or indirectly, own, manage, operate, finance, join, control or in which Executive participates in the ownership, management, operation, financing, or control, or with which Executive may be connected as an officer, director, employee, partner, principal, agent, representative, consultant or otherwise.

8. Records. Upon termination of Executive's relationship with the Company, Executive shall deliver to the Company any property of the Company which may be in Executive's possession including products, materials, memoranda, notes, records, reports, or other documents or photocopies of the same.

9. Insurance. The Company, in its sole discretion, may apply for and procure in its own name (whether or not for its own benefit) policies of insurance insuring Executive's life. Executive agrees to submit to reasonable medical or other examinations and to execute and deliver any applications or other instruments in writing that are reasonably necessary to effectuate such insurance. No adverse employment actions may be based upon the results of any such exam or the failure by the Company to obtain such insurance.

10. No Conflicting Agreements. Executive hereby represents and warrants that Executive has no commitments or obligations inconsistent with this Agreement.

11. "Market Stand-Off" Agreement. Executive agrees, if requested by the Company and an underwriter of common stock (or other securities) of the Company, not to sell or otherwise transfer or dispose of any common stock (or other securities) of the Company held by Executive during a period not to exceed one hundred and eighty (180) days following the effective date of an underwritten public offering of common stock of the Company, offered on a firm commitment basis pursuant to a registration statement filed with the Securities and Exchange Commission (or any successor agency of the Federal government administering the Securities Act of 1933, as amend, and the Securities Exchange Act of 1934, as amended) under the Securities Act of 1933, as amended, on Form S-1 or its then equivalent, and to enter into an agreement to such effect. The Company may impose stop-transfer instructions with respect to the shares (or securities) subject to the foregoing restriction until the end of said period.

12. General.

(a) Notices. All notices, requests, consents and other communications hereunder shall be in writing, shall be addressed to the receiving party's address as follows:

If to the Company: Ocular Therapeutix, Inc.
36 Crosby Drive, Suite 101
Bedford, MA 01730
USA
Attention: Chief Executive Officer
Telephone: (781) 357-4000

With an email copy to: ASawhney@ocutx.com

If to Executive: Andy Hurley
32 Robinson Drive
Bedford, MA 01730
USA
Telephone: 781-799-6758

or to such other address as a party may designate by notice hereunder, and shall be either (i) delivered by hand, (ii) sent by overnight courier, or (iii) sent by registered or certified mail, return receipt requested, postage prepaid. All notices, requests, consents and other communications hereunder shall be deemed to have been given either (i) if by hand, at the time of the delivery thereof to the receiving party at the address of such party set forth above, (ii) if sent by overnight courier, on the next business day following the day such notice is delivered to the courier service, or (iii) if sent by registered or certified mail, on the fifth (5th) business day following the day such mailing is made.

(b) Entire Agreement. This Agreement and the Offer Letter embody the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersede all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement of any kind not expressly set forth in this Agreement or the Offer Letter shall affect, or be used to interpret, change or restrict, the express terms and provisions of this Agreement or the Offer Letter.

(c) Modifications and Amendments. The terms and provisions of this Agreement may be modified or amended only by written agreement executed by the parties hereto.

(d) Waivers and Consents. The terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given, and shall not constitute a continuing waiver or consent.

(e) Assignment. The Company shall assign its rights and obligations hereunder to any person or entity that succeeds to all or substantially all of the Company's business or that aspect of the Company's business in which Executive is principally involved. Executive may not assign Executive's rights and obligations under this Agreement without the prior written consent of the Company.

(f) Benefit. All statements, representations, warranties, covenants and agreements in this Agreement shall be binding on the parties hereto and shall inure to the benefit of the respective successors and permitted assigns of each party hereto. Nothing in this Agreement shall be construed to create any rights or obligations except among the parties hereto, and no person or entity shall be regarded as a third-party beneficiary of this Agreement.

(g) Governing Law. This Agreement and the rights and obligations of the parties hereunder shall be construed in accordance with and governed by the law of The Commonwealth of Massachusetts, without giving effect to the conflict of law principles thereof.

(h) Jurisdiction and Service of Process. Any legal action or proceeding with respect to this Agreement shall be brought in the courts of The Commonwealth of Massachusetts or of the United States of America for the District of Massachusetts. By execution and delivery

of this Agreement, each of the parties hereto accepts for itself and in respect of its property, generally and unconditionally, the jurisdiction of the aforesaid courts. Each of the parties hereto irrevocably consents to the service of process of any of the aforementioned courts in any such action or proceeding by the mailing of copies thereof by certified mail, postage prepaid, to the party at its address set forth in Section 12(a) hereof. THE PARTIES IRREVOCABLY WAIVE ANY RIGHT TO TRIAL BY JURY AS TO ALL CLAIMS HEREUNDER.

(i) Severability. The parties intend this Agreement to be enforced as written. However, (i) if any portion or provision of this Agreement shall to any extent be declared illegal or unenforceable by a duly authorized court having jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law; and (ii) if any provision, or part thereof, is held to be unenforceable because of the duration of such provision or the geographic area covered thereby, the Company and Executive agrees that the court making such determination shall have the power to reduce the duration and/or geographic area of such provision, and/or to delete specific words and phrases (“blue-penciling”), and in its reduced or blue-penciled form such provision shall then be enforceable and shall be enforced.

(j) Headings and Captions; Interpretation. The headings and captions of the various subdivisions of this Agreement are for convenience of reference only and shall in no way modify, or affect the meaning or construction of any of the terms or provisions hereof. The provisions of the following Sections of this Agreement are in addition to, and do not limit, each other: Sections 6 and 5(a); Sections 7 and 5(g); Sections 12(k) and 5(f); and Sections 12(l) and 12(d).

(k) Injunctive Relief. Executive hereby expressly acknowledges that any breach or threatened breach of any of the terms and/or conditions set forth in Section 5 or 6 of this Agreement will result in substantial, continuing and irreparable injury to the Company. Therefore, Executive hereby agrees that, in addition to any other remedy that may be available to the Company, the Company shall be entitled to injunctive or other equitable relief by a court of appropriate jurisdiction.

(l) No Waiver of Rights, Powers and Remedies. No failure or delay by a party hereto in exercising any right, power or remedy under this Agreement, and no course of dealing between the parties hereto, shall operate as a waiver of any such right, power or remedy of the party. No single or partial exercise of any right, power or remedy under this Agreement by a party hereto, nor any abandonment or discontinuance of steps to enforce any such right, power or remedy, shall preclude such party from any other or further exercise thereof or the exercise of any other right, power or remedy hereunder. The election of any remedy by a party hereto shall not constitute a waiver of the right of such party to pursue other available remedies. No notice to or demand on a party not expressly required under this Agreement shall entitle the party receiving such notice or demand to any other or further notice or demand in similar or other circumstances or constitute a waiver of the rights of the party giving such notice or demand to any other or further action in any circumstances without such notice or demand.

(m) Counterparts. This Agreement may be executed in one or more counterparts, and by different parties hereto on separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

(n) Survival. The provisions of Sections 4, 5, 6, 7, 8, 11 and 12 shall survive the termination of this Agreement and Executive's employment hereunder in accordance with their terms.

IN WITNESS THEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

Ocular Therapeutix, Inc.

/s/ Amar Sawhney

Name: Amar Sawhney, Ph.D.

Title: President, Chief Executive Officer and Chairman

Agreed and Accepted

/s/ Andy Hurley

Andy Hurley

EXHIBIT A

Sample Separation and Release Agreement General Release

[Insert Date]

[Insert Executive's address]

Dear [Executive]:

In connection with the termination of your employment with Ocular Therapeutix, Inc. (the "Company") on [Termination Date], you are eligible to receive the Severance Compensation as described in Section 4 of the Employment Agreement executed between you and the Company dated _____, 20____ (the "Employment Agreement") if you sign and return this letter agreement to me by [Return Date –21 days from date of receipt of this letter agreement] and it becomes binding between you and the Company. By signing and returning this letter agreement and not revoking your acceptance, you will be agreeing to the terms and conditions set forth in the numbered paragraphs below, including the release of claims set forth in paragraph 3. Therefore, you are advised to consult with an attorney before signing this letter agreement and you may take up to twenty-one (21) days to do so. If you sign this letter agreement, you may change your mind and revoke your agreement during the seven (7) day period after you have signed it by notifying me in writing. If you do not so revoke, this letter agreement will become a binding agreement between you and the Company upon the expiration of the seven (7) day period.

If you choose not to sign and return this letter agreement by [Return Date-Same as Above], or if you timely revoke your acceptance in writing, you shall not receive any Severance Compensation from the Company. You will, however, receive payment for your final wages and any unused vacation time accrued through the Termination Date, as defined below, on the Company's regular payroll date immediately following the Termination Date. Also, regardless of signing this letter agreement, you may elect to continue receiving group medical insurance pursuant to the federal "COBRA" law, 29 U.S.C. § 1161 et seq. If you so elect, you shall pay all premium costs on a monthly basis for as long as, and to the extent that, you remain eligible for COBRA continuation. You should consult the COBRA materials to be provided by the Company for details regarding these benefits. All other benefits will cease upon your Termination Date in accordance with the plan documents.

The following numbered paragraphs set forth the terms and conditions that will apply if you timely sign and return this letter agreement and do not revoke it in writing within the seven (7) day period.

1. **Termination Date** – Your effective date of termination from the Company is [Insert Date] (the "Termination Date").
2. **Release** – In consideration of the payment of the Severance Compensation, which you acknowledge you would not otherwise be entitled to receive, you hereby fully, forever, irrevocably and unconditionally release, remise and discharge the Company, its affiliates, subsidiaries, parent companies, predecessors, and successors, and all of their respective past and present officers, directors, stockholders, partners, members, employees, agents, representatives, plan administrators, attorneys, insurers and fiduciaries (each in their individual and corporate capacities) (collectively, the "Released Parties") from any and

all claims, charges, complaints, demands, actions, causes of action, suits, rights, debts, sums of money, costs, accounts, reckonings, covenants, contracts, agreements, promises, doings, omissions, damages, executions, obligations, liabilities, and expenses (including attorneys' fees and costs), of every kind and nature that you ever had or now have against any or all of the Released Parties, including, but not limited to, any and all claims arising out of or relating to your employment with and/or separation from the Company, including, but not limited to, all claims under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., the Americans With Disabilities Act of 1990, 42 U.S.C. § 12101 et seq., the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq., the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000ff et seq., the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq., the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101 et seq., the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq., Executive Order 11246, Executive Order 11141, the Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq., and the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq., all as amended; the Massachusetts Fair Employment Practices Act, M.G.L. c.151B, § 1 et seq., the Massachusetts Civil Rights Act, M.G.L. c.12, §§ 11H and 11I, the Massachusetts Equal Rights Act, M.G.L. c.93, § 102 and M.G.L. c.214, § 1C, the Massachusetts Labor and Industries Act, M.G.L. c.149, § 1 et seq., the Massachusetts Privacy Act, M.G.L. c.214, § 1B and the Massachusetts Maternity Leave Act, M.G.L. c.149, § 105(d), all as amended; all common law claims including, but not limited to, actions in defamation, intentional infliction of emotional distress, misrepresentation, fraud, wrongful discharge, and breach of contract, including without limitation, all claims arising from the Employment Agreement; all state and federal whistleblower claims to the maximum extent permitted by law; all claims to any non-vested ownership interest in the Company, contractual or otherwise; and any claim or damage arising out of your employment with and/or separation from the Company (including a claim for retaliation) under any common law theory or any federal, state or local statute or ordinance not expressly referenced above; provided, however, that nothing in this letter agreement shall (i) prevent you from filing a charge with, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission or a state fair employment practices agency (except that you acknowledge that you may not recover any monetary benefits in connection with any such claim, charge or proceeding); (ii) deprive you of any accrued benefits to which you have acquired a vested right under any employee benefit plan or policy, stock plan or deferred compensation arrangement, any health care continuation to the extent required by applicable law or any agreement, or any right to severance benefits or any other benefits due to you upon termination of employment or post-employment consulting arrangements that you may have under the Employment Agreement; or (iii) deprive you of any rights you may have to be indemnified by the Company as provided in the Employment Agreement, any other agreement between the Company and you or pursuant to the Company's Certificate of Incorporation or by-laws. This Release shall not extend to any claims you may have against any persons that are Released Parties to the extent such claims are (i) related solely to your ownership of the Company's stock and (ii) unrelated to your employment with the Company.

3. **Non-Disclosure, Non-Competition and Non-Solicitation** – You acknowledge and reaffirm your obligation to keep confidential and not disclose all non-public information

concerning the Company and its clients that you acquired during the course of your employment with the Company, as stated more fully in Section 5 of the Employment Agreement, which remains in full force and effect.

4. **Return of Company Property** – You confirm that you have returned to the Company all keys, files, records (and copies thereof), equipment (including, but not limited to, computer hardware, software and printers, wireless handheld devices, cellular phones, smartphones, tablets, etc.), Company identification, and any other Company-owned property in your possession or control and have left intact all electronic Company documents, including but not limited to those which you developed or helped to develop during your employment. You further confirm that you have cancelled all accounts for your benefit, if any, in the Company's name, including but not limited to, credit cards, telephone charge cards, cellular phone and/or wireless data accounts and computer accounts.
5. **Business Expenses and Final Compensation** – You acknowledge that you have been reimbursed by the Company for all business expenses incurred in conjunction with the performance of your employment and that no other reimbursements are owed to you. You further acknowledge that you have received payment in full for all services rendered in conjunction with your employment by the Company, including payment for all wages, bonuses and accrued, unused vacation time, and that no other compensation is owed to you except as provided herein.
6. **Non-Disparagement** – To the extent permitted by law, you understand and agree that as a condition for payment to you of the Severance Compensation herein described, for a period of five years following the date hereof you shall not make any false, disparaging or derogatory statements to any person or entity, including any media outlet, regarding the Company or any of its directors, officers, employees, agents or representatives or about the Company's business affairs and financial condition. Further, for a period of five years following the date hereof, neither the Company, nor any of its executive officers or members of its Board will directly or indirectly make, or cause to be made, any false statement, observation or opinion, disparaging your reputation.
7. **Continued Assistance** – You agree that after the Termination Date you will provide all reasonable cooperation to the Company, taking into account any duties you then owe to any future employer, including but not limited to, assisting the Company transition your job duties, assisting the Company in defending against and/or prosecuting any litigation or threatened litigation, and performing any other tasks as reasonably requested by the Company.
8. **Cooperation** – To the extent permitted by law, you agree to cooperate fully with the Company in the defense or prosecution of any claims or actions which already have been brought, are currently pending, or which may be brought in the future against or on behalf of the Company, whether before a state or federal court, any state or federal government agency, or a mediator or arbitrator. Your full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare its claims or defenses, to prepare for trial or discovery or an administrative hearing or a mediation or arbitration and to act as a witness when

requested by the Company at reasonable times designated by the Company. You agree that you will notify the Company promptly in the event that you are served with a subpoena or in the event that you are asked to provide a third party with information concerning any actual or potential complaint or claim against the Company.

9. **Amendment and Waiver** – This letter agreement shall be binding upon the parties and may not be modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by duly authorized representatives of the parties hereto. This letter agreement is binding upon and shall inure to the benefit of the parties and their respective agents, assigns, heirs, executors, successors and administrators. No delay or omission by the Company in exercising any right under this letter agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.
10. **Validity** – Should any provision of this letter agreement be declared or be determined by any court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this letter agreement.
11. **Confidentiality** – To the extent permitted by law, you understand and agree that as a condition for payment to you of the Severance Compensation herein described, the terms and contents of this letter agreement, and the contents of the negotiations and discussions resulting in this letter agreement, shall be maintained as confidential by you and your agents and representatives and shall not be disclosed except to the extent required by federal or state law or as otherwise agreed to in writing by the Company.
12. **Nature of Agreement** – You understand and agree that this letter agreement is a severance agreement and does not constitute an admission of liability or wrongdoing on the part of the Company.
13. **Acknowledgments** – You acknowledge that you have been given at least twenty-one (21) days to consider this letter agreement, and that the Company advised you to consult with an attorney of your own choosing prior to signing this letter agreement. You understand that you may revoke this letter agreement for a period of seven (7) days after you sign this letter agreement by notifying me in writing, and the letter agreement shall not be effective or enforceable until the expiration of this seven (7) day revocation period. You understand and agree that by entering into this agreement, you are waiving any and all rights or claims you might have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefits Protection Act, and that you have received consideration beyond that to which you were previously entitled.
14. **Voluntary Assent** – You affirm that no other promises or agreements of any kind have been made to or with you by any person or entity whatsoever to cause you to sign this letter agreement, and that you fully understand the meaning and intent of this letter agreement. You state and represent that you have had an opportunity to fully discuss and review the terms of this letter agreement with an attorney. You further state and represent that you have carefully read this letter agreement, understand the contents herein, freely and voluntarily assent to all of the terms and conditions hereof and sign your name of your own free act.

15. **Applicable Law** – This letter agreement shall be interpreted and construed by the laws of the Commonwealth of Massachusetts, without regard to conflict of laws provisions. You hereby irrevocably submit to and acknowledge and recognize the jurisdiction of the courts of the Commonwealth of Massachusetts, or if appropriate, a federal court located in the Commonwealth of Massachusetts (which courts, for purposes of this letter agreement, are the only courts of competent jurisdiction), over any suit, action or other proceeding arising out of, under or in connection with this letter agreement or the subject matter hereof.
16. **Entire Agreement** – This letter agreement contains and constitutes the entire understanding and agreement between the parties hereto with respect to your Severance Compensation and the settlement of claims against the Company and cancels all previous oral and written negotiations, agreements and commitments in connection therewith. Nothing in this paragraph, however, shall modify, cancel or supersede your obligations set forth in paragraph 3 herein.
17. **Tax Acknowledgement** – In connection with the payments and consideration provided to you pursuant to this letter agreement, the Company shall withhold and remit to the tax authorities the amounts required under applicable law, and you shall be responsible for all applicable taxes with respect to such payments and consideration under applicable law. You acknowledge that you are not relying upon the advice or representation of the Company with respect to the tax treatment of any of the Severance Compensation set forth in Section 4 of the Employment Agreement.

If you have any questions about the matters covered in this letter agreement, please call me at **[Insert Phone Number]**.

Very truly yours,

By: _____
[Name]
[Title]

I hereby agree to the terms and conditions set forth above. I have been given at least twenty-one (21) days to consider this letter agreement and I have chosen to execute this on the date below. I intend that this letter agreement will become a binding agreement between me and the Company if I do not revoke my acceptance in seven (7) days.

[Executive]

Date

To be returned to me by **[Return Date – 21 days from date of receipt of this letter]**

CERTIFICATIONS

I, Amarpreet Sawhney, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ocular Therapeutix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

By: /s/ Amarpreet Sawhney, Ph.D.

Amarpreet Sawhney, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATIONS

I, W. Bradford Smith, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ocular Therapeutix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

By: /s/ W. Bradford Smith

W. Bradford Smith

Chief Financial Officer

(Principal Financial and Accounting Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,**AS ADOPTED PURSUANT TO****SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Ocular Therapeutix, Inc. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Amarpreet Sawhney, Ph.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2016

By: /s/ Amarpreet Sawhney, Ph.D.

Amarpreet Sawhney, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,**AS ADOPTED PURSUANT TO****SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Ocular Therapeutix, Inc. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, W. Bradford Smith, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2016

By: /s/ W. Bradford Smith

W. Bradford Smith

Chief Financial Officer

(Principal Financial and Accounting Officer)