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

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended March 31, 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

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**Ocular Therapeutix, Inc.**

(Exact name of registrant as specified in its charter)

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**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)

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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 May 1, 2016, there were 24,766,409 shares of Common Stock, \$0.0001 par value per share, outstanding.

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**Ocular Therapeutix, Inc.**

**INDEX**

	<u>Page</u>
<b>PART I – FINANCIAL INFORMATION</b>	
Item 1. <a href="#">Financial Statements (unaudited)</a>	2
<a href="#">Balance Sheets as of March 31, 2016 and December 31, 2015</a>	2
<a href="#">Statements of Operations and Comprehensive Loss for the three months ended March 31, 2016 and 2015</a>	3
<a href="#">Statements of Cash Flows for the three months ended March 31, 2016 and 2015</a>	4
<a href="#">Notes to Financial Statements</a>	5
Item 2. <a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	13
Item 3. <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	24
Item 4. <a href="#">Controls and Procedures</a>	24
<b>PART II – OTHER INFORMATION</b>	
Item 1. <a href="#">Legal Proceedings</a>	25
Item 1A. <a href="#">Risk Factors</a>	25
Item 2. <a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	56
Item 6. <a href="#">Exhibits</a>	56

## 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™, also referred to as OTX-DP 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;
- 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)

	March 31, 2016	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 46,212	\$ 30,784
Marketable securities	49,244	74,280
Accounts receivable	227	193
Inventory	127	134
Prepaid expenses and other current assets	1,287	1,592
Total current assets	97,097	106,983
Property and equipment, net	3,107	3,095
Restricted cash	228	228
Total assets	<u>\$ 100,432</u>	<u>\$ 110,306</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,063	\$ 1,957
Accrued expenses and deferred rent	2,779	3,379
Deferred revenue	—	42
Notes payable, net of discount, current	1,161	—
Total current liabilities	6,003	5,378
Deferred rent, long-term	55	68
Notes payable, net of discount, long-term	14,204	15,272
Total liabilities	<u>20,262</u>	<u>20,718</u>
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at March 31, 2016 and December 31, 2015, no shares issued or outstanding at March 31, 2016 and December 31, 2015	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized at March 31, 2016 and December 31, 2015, 24,758,786 and 24,750,281 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	2	2
Additional paid-in capital	220,184	218,830
Accumulated deficit	(140,016)	(129,176)
Accumulated other comprehensive loss	—	(68)
Total stockholders' equity	<u>80,170</u>	<u>89,588</u>
Total liabilities and stockholders' equity	<u>\$ 100,432</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 March 31,	
	2016	2015
Revenue:		
Product revenue	\$ 416	\$ 238
Collaboration revenue	42	188
Total revenue	<u>458</u>	<u>426</u>
Costs and operating expenses:		
Cost of product revenue	99	56
Research and development	7,073	4,719
Selling and marketing	1,389	870
General and administrative	2,406	1,894
Total costs and operating expenses	<u>10,967</u>	<u>7,539</u>
Loss from operations	<u>(10,509)</u>	<u>(7,113)</u>
Other income (expense):		
Interest income	87	40
Interest expense	(418)	(505)
Total other expense, net	<u>(331)</u>	<u>(465)</u>
Net loss	<u>\$ (10,840)</u>	<u>\$ (7,578)</u>
Net loss per share, basic and diluted	<u>\$ (0.44)</u>	<u>\$ (0.35)</u>
Weighted average common shares outstanding, basic and diluted	<u>24,751,682</u>	<u>21,362,731</u>
Comprehensive loss:		
Net loss	\$ (10,840)	\$ (7,578)
Other comprehensive income:		
Unrealized gains on marketable securities	68	—
Total other comprehensive income	<u>68</u>	<u>—</u>
Total comprehensive loss	<u>\$ (10,772)</u>	<u>\$ (7,578)</u>

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

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$(10,840)	\$ (7,578)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	1,349	921
Non-cash interest expense	35	37
Depreciation and amortization expense	205	173
Purchase discount on marketable securities	—	17
Amortization of premium on marketable securities, net	104	18
Changes in operating assets and liabilities:		
Accounts receivable	(34)	(23)
Prepaid expenses and other current assets	305	170
Inventory	7	(25)
Accounts payable	79	153
Accrued expenses and deferred rent	(424)	(804)
Deferred revenue	(42)	62
Net cash used in operating activities	<u>(9,256)</u>	<u>(6,879)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(127)	(354)
Purchases of investments	—	(17,500)
Maturities of investments	25,000	—
Net cash provided by (used in) investing activities	<u>24,873</u>	<u>(17,854)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of common stock options	5	34
Payments of insurance costs financed by a third-party	(194)	(171)
Net cash used in financing activities	<u>(189)</u>	<u>(137)</u>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>15,428</b>	<b>(24,870)</b>
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>\$ 46,212</u>	<u>\$ 12,523</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Additions to property and equipment included in accounts payable and accrued expenses at balance sheet dates	\$ 109	\$ 5

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

As of March 31, 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 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. 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 through the third 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 March 31, 2016 and for the three months ended March 31, 2016 and 2015 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC, for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with the Company’s audited financial statements and the notes thereto for the year ended December 31, 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 presentation of the Company’s financial position as of March 31, 2016 and results of operations and cash flows for the three months ended March 31, 2016 and 2015 have been made. The results of operations for the three months ended March 31, 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 and preferred stock warrants. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

### *Fair Value Measurements*

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

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

The Company's cash equivalents and marketable securities at March 31, 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.

At March 31, 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	\$ 37,030	\$ 7	\$ (7)	\$ 37,030
Agency bonds	12,214	—	—	12,214
<b>Total</b>	<u>\$ 49,244</u>	<u>\$ 7</u>	<u>\$ (7)</u>	<u>\$ 49,244</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
<b>Total</b>	<u>\$ 74,348</u>	<u>\$ —</u>	<u>\$ (68)</u>	<u>\$ 74,280</u>

At March 31, 2016, marketable securities consisted of investments that mature within one year.



## [Table of Contents](#)

### **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 months ended March 31, 2016 and 2015. The following common stock equivalents outstanding as of March 31, 2016 and 2015 were excluded from the computation of diluted net loss per share for the three months ended March 31, 2016 and 2015, because they had an anti-dilutive impact:

	As of March 31,	
	2016	2015
Options to purchase common stock	2,958,669	2,151,729
Non-vested restricted stock	—	21,328
Warrants for the purchase of common stock	18,939	18,939
Total options, warrants and restricted stock	<u>2,977,608</u>	<u>2,191,996</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 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 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

## [Table of Contents](#)

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.

### 3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 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 March 31, 2016 Using:			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Cash equivalents:				
Money market funds	\$ —	\$ 45,967	\$ —	\$ 45,967
Marketable securities:				
United States treasury notes	—	37,030	—	37,030
Agency bonds	—	12,214	—	12,214
Total	<u>\$ —</u>	<u>\$ 95,211</u>	<u>\$ —</u>	<u>\$ 95,211</u>

	Fair Value Measurements as of December 31, 2015 Using:			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
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:

	March 31, 2016	December 31, 2015
Accrued payroll and related expenses	\$ 729	\$ 1,582
Accrued professional fees	788	471
Accrued research and development expenses	506	430
Accrued insurance	194	389
Accrued other	562	507
	<u>\$ 2,779</u>	<u>\$ 3,379</u>

As of March 31, 2016, 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 month periods ended March 31, 2016 or 2015. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at March 31, 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 March 31, 2016 or December 31, 2015. As of March 31, 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, 2012 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 has a feasibility agreement with a biotechnology company, entered into in 2014. Under this agreement, the biotechnology company will pay up to \$700, of which \$250 was a non-refundable payment due upon contract execution and \$450 is due upon the achievement of certain milestones. The Company recognizes the total expected payments under the contract which include only the non-refundable payments on a straight-line basis over the estimated performance period. If and when a contingent milestone payment is earned, the additional consideration to be received is added to the total expected payments under the contract 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 being recognized over the estimated performance period is \$500. Consideration associated with the final milestone of \$200 will be recorded as revenue in the period earned, if applicable, as there will be no additional performance obligations. The Company recognized revenue of \$42 and \$188 for the three months ended March 31, 2016 and 2015, respectively. As of March 31, 2016, the Company has no deferred revenue and as of December 31, 2015 has 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.

As of March 31, 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	\$ —	\$ 983	\$ 983
2017	5,200	1,105	6,305
2018	5,200	670	5,870
2019	5,200	820	6,020
	<u>\$15,600</u>	<u>\$ 3,578</u>	<u>\$19,178</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 March 31, 2016 at a weighted average exercise price of \$7.92 per share and expiration date of April 17, 2021. No warrants were exercised during the three months ended March 31, 2016.

## 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 March 31, 2016, 1,575,503 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. As of March 31, 2016, 329,843 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 March 31,	
	2016	2015
Research and development	\$ 453	\$ 302
Selling and marketing	107	63
General and administrative	789	556
	<u>\$ 1,349</u>	<u>\$ 921</u>

As of March 31, 2016, the Company had an aggregate of \$13,318 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.84 years.

As of March 31, 2016, there were outstanding unvested service-based stock options held by nonemployees for the purchase of 5,800 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 and June 2018.

## [Table of Contents](#)

Future minimum lease payments for its operating leases as of March 31, 2016 are as follows:

<u>Years Ending December 31,</u>	
2016	\$ 617
2017	676
2018	262
Total	<u>\$1,555</u>

During the three months ended March 31, 2016 and 2015, the Company recognized \$191 and \$195, respectively, of rental expense, related to its office, laboratory and manufacturing space and office equipment.

### ***Intellectual Property Licenses***

The Company has a license agreement with Incept, LLC (“Incept”) (Note 12) to use and develop certain patent rights (the “Incept License”). Under the Incept License, as amended and restated, the Company was granted a worldwide, perpetual, exclusive license to develop and commercialize products that are delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to ophthalmic diseases or conditions. The Company is obligated to pay low single-digit royalties on net sales of commercial products developed using the licensed technology, commencing with the date of the first commercial sale of such products and until the expiration of the last to expire of the patents covered by the license. Any of the Company’s sublicensees also will be obligated to pay Incept a royalty equal to a low single-digit percentage of net sales made by it and will be bound by the terms of the agreement to the same extent as the Company. The Company is obligated to reimburse Incept for its share of the reasonable fees and costs incurred by Incept in connection with the prosecution of the patent applications licensed to the Company under the Incept License. Through March 31, 2016, royalties paid under this agreement related to product sales were \$55.

### ***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 March 31, 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. 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 and a related receivable which is included in prepaid expenses and other current assets as of March 31, 2016. The effect of this error on the statement of operations was considered immaterial for all related periods.

**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 product candidates are designed to provide sustained delivery of therapeutic agents to the eye. Our lead product candidates are DEXTENZA, for the treatment of post-surgical ocular inflammation and pain, allergic conjunctivitis and dry eye, and OTX-TP, for the treatment of glaucoma and ocular hypertension, which are sustained-release, drug-eluting depots that are inserted into the canaliculus through a natural opening called the punctum located in the inner portion of the eyelid near the nose. Our intracanalicular depots 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. 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 intracanalicular depot. DEXTENZA is in Phase 3 clinical development for the treatment of post-surgical ocular inflammation and pain, and, in September 2015, we submitted to the FDA a New Drug Application, or NDA, for DEXTENZA for the treatment of post-surgical ocular pain. The FDA has accepted the NDA for filing and established a target action date under the Prescription Drug User Fee Act, or PDUFA, of July 24, 2016. 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 pain. In October 2015, we initiated a third Phase 3 clinical trial for the treatment of post-surgical ocular inflammation and pain. As of May 3, 2016, we have enrolled 395 patients in this trial out of a total of 436 patients expected to be enrolled. We anticipate having topline efficacy data available from this third trial in the fourth quarter of 2016. If the results of this third trial 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. 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. Our second Phase 3 clinical trial for allergic conjunctivitis is fully enrolled and we expect topline efficacy data by the middle of 2016. 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 plan to meet with the FDA in 2016 to discuss the design of future clinical trials of DEXTENZA for the treatment of dry eye. We are considering as a long term strategy for our dry eye program the use DEXTENZA either as an initial mode of therapy or for the treatment of episodic acute flare-ups of dry eye followed by an intracanalicular depot containing an immunosuppressant drug such as cyclosporine.

If our NDA for DEXTENZA for the treatment of post-surgical ocular pain is approved by the FDA in the third quarter of 2016, we expect to commercially launch this product in the United States. in the first quarter 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 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 code from the Center of Medicare and Medicaid Services, or CMS, for DEXTENZA for the treatment of post-surgical ocular pain. We would expect pass-through reimbursement status to remain in effect for up to three years depending on the timing of when we apply for and receive this code. We expect to submit to CMS for a standard J code for DEXTENZA for the treatment of other indications, including allergic conjunctivitis.

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 depot. 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 plan to initiate the first of two Phase 3 clinical trials of OTX-TP in the third quarter of 2016. 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 depot. 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 of statistically superior and clinically meaningful reduction of mean IOP from baseline with OTX-TP compared to placebo at all of the nine diurnal time points at day 15, 45 and 90 visits.



## [Table of Contents](#)

In addition to DEXTENZA and OTX-TP, we are engaged in the preclinical development of our intravitreal 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 wet age related macular degeneration, or wet AMD. 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. We also have a pipeline of earlier stage intracanalicular depot product candidates, including OTX-MP, which has completed a Phase 1 clinical trial evaluating safety and pharmacokinetics in patients following cataract surgery.

Following our receipt of FDA approval for ReSure Sealant, we commercially launched this product in the United States in 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. 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. Since inception, we have incurred significant operating losses. Our net loss was \$10.8 million for the three months ended March 31, 2016. As of March 31, 2016, we had an accumulated deficit of \$140.0 million.

Our total operating expenses were \$11.0 million for the three months ended March 31, 2016, including \$1.3 million in non-cash stock-based compensation expense. We anticipate that our operating expenses will increase substantially as we pursue the clinical development of our most advanced product candidates, 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 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 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 may need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

In July 2014, we completed an initial public offering, or IPO, of our common stock, and in August 2014 the underwriters in our IPO exercised their over-allotment option in full. We received total net proceeds of approximately \$66.4 million from the issuance and sale of 5,750,000 shares of common stock, including in connection with the exercise by the underwriters of their over-allotment option, after deducting underwriting discounts and offering costs. 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. 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 through the third quarter of 2017. See “—Liquidity and Capital Resources.”



## Financial Operations Overview

### *Revenue*

From our inception through March 31, 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 has agreed to pay us up to \$0.7 million, of which \$0.3 million was a non-refundable up-front payment due upon contract execution and \$0.4 million will be due upon the achievement of certain milestones. We recognize the total expected payments under the contract which included only the non-refundable payments on a straight-line basis over the estimated performance period. If and when a contingent milestone payment is earned, the additional consideration to be received is added to the total expected payments under the contract and then recognized over the estimated performance period. In January 2015, we achieved the first milestone under the feasibility agreement triggering a payment due of \$0.3 million. Through March 31, 2016, we have recognized revenue of \$0.5 million related to this agreement. Consideration associated with the final milestone of \$0.2 million will be recorded as revenue in the period earned, if applicable, as there will be no additional performance obligations.

### *Operating Expenses*

#### *Research and Development Expenses*

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

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

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

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

## [Table of Contents](#)

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

	Three Months Ended	
	March 31,	
	2016	2015
	(in thousands)	
ReSure Sealant	\$ 77	\$ 51
DEXTENZA for post-surgical ocular inflammation and pain	851	661
DEXTENZA for allergic conjunctivitis	1,478	100
DEXTENZA for inflammatory dry eye	41	—
OTX-TP for glaucoma and ocular hypertension	317	554
Unallocated expenses	4,309	3,353
Total research and development expenses	<u>\$ 7,073</u>	<u>\$ 4,719</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 months ended March 31, 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 inflammation and pain, subject to approval by the FDA.

### **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 three months ended March 31, 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 Securities and Exchange Commission, or 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;
- stock-based compensation; and
- inventory valuation.

Accordingly, we believe the policies set forth above 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 March 31, 2016 and 2015**

The following table summarizes our results of operations for the three months ended March 31, 2016 and 2015:

	Three Months Ended March 31,		Increase (Decrease)
	2016	2015	
	(in thousands)		
Revenue:			
Product revenue	\$ 416	\$ 238	\$ 178
Collaboration revenue	42	188	(146)
Total revenue	458	426	32
Costs and operating expenses:			
Cost of product revenue	99	56	43
Research and development	7,073	4,719	2,354
Selling and marketing	1,389	870	519
General and administrative	2,406	1,894	512
Total costs and operating expenses	10,967	7,539	3,428
Loss from operations	(10,509)	(7,113)	(3,396)
Other income (expense):			
Interest income	87	40	47
Interest expense	(418)	(505)	87
Total other expense, net	(331)	(465)	134
Net loss	<u><u>\$ (10,840)</u></u>	<u><u>\$ (7,578)</u></u>	<u><u>\$ (3,262)</u></u>

## [Table of Contents](#)

### *Revenue*

We generated \$42,000 of revenue from our feasibility agreements during the three months ended March 31, 2016 compared to \$0.2 million for the three months ended March 31, 2015. We generated \$0.4 million of revenue during the three months ended March 31, 2016 from sales of our ReSure Sealant product compared to \$0.2 million for the three months ended March 31, 2015.

### *Research and Development Expenses*

	Three Months Ended March 31,		Increase (Decrease)
	2016	2015	
(in thousands)			
Direct research and development expenses by program:			
ReSure Sealant	\$ 77	\$ 51	\$ 26
DEXTENZA for post-surgical ocular inflammation and pain	851	661	190
DEXTENZA for allergic conjunctivitis	1,478	100	1,378
DEXTENZA for inflammatory dry eye	41	—	41
OTX-TP for glaucoma and ocular hypertension	317	554	(237)
Unallocated expenses:			
Personnel costs (including stock-based compensation)	2,789	2,187	602
All other costs	1,520	1,166	354
Total research and development expenses	<u>\$ 7,073</u>	<u>\$ 4,719</u>	<u>\$ 2,354</u>

Research and development expenses was \$7.1 million for the three months ended March 31, 2016, compared to \$4.7 million for the three months ended March 31, 2015. Research and development costs increased by \$2.4 million primarily as a result of an increase 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 dry eye and our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension and an increase of \$0.6 million in unallocated personnel costs and \$0.4 million in all other costs.

For the three months ended March 31, 2016, we incurred \$2.7 million in direct research and development expenses for our sustained release drug delivery product candidates for the front of the eye, including \$0.9 million for our DEXTENZA product candidate for the treatment of post-surgical ocular inflammation and pain which was in Phase 3 clinical trials, \$1.5 million for our DEXTENZA product candidate for the treatment of allergic conjunctivitis which was in a Phase 3 clinical trial, \$41,000 for our DEXTENZA product candidate for the treatment of inflammatory dry eye disease which was in an exploratory Phase 2 clinical trial and \$0.3 million for our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension which was in Phase 2b clinical trials. In comparison, for the three months ended March 31, 2015, we incurred \$1.3 million in direct research and development expenses for our sustained release drug delivery product candidates for the front of the eye, including \$0.7 million for our DEXTENZA product candidate for the treatment of post-surgical ocular inflammation and pain which was in Phase 3 clinical trials, \$0.1 million for our DEXTENZA product candidate for the treatment of allergic conjunctivitis which entered Phase 3 clinical trials in the middle of 2015 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 \$1.0 million for the three months ended March 31, 2016, compared to the three months ended March 31, 2015, due to an increase in personnel costs of \$0.6 million due to additional hiring primarily in our clinical, regulatory and quality department and an increase in stock-based compensation expense and an increase of \$0.4 million due to higher testing and laboratory costs.

## [Table of Contents](#)

### *Selling and Marketing Expenses*

	Three Months Ended March 31,		Increase (Decrease)
	2016	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 596	\$ 343	\$ 253
Professional, advertising and promotion costs	566	406	160
Facility-related and other	227	121	106
Total selling and marketing expenses	<u>\$ 1,389</u>	<u>\$ 870</u>	<u>\$ 519</u>

Selling and marketing expenses were \$1.4 million for the three months ended March 31, 2016, compared to \$0.9 million for the three months ended March 31, 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 advertising and promotion costs relating to the ReSure Sealant, and an increase of \$0.1 million in facility-related and other costs.

### *General and Administrative Expenses*

	Three Months Ended March 31,		Increase (Decrease)
	2016	2015	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 1,237	\$ 1,199	\$ 38
Professional, insurance and consultant fees	869	488	381
Facility-related and other	300	207	93
Total general and administrative expenses	<u>\$ 2,406</u>	<u>\$ 1,894</u>	<u>\$ 512</u>

General and administrative expenses were \$2.4 million for the three months ended March 31, 2016, compared to \$1.9 million for the three months ended March 31, 2015. The increase of \$0.5 million was primarily due an increase of \$0.4 million in professional, insurance and consultant fees and an increase of \$0.1 million in facility-related and other costs. Professional, insurance and consultant fees increased primarily due to an increase in consulting fees of \$0.4 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 \$0.3 million for the three months ended March 31, 2016, compared to \$0.5 million for the three months ended March 31, 2015. The decrease was related to an increase in interest income of \$47,000 offset by a decrease in interest expense of \$0.1 million.

## **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 March 31, 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.

## [Table of Contents](#)

As of March 31, 2016, we had cash and cash equivalents and marketable securities of \$95.5 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 March 31, 2016, we had cash and cash equivalents and marketable securities of \$95.5 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

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

	Three Months Ended	
	March 31,	
	2016	2015
	(in thousands)	
Cash used in operating activities	\$ (9,256)	\$ (6,879)
Cash provided by (used in) investing activities	24,873	(17,854)
Cash used in financing activities	(189)	(137)
Net increase (decrease) in cash and cash equivalents	<u>\$15,428</u>	<u>\$(24,870)</u>

*Operating activities.* Net cash used in operating activities was \$9.3 million for the three months ended March 31, 2016, primarily resulting from our net loss of \$10.8 million partially offset by non-cash charges of \$1.6 million. Our net loss was primarily attributed to research and development activities and our general and administrative expenses, as we had minimal product revenue in the period. Our net non-cash charges during the three months ended March 31, 2016 consisted primarily of \$1.3 million of stock-based compensation expense. Net cash used by changes in our operating assets and liabilities during the three months ended March 31, 2016 consisted primarily of a decrease in accounts payable and accrued expenses of \$0.3 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.

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

*Investing activities.* Net cash provided by investing activities for the three months ended March 31, 2016 totaled \$24.9 million and net cash used in investing activities for the three months ended March 31, 2015 totaled \$17.9 million. For the three months ended March 31, 2016, net cash provided is primarily due to the sale of marketable securities of \$25.0 million. For the three months ended March 31, 2016, the purchases of property and equipment, primarily laboratory equipment was \$0.1 million. For the three months ended March 31, 2015, net cash used is primarily due to the purchase of marketable securities of \$17.5 million. For the three months ended March 31, 2015, the purchases of property and equipment, primarily laboratory equipment and additional investment in a manufacturing clean room was \$0.4 million.

*Financing activities.* Net cash used in financing activities for the three months ended March 31, 2016 and 2015 was \$0.2 million and \$0.1 million, respectively. Net cash used in financing activities for the three months ended March 31, 2016 consisted of payments of \$0.2 million for insurance costs financed by a third party and \$5,000 from the exercise of common stock options. Net cash used by financing activities for the three months ended March 31, 2015 consisted primarily of payments of insurance costs financed by a third party offset by proceeds from the exercise of common stock options.

### ***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.

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

- pursue the clinical development of our most advanced intracanalicular depot product candidates, DEXTENZA and OTX-TP;
- continue the research and development of our other product candidates;
- seek to identify and develop additional product candidates, including through preclinical development activities associated with our back-of-the-eye program;
- seek marketing approvals for any of our product candidates that successfully complete clinical development;
- develop and expand our sales, marketing and distribution capabilities for ReSure Sealant and any of our product candidates, including potentially DEXTENZA, for which we 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;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts; and
- operate as a public company.

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 through the third quarter of 2017. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

- the level of product sales from ReSure Sealant and any additional products for which we obtain marketing approval in the future;
- the costs of manufacturing, sales, marketing, distribution and other commercialization efforts with respect to ReSure Sealant and any additional products, including potentially DEXTENZA, 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 intracanalicular depot product candidates, in particular DEXTENZA and OTX-TP;
- 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;
- the extent to which we choose to establish collaboration, distribution or other marketing arrangements for our products and product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or invest in other businesses, products and technologies.

## [Table of Contents](#)

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

Since our inception in 2006, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 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 March 31, 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	\$ 1,555	\$ 824	\$ 731	\$ —	\$ —
Purchase commitments	3,445	3,445	—	—	—
Manufacturing commitments	1,680	1,680	—	—	—
Debt obligations	19,178	2,596	11,961	4,621	—
Total	<u>\$25,858</u>	<u>\$ 8,545</u>	<u>\$12,692</u>	<u>\$4,621</u>	<u>\$ —</u>

In the table above, we set forth our enforceable and legally binding obligations and future commitments at March 31, 2016, as well as obligations related to contracts that we are likely to continue, regardless of the fact that they may be cancelable at March 31, 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.

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 and June 2018.

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

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.



## [Table of Contents](#)

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 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 disclosure.

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.

## [Table of Contents](#)

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.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

We are exposed to market risk related to changes in interest rates. As of March 31, 2016, we had cash and cash equivalents and marketable securities of \$95.5 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 March 31, 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 March 31, 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 March 31, 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 \$28.7 million for the year ended December 31, 2014 and \$39.7 million for the year ended December 31, 2015 and \$10.8 million for the three months ended March 31, 2016. As of March 31, 2016, we had an accumulated deficit of \$140.0 million. Through March 31, 2016, we have financed our operations primarily through private placements of our preferred stock, public offerings of our common stock and borrowings under credit facilities. In June 2015, we completed a follow-on offering of our common stock, which resulted in the sale of 4,600,000 shares consisting of 3,200,000 shares being sold by us and 1,400,000 shares being sold by certain stockholders of the Company, including those shares sold in connection with the exercise by the underwriters of their option to purchase additional shares. We received net proceeds from the follow-on offering of approximately \$65.6 million after deducting underwriting discounts and offering costs. In the first quarter of 2014, we began recognizing revenue from sales of ReSure Sealant, which was approved in January 2014 by the U.S. Food and Drug Administration, or FDA, to seal clear corneal incisions following cataract surgery. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials and, beginning in the first quarter of 2014, commercialization of ReSure Sealant. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year.

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

- pursue the clinical development of our most advanced intracanalicular depot product candidates, DEXTENZA and OTX-TP;
- continue the research and development of our other product candidates;
- seek to identify and develop additional product candidates, including through preclinical development activities associated with our back-of-the-eye program;
- seek marketing approvals for any of our product candidates that successfully complete clinical development;
- develop and expand our sales, marketing and distribution capabilities for ReSure Sealant and 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;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts; and
- operate as a public company.

## [Table of Contents](#)

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

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

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

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

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

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

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

As of March 31, 2016, we had cash and cash equivalents and marketable securities of \$95.5 million. 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 through the third quarter of 2017. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the level of product sales from ReSure Sealant and any additional products for which we obtain marketing approval in the future;
- the costs of manufacturing, sales, marketing, distribution and other commercialization efforts with respect to ReSure Sealant and any additional products, including potentially DEXTENZA, 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;

## [Table of Contents](#)

- 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;
- the extent to which we choose to establish collaboration, distribution or other marketing arrangements for our products and product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or invest in other businesses, products and technologies.

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

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

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

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

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

We have a significant amount of indebtedness. In April 2014, we entered into a credit facility with Silicon Valley Bank and MidCap Financial SBIC, L.P. 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.

## [Table of Contents](#)

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

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

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

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

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

### ***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 depot 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 depot 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 dry eye 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 depot product candidates will depend on many factors, including the following:

- successful completion of preclinical studies and clinical trials;
- applying for and receiving marketing approvals from applicable regulatory authorities for our product candidates;



## [Table of Contents](#)

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

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

***If clinical trials of our intracanalicular depot 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 depot 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.

## [Table of Contents](#)

We have also initiated enrollment in a third Phase 3 clinical trial 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 believe our planned approach for seeking marketing approval of DEXTENZA is supported by our discussions with the FDA, and by the acceptance by the FDA of our NDA for filing, 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.

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

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. We expect that our planned phase 3 clinical trials for OTX-TP, one of which we intend to initiate 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 depot in mean IOP lowering compared with baseline at all of the nine diurnal time points at day 15, 45 and 90 visits. The trial design will not have eye drops, placebo or active, administered in either the treatment or the placebo-controlled arm. However, results from our Phase 2 clinical trials may not necessarily predict a likelihood of achieving our primary endpoint in the Phase 3 clinical trials with statistical significance, including as a result of differences in trial design. If we do not achieve our primary endpoint in the Phase 3 clinical trials with statistical significance, we may not obtain marketing approval for OTX-TP.

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

The success of our intracanalicular depot product candidates is dependent upon retention following insertion and during the course of intended therapy. As such, we continue to conduct non-significant risk, or NSR, studies in the United States for our sustained-release intracanalicular depots in an effort to increase the rate of retention. All NSR studies that we have performed to date have involved placebo vehicle control intracanalicular depots 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 are using a different version of intracanalicular depot than either of the depots 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



## [Table of Contents](#)

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 plan to conduct additional non-significant risk studies on additional modified depot designs as we design our Phase 3 trials for 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 depot 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 depot product candidates in the United States. The FDA, however, could require us to conduct additional studies or require us to modify our planned pivotal clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated. For example, in connection with our initial development of ReSure Sealant, in June 2010 the FDA requested that we withdraw an application that we had submitted under Section 510(k) of the Food, Drug and Cosmetic Act, or FDCA, for the marketing of an earlier version of ReSure Sealant as an ocular bandage because the FDA believed that the technical characteristics of the earlier version of ReSure Sealant were not substantially equivalent to a predicate device. In particular, unlike predicate devices that could be removed if there is discomfort, our product candidate adhered to the corneal surface and was not easily removable by the patient. As a result of this determination by the FDA, we needed to pursue a different regulatory approval pathway and conduct additional clinical development of our product candidate to demonstrate safety and effectiveness. After withdrawing our 510(k) application, we filed an investigational device exemption application to conduct a pivotal clinical trial to support approval of ReSure Sealant as an ocular sealant. The results of this pivotal trial ultimately supported the marketing approval of ReSure Sealant in January 2014, although not in the time frame we had initially expected. The FDA is not obligated to comment on our trial protocols within any specified time period or at all or to affirmatively clear or approve our planned pivotal clinical trials. Subject to a waiting period of 30 days, we could choose to initiate our pivotal clinical trials in the United States without waiting for any additional period for comments from the FDA.

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

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

## [Table of Contents](#)

### ***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 may fail to comply with regulatory requirements or meet their obligations to us in a timely manner, or at all;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may decide, or regulators or institutional review boards may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

For example, we applied for a deferral from the FDA for the requirement to conduct pediatric studies for DEXTENZA for the treatment of post-surgical ocular inflammation and pain following cataract surgery until after approval of such product in adult populations for that indication. While the FDA ultimately approved our request, if the FDA had required us to conduct pediatric studies in advance of FDA approval in adult populations, we would have experienced significant delays in our ability to obtain marketing approval for 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.

## [Table of Contents](#)

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

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

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

***If serious adverse or unacceptable side effects are identified during the development of our 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 recent Phase 3 clinical trials of DEXTENZA for the treatment of post-surgical ocular inflammation and pain, there were two 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 was reduced visual acuity, which occurred twice. In our two pilot studies of OTX-TP for the treatment of glaucoma and ocular hypertension and our Phase 2a clinical trial of OTX-TP for the same indication, the most common adverse event was inflammatory reaction, which was noted in three patients in our pilot studies and in five patients in our Phase 2a clinical trial. No hyperemia-related adverse events were noted in any of the patients treated with OTX-TP in our Phase 2b clinical trial. Further, there have been no serious adverse events observed to date in the Phase 2b clinical trial. However, a complete analysis of all safety data is pending study completion. All adverse events have been transient in nature and resolved by the end of the applicable trial. However, many compounds that initially showed promise in clinical or early stage testing for treating ophthalmic disease have later been found to cause side effects that prevented further development of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later be found to be caused by the study treatment.

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

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

## [Table of Contents](#)

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

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

### **Risks Related to Manufacturing**

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

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

We must comply with federal, state and foreign regulations, including quality assurance standards applicable to medical device and drug manufacturers, such as cGMP, which is enforced by the FDA through its facilities inspection program and by similar regulatory authorities in other jurisdictions where we do business. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Following 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 have responded to the FDA with a corrective action plan to complete the inspection process. 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. The failure to resolve the Form 483 inspectional observations from the February 2016 inspection could result in a delay in the PDUFA date and potential approval for the NDA we have filed for DEXTENZA for the treatment of post-surgical ocular pain.

Any manufacturing defect or error discovered after products have been produced and distributed also could result in significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

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

If the manufacturing facility at our corporate headquarters or the equipment in it is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of this facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before selling any products manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales.

## [Table of Contents](#)

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, polyethylene glycol, or PEG, the molecule that forms the basis of our hydrogels, and other raw materials and for sterilization of the finished product. In addition, while we believe that our existing manufacturing facility, or additional facilities that we will be able to build, will be sufficient to meet our requirements for manufacturing ReSure Sealant and any of our product candidates for which we obtain marketing approval, we may in the future need to rely on third-party manufacturers for some aspects of the manufacture of our products or product candidates.

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

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

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

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

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

### **Risks Related to Commercialization**

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

ReSure Sealant or any of our product candidates that receives marketing approval may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. We commercially launched ReSure Sealant in the first quarter of 2014 and cannot yet accurately predict whether it will 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.

## [Table of Contents](#)

However, we ceased our commercialization of the product in 2012 to focus on the ongoing clinical development of ReSure Sealant pursuant to FDA requirements. If our products do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable.

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

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

For example, because we do not plan to conduct any clinical trials comparing the effectiveness of 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.

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

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

We have limited experience in the sale, marketing and distribution of drug and device products. To achieve commercial success for ReSure Sealant and any product candidate for which we obtain marketing approval, we will need to establish and maintain adequate sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties. We sell ReSure Sealant through a network of independent medical device distributors across the United States. We may determine to build a direct sales force to sell DEXTENZA, if approved for marketing and may initially use a contract sales organization to staff a dedicated team of sales representatives. We may also consider co-promotional arrangements with larger ophthalmology companies. We expect that a direct sales force will be required to effectively market and sell OTX-TP, if approved for marketing. 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



## [Table of Contents](#)

our products effectively. Our product revenues and our profitability, if any, under third-party collaboration, distribution or other marketing arrangements may also be lower than if we were to sell, market and distribute a product ourselves. On the other hand, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of any product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

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

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

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

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

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

Because the active pharmaceutical ingredients in our product candidates are available on a generic basis, or are soon to be available on a generic basis, competitors will be able to offer and sell products with the same active pharmaceutical ingredient as our products so long as these competitors do not infringe the patents that we license. For example, our licensed patents related to our intracanalicular depot product candidates largely relate to the hydrogel composition of the intracanalicular depots 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 depot product candidates. ReSure Sealant is the first and only surgical sealant approved for ophthalmic use in the United States, but will compete with sutures as an alternative method for closing ophthalmic wounds. Multiple companies are exploring in early stage development alternative means to deliver anti-VEGF 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.

## [Table of Contents](#)

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

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

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

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

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

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

ReSure Sealant or any product candidate for which we obtain marketing approval in the United States or in other countries may not be considered medically reasonable and necessary for a specific indication, may not be considered cost-effective by third-party payors, coverage and an adequate level of reimbursement may not be available, and reimbursement policies of third-party payors may adversely affect our ability to sell our product candidates profitably. ReSure Sealant is not separately reimbursed when used as part of



## [Table of Contents](#)

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

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

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

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

We currently hold \$10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of \$10.0 million, which may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage as we expand our clinical trials and our sales of ReSure Sealant and any other product candidates for which we obtain marketing approval. We will need to further increase our insurance coverage if we commence commercialization of any of our product candidates for which we obtain marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

### **Risks Related to Our Dependence on Third Parties**

#### ***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. As ReSure Sealant is a newly marketed product, we will continue to expend significant time and resources to train the independent distributors to be credible and persuasive in convincing physicians and hospitals to use ReSure Sealant. In addition, we also must train our independent distributors to ensure that a consistent and appropriate message about ReSure Sealant is delivered to our potential customers. We believe that, if approved for marketing, DEXTENZA could be commercialized by the same independent network of distributors that sell ReSure Sealant.

Our relationships with our distributors are non-exclusive, and our distributors will simultaneously sell products on behalf of third parties, including products that may compete directly or indirectly with our products or product candidates. If our independent distributors fail to devote sufficient time to the sale of ReSure Sealant, or if they otherwise fail to adequately promote, market and sell ReSure Sealant, our sales could decrease. We face significant challenges and risks in managing our geographically dispersed distribution network and retaining the individuals who make up that network. If a substantial number of our independent distributors, or any significant independent distributor, were to cease to do business with us within a short period of time, our sales could be adversely affected. In such a situation, we may need to seek alternative independent distributors. Because of the competition for their

## [Table of Contents](#)

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.

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

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

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

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

## [Table of Contents](#)

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 Annual Report on Form 10-K also apply to the activities of our collaborators.

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

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

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

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

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

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

Our employees have administered and managed most of our clinical development work, including our clinical trials for ReSure Sealant and our clinical trials for 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 OTX-MP, as well as our pilot studies of OTX-TP in Singapore and South Africa 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

## [Table of Contents](#)

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, or Integra, another licensee of Incept, has filed suit against HyperBranch Medical Technology, Inc. alleging infringement of several patents which we also license. This litigation could result in one or more of the patents which both we and Integra license 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 two issued patents outside of the United States for two of our three intracanalicular depot product candidates, and these expire by 2019. We have three licensed patent families in Europe and certain other parts of the world, but these families consist only of patent applications outside of the United States and have no issued or allowed patents. Patents might not be issued and we may never obtain any patent protection or may only obtain substantially limited patent protection outside of the United States with respect to our products.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensor were the first to make the inventions claimed in our licensed patents or pending

## [Table of Contents](#)

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

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

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

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

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

Because the active pharmaceutical ingredients in our product candidates are available on a generic basis, or are soon to be available on a generic basis, competitors will be able to offer and sell products with the same active pharmaceutical ingredient as our products so long as these competitors do not infringe any patents that we license. Our licensed patents largely relate to the hydrogel composition of our intracanalicular depots 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.

## [Table of Contents](#)

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

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

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

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

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

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

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

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

We are aware of a family of U.S. patent applications and issued patents that expired in approximately December 2015 and which have claims that ReSure Sealant could be considered as having infringed. We believe that the claims of this patent family are subject to a claim of invalidity. We are also aware of a U.S. patent with an expiration in 2020 with claims directed to formulations of hydrogels and which could be alleged to cover the hydrogel formulations used in our product candidates OTX-TP and OTX-MP.



## [Table of Contents](#)

Based on the specifications and file history of that patent, we believe its claims should be construed with a scope that does not cover our product candidates. We also believe that such claims, if and to the extent they were asserted against our product candidates, would be subject to a claim of invalidity.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



## [Table of Contents](#)

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

The FDA required two post-approval studies as a condition for approval of our premarket approval application, or PMA application, for ReSure Sealant. The first post-approval study, identified as the Clinical PAS, is to confirm that ReSure Sealant can be used safely by physicians in a standard cataract surgery practice and to confirm the incidence of the most prevalent adverse ocular events identified in our pivotal study of ReSure Sealant in eyes treated with ReSure Sealant. The FDA has approved the protocol for the Clinical PAS, and we initiated enrollment in December 2014. We have completed enrollment in the Clinical PAS and anticipate submitting the final study report to the FDA in June 2016. 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

## [Table of Contents](#)

this registry study while maintaining the objective for linking ReSure Sealant use to the Medicare database. We believe the FDA may approve the Device Exposure Registry protocol, which could 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 each post-approval study until it is completed. Following review of the results from these studies, any concerns raised by the FDA could lead to modifications in product labeling, the approved indication for use or negative publicity impacting our commercialization efforts.

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

Accordingly, assuming we, or any 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 future collaborators, are not able to comply with post-approval regulatory requirements, we, and any future collaborators, could have the marketing approvals for our products withdrawn by regulatory authorities and our, or any current or future collaborators', ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

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

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- injunctions or the imposition of civil or criminal penalties;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation; or
- litigation involving patients using our products.

## [Table of Contents](#)

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

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

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription and use of ReSure Sealant and any other product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at \$5,500 to \$11,000 per false claim;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals, with data collection beginning in August 2013; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from

## [Table of Contents](#)

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 future collaborators to obtain marketing approval of our other product candidates and affect the prices we, or they, may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our other product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA. Among the provisions of the PPACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within 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

## [Table of Contents](#)

and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any collaborators to more stringent product labeling and post-marketing testing and other requirements.

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

In some countries, such as the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we, or any current or future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

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

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

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

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

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

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

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

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

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

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

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

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

### **Risks Related to Employee Matters and Managing Growth**

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

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

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

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

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



## Risks Related to Our Common Stock

***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;
- 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 to discover, develop, acquire or in-license additional products, product candidates or technologies for the treatment of ophthalmic diseases or conditions, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the ability to secure third party reimbursement for our product candidates;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

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

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

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

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

## [Table of Contents](#)

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

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

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

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

We expect to continue to take advantage of some or all of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal

## [Table of Contents](#)

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 three months ended March 31, 2016 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 Quarterly Report on Form 10-Q.

### **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.

### **Use of Proceeds from Registered Securities**

On July 30, 2014, we closed our initial public offering of 5,000,000 shares of our common stock at a public offering price of \$13.00 per share for an aggregate public offering price of \$65.0 million. In August 2014, the underwriters in our initial public offering exercised their over-allotment option to purchase an additional 750,000 shares of our common stock. The over-allotment shares had an aggregate public offering price of \$9.75 million. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-196932), which was declared effective by the SEC on July 24, 2014.

We received aggregate net proceeds from the offering, including in connection with the exercise by the underwriters of their over-allotment option, of approximately \$66.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. As of March 31, 2016, we have used approximately \$65.1 million of the net proceeds from the offering as follows: \$40.2 million for research and development costs, \$5.9 million for sales and marketing costs, \$13.2 million for general and administrative purposes, \$3.7 million for capital spending, and \$2.1 million to pay interest expense. We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer of ours or any of their associates, to any person owning 10 percent or more of our common stock, or to any affiliate of ours. We have invested the remaining net proceeds from the offering in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and money market funds backed by U.S. government securities. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus dated as of July 24, 2014 filed with the SEC pursuant to Rule 424(b) under the Securities Act.

## **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.

**OCULAR THERAPEUTIX, INC.**

Date: May 10, 2016

By: /s/ W. Bradford Smith

W. Bradford Smith

Chief Financial Officer

(Principal Financial and Accounting Officer)

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
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.

## 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: May 10, 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: May 10, 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 March 31, 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: May 10, 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 March 31, 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: May 10, 2016

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