UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2018

OR

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

For the transition period from _____ to _____

Commission file number: 001-36554

Ocular Therapeutix, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-5560161**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
15 Crosby Drive Bedford, MA	**01730**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

As of May 1, 2018, there were 37,280,054 shares of Common Stock, $0.0001 par value per share, outstanding.

Ocular Therapeutix, Inc.

INDEX

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 plans and ability to resolve the current manufacturing deficiencies cited by the U.S. Food and Drug Administration, or FDA, in order to resubmit our New Drug Application, or NDA, for DEXTENZA™ for the treatment of post-surgical ocular pain;
- our ability to manufacture DEXTENZA in compliance with current Good Manufacturing Practices, or cGMP;
- our plans to raise additional capital, including through equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements and marketing and distribution arrangements, generally, and to fund the regulatory submission and commercialization of DEXTENZA, specifically;
- our ongoing and planned clinical trials, including our Phase 3 clinical trials of OTX-TP for the treatment of glaucoma and ocular hypertension, our Phase 1 clinical trial of OTX-TIC for the reduction of IOP in patients with glaucoma and ocular hypertension and our Phase 1 clinical trial of OTX-TKI for the treatment of VEGF induced retinal leakage for an extended duration;
- the timing of and our ability to submit applications and obtain and maintain regulatory approvals for DEXTENZA, OTX-TP and our other product candidates;
- our plans to raise additional capital, including through equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements;
- 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, or wet AMD, and other retinal diseases;
- our strategic collaboration, option and license agreement with Regeneron Pharmaceuticals, Inc. under which we are collaborating on the development of an extended-delivery formulation of the vascular endothelial growth factor, trap aflibercept, currently marketed under the brand name Eylea, for the treatment of wet AMD, and other serious retinal diseases;
- our estimates regarding the potential market opportunity for DEXTENZA, OTX-TP, ReSure Sealant and our other product candidates;

- our commercialization, marketing and manufacturing plans, capabilities and strategy;
- the costs and timing of manufacturing, sales, marketing, distribution and other commercialization efforts with respect to ReSure Sealant and any additional products, including DEXTENZA, for which we may 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;
- the impact of government laws and regulations;
- the outcome of certain legal actions and proceedings, including the current lawsuits described under “Part II, Item 1 — Legal Proceedings”;
- our ability to continue as a going concern; 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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 62,911	$ 41,538
Accounts receivable	170	226
Inventory	139	122
Prepaid expenses and other current assets	1,256	1,453
Total current assets	64,476	43,339
Property and equipment, net	10,595	10,478
Restricted cash	1,614	1,614
Total assets	$ 76,685	$ 55,431
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,477	$ 3,571
Accrued expenses and deferred rent	3,603	4,310
Notes payable, net of discount, current	6,071	5,545
Total current liabilities	13,151	13,426
Deferred rent, long-term	3,336	3,387
Notes payable, net of discount, long-term	11,014	12,471
Total liabilities	27,501	29,284
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at March 31, 2018 and December 31, 2017, respectively	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized and 37,280,054 and 29,658,202 shares issued and outstanding at March 31, 2018 and December 31, 2017	4	3
Additional paid-in capital	300,210	263,409
Accumulated deficit	(251,030)	(237,265)
Total stockholders' equity	49,184	26,147
Total liabilities and stockholders' equity	$ 76,685	$ 55,431

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,	
	2018	2017
Revenue:		
Product revenue	$ 340	$ 475
Total revenue	340	475
Costs and operating expenses:		
Cost of product revenue	80	115
Research and development	8,227	6,729
Selling and marketing	717	6,027
General and administrative	4,771	3,276
Total costs and operating expenses	13,795	16,147
Loss from operations	(13,455)	(15,672)
Other income (expense):		
Interest income	176	92
Interest expense	(486)	(443)
Total other expense, net	(310)	(351)
Net loss	$ (13,765)	$ (16,023)
Net loss per share, basic and diluted	$ (0.40)	$ (0.58)
Weighted average common shares outstanding, basic and diluted	34,792,848	27,643,746
Comprehensive loss:		
Net loss	$ (13,765)	$ (16,023)
Other comprehensive loss:		
Unrealized loss on marketable securities	—	(4)
Total other comprehensive loss	—	(4)
Total comprehensive loss	$ (13,765)	$ (16,027)

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

Ocular Therapeutix, Inc.

Statements of Cash Flows
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (13,765)	$ (16,023)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	1,831	1,705
Non-cash interest expense	98	110
Depreciation and amortization expense	565	261
Purchase of premium on marketable securities	—	(3)
Amortization of premium on marketable securities	—	11
Changes in operating assets and liabilities:		
Accounts receivable	56	6
Prepaid expenses and other current assets	197	(1,167)
Inventory	(17)	17
Accounts payable	(662)	659
Accrued expenses and deferred rent	(776)	(153)
Net cash used in operating activities	(12,473)	(14,577)
Cash flows from investing activities:		
Purchases of property and equipment	(381)	(1,654)
Purchases of marketable securities	—	(3,000)
Proceeds from maturities of marketable securities	—	12,500
Net cash (used in) provided by investing activities	(381)	7,846
Cash flows from financing activities:		
Proceeds from issuance of notes payable	—	3,700
Proceeds from exercise of stock options	266	2
Proceeds from issuance of common stock offering, net	34,990	26,272
Payments of insurance costs financed by a third party	—	(197)
Repayment of notes payable	(1,029)	(1,300)
Net cash provided by financing activities	34,227	28,477
Net increase in cash, cash equivalents and restricted cash	21,373	21,746
Cash, cash equivalents and restricted cash at beginning of period	43,152	34,664
Cash, cash equivalents and restricted cash at end of period	$ 64,525	$ 56,410
Supplemental disclosure of non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable and accrued expenses at balance sheet dates	$ 301	$ 987
Public offering costs included in accounts payable and accrued expenses at balance sheet dates	$ 285	$ 55

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 formulation, development and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary bioresorbable hydrogel platform technology. The Company's bioresorbable hydrogel product candidates are designed to tailor amount and duration of delivery of a range of therapeutic agents of varying duration in its product candidates. 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, securing reimbursement 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, 2018, the Company's lead product candidates were in clinical stage 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 may not be able 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, including to support the planned commercial launch of DEXTENZA, subject to submitting its new drug application, or NDA, for post-surgical ocular pain and receiving FDA approval.

The Company believes that its existing cash and cash equivalents as of March 31, 2018, will enable it to fund its operating expenses, debt service obligations and capital expenditure requirements through the first quarter of calendar year 2019. Management has determined that the Company's accumulated deficit, history of losses, negative cash flows from operations and future expected losses raise substantial doubt about the Company's ability to continue as a going concern within one year of the issuance date of these financial statements. The Company has incurred losses and negative cash flows from operations since its inception, and the Company expects to continue to generate operating losses and negative cash flows from operations in the foreseeable future. As of March 31, 2018, the Company had an accumulated deficit of $251,030.

If the Company is unable to obtain other financing, the Company would 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. The actions necessary to reduce spending to a level that mitigates the factors described above are not considered probable, as defined in the accounting standards.

The accompanying unaudited interim financial statements of the Company have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying unaudited interim financial statements do not include any adjustments to reflect the possible future effects

on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the ability to continue as a going concern.

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, 2017 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of March 31, 2018 and for the three months ended March 31, 2018 and 2017 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K on file with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of March 31, 2018 and results of operations and cash flows for the three months ended March 31, 2018 and 2017 have been made. The results of operations for the three months ended March 31, 2018 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2018.

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, including clinical trials, and the valuation of common stock and stock-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Fair Value Measurements

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

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

The Company's cash equivalents at March 31, 2018 and December 31, 2017, 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 6) approximates fair value reflecting interest rates currently available to the Company.

Restricted Cash

The Company held certificates of deposit totaling $1,614 at March 31, 2018 and December 31, 2017, as security deposits for the lease of the Company's manufacturing space and current corporate headquarters. The Company has classified these certificates of deposit as long-term restricted cash on its balance sheet.

Comprehensive Loss

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

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the diluted net 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.

Recently Issued and Adopted Accounting Pronouncements

Recently Adopted Accounting Pronouncements

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 which delays the effective date of ASU 2014-09 such that the standard is effective for public entities for annual periods beginning after December 15, 2017 and for interim periods within those fiscal years. The FASB subsequently issued amendments to ASU No. 2014-09 that have the same effective date and transition date, all of which collectively are herein referred to as "the New Revenue Standard."

The Company adopted the New Revenue Standard on January 1, 2018 using the modified retrospective method. The adoption of the New Revenue Standard did not have a material impact on its financial statements and footnote disclosures. Under the New Revenue Standard, the Company recognizes revenue when the customer obtains control of the good in an amount that reflects the consideration which the Company expects to receive in exchange for those goods. The Company only applies the New Revenue Standard to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods transferred to the customer.

In August 2016, the FASB issued Accounting Standards Update No. 2016-15, Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15"). ASU 2016-15 is intended to clarify guidance on the classification of certain cash receipts and payments in the statement of cash flows and to eliminate the diversity in practice related to such classifications. The Company adopted ASU 2016-15 effective January 1, 2018 and its adoption did not have a material impact on its financial statements.

In November 2016, the FASB issued ASU 2016-18, "Statement of Cash Flows (Topic 230) - Restricted Cash" ("ASU 2016-18"). ASU 2016-18 requires a statement of cash flows to explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents

when reconciling the beginning-of-period and end-of- period total amounts shown on the statement of cash flows. The Company adopted ASU 2016-18 effective January 1, 2018 and has reflected the adoption retrospectively to all periods presented. The Company's statements of cash flows includes restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on such statements. A reconciliation of the cash, cash equivalents, and restricted cash reported within the balance sheet that sum to the total of the same amounts shown in the statement of cash flows:

	March 31, 2018	March 31, 2017	December 31, 2017	December 31, 2016
Cash and cash equivalents	$ 62,911	$ 54,682	$ 41,538	$ 32,936
Restricted cash	1,614	1,728	1,614	1,728
Total cash, cash equivalents and restricted cash as shown on the statement of cash flow	$ 64,525	$ 56,410	$ 43,152	$ 34,664

In May 2017, the FASB issued ASU 2017-09, "Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting" ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. The new standard does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if the fair value, vesting conditions, or classification of the award changes as a result of the change in terms or conditions. The new standard is effective for fiscal years, and interim periods within, beginning after December 15, 2017. Early adoption is permitted. A reporting entity must apply the amendments in the ASU prospectively to an award modified on or after the adoption date. The Company adopted ASU 2017-09 effective January 1, 2018 and its adoption did not have a material impact on the Company's financial statements. The adoption of ASU 2017-09 will have an impact on the accounting for the modification of stock-based awards, if any, to the extent stock-based awards are modified.

Recently Issued Accounting Pronouncements

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

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, 2018 and December 31, 2017 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of March 31, 2018 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ —	$ 61,424	$ —	$ 61,424
Total	$ —	$ 61,424	$ —	$ 61,424

	Fair Value Measurements as of December 31, 2017 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ —	$ 40,386	$ —	$ 40,386
Total	$ —	$ 40,386	$ —	$ 40,386

During the three months ended March 31, 2018 there were no transfers between Level 1, Level 2 and Level 3.

4. Income Taxes

The Company did not provide for any income taxes in its statement of operations for the three month period ended March 31, 2018 or 2017. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at March 31, 2018 and December 31, 2017, 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.

As provided for in SEC Staff Accounting Bulletin No. 118, which addresses the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Cut and Jobs Act, or TCJA, the Company is still in the process of analyzing the impact to the Company of the TCJA. Where the Company has been able to make reasonable estimates of the effects, the Company has recorded provisional amounts during the year ended December 31, 2017. The ultimate impact to the Company's financial statements of the TCJA may differ from the provisional amounts due to, among other things, additional analysis, changes in interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of the TCJA. The accounting is expected to be complete when the Company's 2017 U.S. corporate income tax return is filed in 2018.

The Company has not recorded any amounts for unrecognized tax benefits as of March 31, 2018 or December 31, 2017. As of March 31, 2018 and December 31, 2017, 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, 2014 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.

5. Collaboration and Feasibility Agreements

In October 2016, the Company entered into a Collaboration, Option and License Agreement (the "Collaboration Agreement") with Regeneron Pharmaceuticals, Inc. ("Regeneron") for the development and potential commercialization of products containing the Company's extended-delivery hydrogel formulation in combination with Regeneron's large molecule VEGF-targeting compounds for the treatment of retinal diseases. The Collaboration Agreement does not cover the development of any products that deliver small molecule drugs, including tyrosine kinase inhibitors, or TKIs, or deliver large molecule drugs other than those that target VEGF proteins.

Under the terms of the Collaboration Agreement, the Company and Regeneron have agreed to conduct a joint research program with the aim of developing an extended-delivery formulation of aflibercept, currently marketed under the tradename Eylea, that is suitable for advancement into clinical development. The Company has granted Regeneron an option (the "Option") to enter into an exclusive, worldwide license to develop and commercialize products containing the Company's hydrogel in combination with Regeneron's large molecule VEGF-targeting compounds ("Licensed Products"). Under the term of the Collaboration Agreement, Regeneron is responsible for funding an initial preclinical tolerability study, which it initiated in early 2018.

If the Option is exercised, Regeneron will conduct further preclinical development and an initial clinical trial under a collaboration plan. The Company is obligated to reimburse Regeneron for certain development costs incurred by Regeneron under the collaboration plan during the period through the completion of the initial clinical trial, subject to a cap of $25,000, which cap may be increased by up to $5,000 under certain circumstances. If Regeneron elects to

proceed with further development following the completion of the collaboration plan, it will be solely responsible for conducting and funding further development and commercialization of product candidates. If the Option is exercised, Regeneron is required to use commercially reasonable efforts to research, develop and commercialize at least one Licensed Product. Such efforts shall include initiating the dosing phase of a subsequent clinical trial within specified time periods following the completion of the first-in-human clinical trial or the initiation of preclinical toxicology studies, subject to certain extensions.

Under the terms of the Collaboration Agreement, Regeneron has agreed to pay the Company $10,000 upon the exercise of the Option. The Company is also eligible to receive up to $145,000 per Licensed Product upon the achievement of specified development and regulatory milestones, $100,000 per Licensed Product upon first commercial sale of such Licensed Product and up to $50,000 based on the achievement of specified sales milestones for all Licensed Products. In addition, the Company is entitled to tiered, escalating royalties, in a range from a high-single digit to a low-to-mid teen percentage of net sales of Licensed Products.

6. Notes Payable

The Company has outstanding borrowings under a credit and security agreement entered into in 2014 and as most recently amended in March 2017 (the “Amended Credit Facility”) totaling $18,000, which is collateralized by substantially all of the Company’s personal property, other than its intellectual property. The $18,000 of borrowings were drawn at the closing of the March 2017 amendment, which was used primarily to pay-off outstanding balances on the facility as of the amendment date of $14,300, resulting in net proceeds to the Company of $3,700.

The Company was obligated to make interest-only payments under the Amended Credit Facility until February 1, 2018, at which time the Company became obligated to make monthly principal and interest payments through December 1, 2020. Amounts borrowed under the Amended Credit Facility are at LIBOR base rate, subject to 1.00% floor, plus 7.25% with an indicative interest rate of 8.25% as of the amendment date. In addition, a final payment equal to 3.5% of amounts drawn under the Amended Credit Facility is due upon the maturity date of December 1, 2020, which the Company has accrued for using the effective interest rate method.

There are no financial covenants associated with the Amended Credit Facility; however, there are certain 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 Credit Facility are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the Company’s business, operations or financial or other condition.

The Company accounted for the amendment of the Amended Credit Facility in March 2017 as a modification in accordance with the guidance in ASC 470-50, Debt. Amounts paid to the lenders were recorded as debt discount and a new effective interest rate was established. The effective annual interest rate of the outstanding debt under the Amended Credit Facility is 10.5%.

As of March 31, 2018, the annual repayment requirements for the Amended Credit Facility, inclusive of the final payment of $630 due at expiration, were as follows:

Year Ending December 31,	Principal	Interest and Final Payment	Total
2018	$ 4,630	$ 940	$ 5,570
2019	6,171	796	6,967
2020	6,171	911	7,082
	$ 16,972	$ 2,647	$ 19,619

7. Common Stock

In January 2018, the Company completed a follow-on offering of its common stock at a public offering price of $5.00 per share. The offering consisted of 7,475,000 shares of common stock sold by the Company, including those shares sold in connection with the exercise by the underwriter of its option to purchase additional shares. The Company

received net proceeds from the follow-on offering of $34,704 after deducting underwriting discounts, commissions and expenses.

In January 2017, the Company completed a follow-on offering of its common stock at a public offering price of $7.00 per share. The offering consisted of 3,571,429 shares of common stock sold by the Company. The Company received net proceeds from the follow-on offering of $23,261 after deducting underwriting discounts, commissions and expenses.

In November 2016, the Company entered into an at-the-market sales agreement (the "2016 ATM Agreement") with Cantor Fitzgerald & Co., under which the Company may offer and sell its common stock having aggregate proceeds of up to $40,000 from time to time. In January 2017, the Company sold 161,341 shares of common stock under the 2016 ATM Agreement, resulting in net proceeds of approximately $1,395 after underwriting discounts and commissions. In March 2017, the Company sold 177,068 shares of common stock under the 2016 ATM Agreement, resulting in net proceeds of approximately $1,561 after underwriting discounts, commissions and expenses. During the three months ended March 31, 2018, the Company did not issue any shares of Common Stock under our 2016 ATM Agreement. Through April 30, 2018, the Company has sold an aggregate of 890,568 shares of common stock under the 2016 ATM Agreement, resulting in net proceeds of approximately $6.6 million after underwriting discounts, commission and other offering expenses. The Company has $32.8 million that remains available under the 2016 ATM Agreement.

8. Net Loss Per Share

Basic and diluted net loss per share was calculated as follows for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,	
	2018	2017
Numerator:		
Net loss attributable to common stockholders	$ (13,765)	$ (16,023)
Denominator:		
Weighted average common shares outstanding, basic and diluted	34,792,848	27,643,746
Net loss per share attributable to common stockholders, basic and diluted	$ (0.40)	$ (0.58)

The Company excluded the following common stock equivalents, outstanding as of March 31, 2018 and 2017, from the computation of diluted net loss per share for the three months ended March 31, 2018 and 2017 because they had an anti-dilutive impact due to the net loss incurred for the periods.

	As of March 31,	
	2018	2017
Options to purchase common stock	5,062,284	4,207,234
Warrants for the purchase of common stock	18,939	18,939
	5,081,223	4,226,173

9. 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, 2018, the number of shares available for issuance under the 2014 Plan was increased by 1,186,328. As of March 31, 2018, 1,785,199 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, 2018, the number of shares available for issuance under the 2014 Plan was increased by 148,291. During the three months ended March 31, 2018, no shares of common stock were issued. As of March 31, 2018, 482,965 shares remained available for issuance under the ESPP.

Inducement Stock Option Awards

On June 20, 2017, the Company issued to Antony Mattessich, who became a director of the Company on June 20, 2017 and the Company's President and Chief Executive Officer on July 26, 2017, a non-statutory stock option to purchase an aggregate of 590,000 shares of the Company's common stock at an exercise price of $10.94 per share. Subject to Mr. Mattessich's continued service to the Company, the stock option will vest over a four-year period, with 25% of the shares underlying the option award vesting on the one-year anniversary of the grant date and the remaining 75% of the shares underlying the award vesting monthly thereafter. The stock option was issued outside of the Company's 2014 Plan as an inducement material to Mr. Mattessich's acceptance of entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

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,	
	2018	2017
Research and development	$ 608	$ 532
Selling and marketing	111	206
General and administrative	1,112	967
	$ 1,831	$ 1,705

As of March 31, 2018, the Company had an aggregate of $15,406 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.0 years.

As of March 31, 2018, there were outstanding unvested service-based stock options held by nonemployees for the purchase of 19,584 shares of common stock.

10. Commitments and Contingencies

Intellectual Property Licenses

The Company has a license agreement with Incept, LLC ("Incept") 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, 2018, royalties paid under this agreement related to product sales were $169 and have been charged to cost of product revenue.

Collaboration Agreement

In October 2016, the Company entered into a Collaboration Agreement with Regeneron (Note 5). If the Option to enter into an exclusive worldwide license is exercised, Regeneron will conduct further preclinical development and an initial clinical trial under a collaboration plan. The Company is obligated to reimburse Regeneron for certain development costs incurred by Regeneron under the collaboration plan during the period through the completion of the initial clinical trial, subject to a cap of $25,000, which cap may be increased by up to $5,000 under certain circumstances, the timing of such payments is not known. If Regeneron elects to proceed with further development following the completion of the collaboration plan, it will be solely responsible for conducting and funding further development and commercialization of product candidates. If the Option is exercised, Regeneron is required to use commercially reasonable efforts to research, develop and commercialize at least one Licensed Product. Such efforts shall include initiating the dosing phase of a subsequent clinical trial within specified time periods following the completion of the first-in-human clinical trial or the initiation of preclinical toxicology studies, subject to certain extensions. Through March 31, 2018, the Option has not been exercised and no payments have been made to Regeneron.

Legal Proceedings

Securities Class Actions

On July 7, 2017, a putative class action lawsuit was filed against the Company and certain of the Company's current and former executive officers in the United States District Court for the District of New Jersey, captioned *Thomas Gallagher v. Ocular Therapeutix, Inc, et al.*, Case No. 2:17-cv-05011. The complaint purports to be brought on behalf of shareholders who purchased the Company's common stock between May 5, 2017 and July 6, 2017. The complaint generally alleges that the Company and certain of the Company's current and former officers violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning the Form 483 issued by the FDA related to DEXTENZA and the Company's manufacturing operations for DEXTENZA. The complaint seeks unspecified damages, attorneys' fees, and other costs. On July 14, 2017, an amended complaint was filed; the amended complaint purports to be brought on behalf of shareholders who purchased the Company's common stock between May 5, 2017 and July 11, 2017, and otherwise includes allegations similar to those made in the original complaint.

On July 12, 2017, a second putative class action lawsuit was filed against the Company and certain of the Company's current and former executive officers in the United States District Court for the District of New Jersey, captioned *Dylan Caraker v. Ocular Therapeutix, Inc., et al.*, Case No. 2:17-cv-05095. The complaint purports to be brought on behalf of shareholders who purchased the Company's common stock between May 5, 2017 and July 6, 2017. The complaint includes allegations similar to those made in the Gallagher complaint, and seeks similar relief.

On August 3, 2017, a third putative class action lawsuit was filed against the Company and certain of the Company's current and former executive officers in the United States District Court for the District of New Jersey, captioned *Shawna Kim v. Ocular Therapeutix, Inc., et al.*, Case No. 2:17-cv-05704. The complaint purports to be brought on behalf of shareholders who purchased the Company's common stock between March 10, 2016 and July 11, 2017. The complaint includes allegations similar to those made in the Gallagher complaint, and seeks similar relief.

On October 27, 2017, a magistrate judge for the United States District Court for the District of New Jersey granted the defendants' motion to transfer the above-referenced *Gallagher, Caraker, and Kim* litigations to the United States District Court for the District of Massachusetts. These matters were assigned the following docket numbers in the District of Massachusetts: 1:17-cv-12288 (*Gallagher*), 1:17-cv-12146 (*Caraker*), and 1:17-cv-12286 (*Kim*).

On March 9, 2018, the court granted plaintiffs' motion to consolidate the three actions and appointed co-lead plaintiffs and co-lead counsel for the consolidated action. On May 7, 2018, co-lead plaintiffs filed a consolidated amended class action complaint. The amended complaint makes allegations similar to those in the original complaints, against the same defendants, and seeks similar relief on behalf of shareholders who purchased the Company's common stock between March 10, 2016 and July 11, 2017. The amended complaint generally alleges that defendants violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. Defendants' response to the consolidated amended complaint is due on July 6, 2018.

The Company denies any allegations of wrongdoing and intends to vigorously defend against these lawsuits.

Shareholder Derivative Litigation

On July 11, 2017, a purported shareholder derivative lawsuit was filed against certain of the Company's current and former executive officers, certain current and former board members, and the Company as a nominal defendant, in the United States District Court for the District of Massachusetts, captioned *Robert Corwin v. Sawhney et al.*, Case No. 1:17-cv-11270. The complaint generally alleged that the individual defendants breached fiduciary duties owed to the Company by making allegedly false and/or misleading statements concerning the Form 483 related to DEXTENZA and our manufacturing operations for DEXTENZA. The complaint purported to assert claims against the individual defendants for breach of fiduciary duty, and sought to recover on behalf of the Company for any liability the Company incurs as a result of the individual defendants' alleged misconduct. The complaint also sought contribution on behalf of the Company from all individual defendants for their alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. The complaint sought declaratory, equitable, and monetary relief, an unspecified amount of damages, with interest, and attorneys' fees and costs. On September 20, 2017, counsel for the plaintiff filed a notice of voluntary dismissal, stating that the plaintiff wished to coordinate his efforts and proceed in a consolidated fashion with the plaintiff in a similar derivative suit that was pending in the Superior Court of Suffolk County of the Commonwealth of Massachusetts captioned Angel Madera v. Sawhney et al., Case. No. 17-2273 (which is discussed in the paragraph immediately below) by filing an action in that court subsequent to the dismissal of this lawsuit. The Corwin lawsuit was dismissed without prejudice on September 21, 2017. On October 24, 2017, the plaintiff filed a new derivative complaint in Massachusetts Superior Court (Suffolk County), captioned Robert Corwin v. Sawhney et al., Case No. 17-3425 (BLS2). The new Corwin complaint includes allegations similar to those made in the federal court complaint and asserts a derivative claim for breach of fiduciary duty against certain of our current and former officers and directors. The complaint also asserts an unjust enrichment claim against two additional defendants, SV Life Sciences Fund IV, LP and SV Life Sciences Fund IV Strategic Partners, LP. The complaint also names the Company as a nominal defendant.

On July 19, 2017, a second purported shareholder derivative lawsuit was filed against certain of the Company's current and former executive officers, all current board members, one former board member, and the Company as a nominal defendant, in the Superior Court of Suffolk County of the Commonwealth of Massachusetts, captioned *Angel Madera v. Sawhney et al.*, Case. No. 17-2273. The complaint included allegations similar to those made in the Corwin complaint. The complaint purported to assert derivative claims against the individual defendants for breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets, and sought to recover on behalf of the Company for any liability the Company incurs as a result of the individual defendants' alleged misconduct. The complaint sought declaratory, equitable, and monetary relief, an unspecified amount of damages, with interest, and attorneys' fees and costs. On November 6, 2017, the court dismissed this action without prejudice due to plaintiff's failure to complete service of process within the time permitted under applicable court rules. On December 21, 2017, the same plaintiff filed a new derivative complaint in the same court, captioned *Angel Madera v. Sawhney et al.*, Case. No. 17-4126 (BLS2). The new *Madera* complaint is premised on substantially similar allegations as the previous complaint and purports to assert derivative claims against certain current and former executive officers and board members for breach of fiduciary duty, unjust enrichment, and waste of corporate assets, and names the Company as a nominal defendant. Like the new *Corwin* complaint, the new *Madera* complaint also asserts an unjust enrichment claim against two additional defendants, SV Life Sciences Fund IV, LP and SV Life Sciences Fund IV Strategic Partners, LP.

By order dated January 29, 2018, the court consolidated the state court *Corwin* and *Madera* complaints under the Corwin docket and appointed lead counsel for plaintiffs. On February 28, 2018, plaintiffs filed a consolidated amended complaint. The consolidated complaint names substantially the same defendants and is premised on substantially similar allegations as the previous *Corwin* and *Madera* complaints, asserting claims for breach of fiduciary duty against the individual defendants and unjust enrichment against the two SV entity defendants. On April 17, 2018, all defendants served a motion to dismiss the consolidated amended complaint. Pursuant to the briefing schedule the court set, plaintiffs will serve their opposition brief by June 1, 2018, and defendants will serve their reply within 21 days thereafter.

On January 31, 2018, a third purported shareholder derivative suit was filed against certain of the Company's current and former executive officers, certain current and former board members, and the Company as a nominal defendant, in the United States District Court for the District of Massachusetts, captioned *Brian Robinson v. Sawhney et al.*, Case. No. 1:18-cv-10199. The complaint includes allegations similar to those made in the *Corwin* and *Madera*

complaints. The complaint does not name either SV Life Sciences Fund, IV, LP or SV Life Sciences Fund IV Strategic Partners, LP as defendants, and adds two former officers as defendants. The complaint purports to assert derivative claims against the individual defendants for breach of fiduciary duty, waste of corporate assets, and unjust enrichment, and seeks to recover on behalf of the Company for any liability the Company incurs as a result of the individual defendants' alleged misconduct. The complaint seeks declaratory, equitable, and monetary relief, an unspecified amount of damages, with interest, and attorneys' fees and costs. On April 30, 2018, the Company filed a motion to dismiss or stay the complaint. Pursuant to the briefing schedule the court set, plaintiffs will serve their opposition brief by June 11, 2018, and defendants will serve their reply within 20 days thereafter.

On February 16, 2018, a fourth purported shareholder derivative suit was filed against certain of the Company's current and former executive officers, certain current and former board members, and the Company as a nominal defendant, in the United States District Court for the District of Delaware, captioned *Terry Kelly v. Sawhney et al.*, Case. No. 1:18-cv-00277. The complaint includes allegations similar to those made in the *Corwin* and *Madera* complaints. The complaint purports to assert derivative claims against the individual defendants for breach of fiduciary duty, unjust enrichment and waste of corporate assets, and seeks to recover on behalf of the Company for any liability the Company incurs as a result of the individual defendants' alleged misconduct. The complaint also asserts an unjust enrichment claim against SV Life Sciences Fund IV, LP and SV Life Sciences Fund IV Strategic Partners, LP. The complaint seeks declaratory, equitable, and monetary relief, an unspecified amount of damages, with interest, and attorneys' fees and costs.

The Company denies any allegations of wrongdoing and intend to vigorously defend against these lawsuits.

In addition, the Company has received a subpoena from the SEC, dated December 15, 2017, requesting documents and information concerning DEXTENZA™ (dexamethasone insert) 0.4mg, including related communications with the FDA, investors and others. The Company intends to fully cooperate with the SEC regarding this non-public, fact-finding inquiry. The SEC has informed the Company that this inquiry should not be construed as an indication that any violations of law have occurred or that the SEC has any negative opinion of any person, entity or security.

The Company is unable to predict the outcome of these lawsuits or proceedings at this time. Moreover, any conclusion of these matters in a manner adverse to the Company and for which it incurs substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on the Company's financial condition and business. In addition, the proceedings could adversely impact the Company's reputation and divert management's attention and resources from other priorities, including the execution of business plans and strategies that are important to the Company's ability to grow the Company's business, any of which could have a material adverse effect on the Company's business.

11. Related Party Transactions

The Company has a license agreement with Incept to use and develop certain patent rights that it entered into in 2007 (see Note 10). 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 Executive Chairman of the Board of Directors and former President and Chief Executive Officer ("CEO") is a general partner of Incept.

In March 2016, the Company entered into a Master Services Agreement with Axtria, Inc. ("Axtria"). In March 2016, the Company entered into a statement of work totaling approximately $104 under which Axtria would provide certain sales and marketing analytics to the Company. In February 2017, the Company entered into a separate statement of work totaling approximately $1,400 under which Axtria would provide data warehouse implementation, operations and maintenance support services to the Company. Jaswinder Chadha, co-founder and CEO of Axtria, is also a member of the Company's Board of Directors and a cousin to the Company's Executive Chairman of the Board of Directors and former President and CEO. In the three months ended March 31, 2017, payments paid to Axtria were $388 under the 2017 statement of work. In the three months ended March 31, 2017, the Company has expensed to sales and marketing $577 under the 2017 statement of work for sales and marketing analytics. On July 20, 2017, the Company terminated the 2017 and 2016 statements of work with Axtria. As of March 31, 2018 and December 31, 2017, there were no amounts due in accounts payable to Axtria.

Since 2014, the Company has engaged Wilmer Cutler Pickering Hale and Dorr LLP ("WilmerHale") to provide legal services to the Company, including with respect to general corporate, finance, securities law, regulatory and

licensing matters. The Company's former Chief Medical Officer, Jonathan H. Talamo, M.D., who served as Chief Medical Officer from July 2016 until his resignation in June 2017, is married to a partner at WilmerHale, who has not participated in providing legal services to the Company. The Company incurred fees for legal services rendered by WilmerHale of $1,578 and $285 for the three months ended March 31, 2018 and 2017, respectively. As of March 31, 2018 and December 31, 2017, there was $1,008 and $194, respectively, recorded in accounts payable for WilmerHale. As of March 31, 2018 and December 31, 2017, there was $547 and $80, respectively, recorded in accrued expenses for WilmerHale.

Since October 2017, the Company has engaged McCarter English LLP ("McCarter") to provide legal services to the Company, including with respect to intellectual property matters. The Company's Senior Vice President, Technical Operations, Kevin Hanley, who joined the Company in January 2018, is married to a partner at McCarter, who has not participated in providing legal services to the Company. The Company incurred fees for legal services rendered by McCarter of $93 for the three months ended March 31, 2018. As of March 31, 2018, there was $38, recorded in accrued expenses for McCarter.

12. Restructuring and Other Costs

On July 31, 2017, the Board of Directors approved a strategic restructuring to eliminate a portion of the Company's workforce as part of an initiative to enhance operations and reduce expenses. As part of this strategic restructuring, the Company eliminated 30 positions across the organization. During the third quarter of 2017, the Company recorded $1,703 of restructuring-related costs in operating expenses in research and development and selling and marking, including employee severance, benefits and related costs.

On July 31, 2017, the Company entered into a transition, separation and release of claims agreement (the "Ankerud Transition Agreement"), pursuant to which Eric Ankerud resigned from his role as Executive Vice President, Regulatory, Quality and Compliance of the Company, effective immediately. Mr. Ankerud continued to serve as an at-will employee of the Company in the capacity of Senior Advisor until October 31, 2017. He currently serves as a consultant to the Company. Under the Ankerud Transition Agreement, Mr. Ankerud is entitled to separation benefits until October 31, 2018, in the form of continuation of his base salary in the same amount in effect as of October 31, 2018; the payment of monthly premiums for healthcare and/or dental coverage; and provided he continues to provide services to the Company as a consultant, the continued vesting of his outstanding stock options awards in accordance with the applicable equity plans and stock option agreements. During the third quarter of 2017, the Company recorded $386 of severance expense which are included in operating expenses in research and development.

On October 13, 2017, the Company entered into a transition, separation and release of claims agreement (the "Fortune Transition Agreement") with James Fortune, pursuant to which Mr. Fortune resigned from his role as Chief Operating Officer and any and all other positions he holds as an officer or employee of the Company, effective December 31, 2017 (the "Separation Date"). Pursuant to the Fortune Transition Agreement, effective as of October 13, 2017, the Employment Agreement, by and between the Company and Mr. Fortune, dated June 19, 2014, was terminated. Under the Fortune Transition Agreement, Mr. Fortune will be entitled to separation benefits in the form of (i) the continuation of his base salary for twelve months after the Separation Date in the same amount in effect as of the October 13, 2017 and (ii) the payment of monthly premiums for healthcare and/or dental coverage at the same rate that is in effect on the Separation Date until the earlier of twelve months from the Separation Date or the date Mr. Fortune becomes eligible to receive such benefits under another employer's benefit plan. For the calendar year 2017, Mr. Fortune was eligible to receive a bonus payment in such amount, if any, as he would have received had he remained employed with the Company through the date of such bonus payments. On January 31, 2018, the Company's Compensation Committee determined to grant Mr. Fortune a bonus of $62 for his performance in 2017 and this amount was included in accrued expenses as of December 31, 2017. During the fourth quarter of 2017, the Company recorded $417 of severance expense which was included in operating expenses in general and administration.

The following table summarizes the restructuring and other costs reserve for the period indicated, which is included in accrued expenses in the accompany balance sheets for the period indicated:

	Three Months Ended March 31, 2018
Restructuring and other costs at December 31, 2017	$ 960
Amounts paid during the period	(301)

Restructuring and other costs at March 31, 2018	$ 659

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 8, 2018. 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.

Overview

We are a biopharmaceutical company focused on the formulation, development and commercialization of innovative therapies for diseases and conditions of the eye using our proprietary, bioresorbable hydrogel platform technology. We use this technology to tailor duration and amount of delivery of a range of therapeutic agents of varying duration in our product candidates.

We currently incorporate U.S. Food and Drug Administration, or FDA, approved therapeutic agents, including small molecules and proteins, into our hydrogel technology with the goal of providing extended delivery of drug to the eye. We believe that our extended delivery technology allows us to treat conditions and diseases of both the front and the back of the eye and can be administered through a range of different modalities including intracanalicular inserts, intracameral implants and intravitreal implants. We have product candidates in clinical and preclinical development applying this technology to treat post-surgical ocular pain and inflammation, allergic conjunctivitis, dry eye disease, glaucoma and ocular hypertension, and wet age-related macular degeneration, or wet AMD, among other conditions.

Our lead product candidates are DEXTENZA™ (dexamethasone insert), for the treatment of post-surgical ocular pain and inflammation, allergic conjunctivitis and dry eye disease, and OTX-TP (travoprost insert), for the reduction of intraocular pressure, or IOP, in patients with glaucoma and ocular hypertension. Both product candidates are extended-delivery, drug-eluting, preservative-free intracanalicular inserts that are placed into the canaliculus through a natural opening called the punctum located in the inner portion of the eyelid near the nose. We also have a preclinical product development candidate that is injected into the intracameral space for the reduction of IOP in patients with glaucoma and ocular hypertension where greater IOP reduction is needed.

Our early stage assets include two development programs that are beginning human clinical trials: OTX-TIC, an intracameral travoprost implant for the reduction of IOP in patients with glaucoma and ocular hypertension; and OTX-TKI, a tyrosine kinase inhibitor intravitreal injection by fine gauge needle, delivering a hydrogel, anti-angiogenic formulation for the treatment of wet AMD. Finally, we continue our collaboration with Regeneron Pharmaceuticals, Inc., or Regeneron, for the development and potential commercialization of products containing our extended-delivery hydrogel in combination with Regeneron's VEGF inhibitor, aflibercept, currently marketed under the brand name Eylea.

In addition to our ongoing drug product development, we currently market our sole commercial product ReSure Sealant, a hydrogel ophthalmic wound sealant approved by the FDA to seal corneal incisions following cataract surgery. ReSure Sealant is the first and only surgical sealant to be approved by the FDA for ophthalmic use.

DEXTENZA™ (dexamethasone insert)

Our most advanced product candidate, DEXTENZA, incorporates the FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient into a hydrogel, drug-eluting intracanalicular insert. In September 2015, we submitted to the FDA a New Drug Application, or NDA, for DEXTENZA for the treatment of post-surgical ocular pain. In July 2016, we received a Complete Response Letter, or CRL, from the FDA regarding our NDA for DEXTENZA. This CRL pertained to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of our manufacturing facility. In January 2017, we resubmitted our NDA. Following a re-inspection of manufacturing operations by the FDA which was completed in May 2017, we received an FDA Form 483 containing new inspectional observations focused on manufacturing processes and analytical testing related to the manufacture of drug product for commercial production. In July 2017, we received a second CRL from the FDA

regarding our NDA for DEXTENZA for the treatment of post-surgical ocular pain, which states that the FDA has determined that it cannot approve the NDA in its present form. FDA concerns included deficiencies in manufacturing processes and analytical testing related to manufacturing of drug product identified during the May 2017 pre-NDA approval inspection. We have corresponded with the FDA regarding these inspectional observations and are working to resolve the issues that have been identified. In May 2017 we submitted our initial response to the Form 483 and in November 2017 we submitted our responses to the FDA's remaining inspectional observations in an effort to close out the items identified in the Form 483.

Subject to satisfactorily addressing the FDA inspectional observations and demonstrating consistency in our commercial stage manufacturing process, we plan to resubmit our NDA for DEXTENZA for the treatment of post-surgical ocular pain in the second quarter of 2018. Adequate resolution of the outstanding Form 483 inspectional observations and the final decision as to the adequacy of our manufacturing processes are determined by the FDA with input from the Office of Process and Facilities within its Center for Drug Evaluation and Research, or CDER, as part of the NDA review process, and are necessary prior to NDA approval.

If DEXTENZA is approved for marketing, we are considering potential commercialization options available for DEXTENZA in the United States, including building our own highly targeted, key account sales force that would focus on the ambulatory surgical centers responsible for the largest volumes of cataract surgery.

We have completed three Phase 3 clinical trials of DEXTENZA for the treatment of post-surgical ocular pain and inflammation. The data from two of these three completed Phase 3 clinical trials and a prior Phase 2 clinical trial are being used to support our NDA for post-surgical ocular pain. Subject to receiving approval for the pain indication, we plan to submit an NDA supplement, or sNDA, for DEXTENZA for the treatment of post-surgical ocular inflammation. We have also completed two Phase 3 clinical trials of DEXTENZA for the treatment of allergic conjunctivitis. In October 2015, we announced topline results of our first Phase 3 clinical trial for allergic conjunctivitis, and in June 2016 we announced topline results of our second Phase 3 clinical trial for this indication. Finally, DEXTENZA completed a Phase 2 clinical trial for the treatment of dry eye disease, with topline results announced in December 2015.

OTX-TP (*intracanalicular travoprost insert****)***

Our second product candidate, OTX-TP, incorporates travoprost, an FDA-approved prostaglandin analog, or PGA, that reduces elevated IOP as its active pharmaceutical ingredient, into a hydrogel, drug-eluting intracanalicular insert. This preservative-free insert is designed to elute drug for up to 90 days. OTX-TP is being developed as a treatment to lower IOP in patients with primary open angle glaucoma and ocular hypertension. We reported topline results from a Phase 2b clinical trial for this indication in October 2015. We completed an End-of-Phase 2 review with the FDA in April 2016 and initiated the first of two Phase 3 clinical trials of OTX-TP in September 2016. We expect our first Phase 3 trial to enroll approximately 550 patients at 50 sites in the United States. Based on discussions with the FDA, the first Phase 3 clinical trial design includes an OTX-TP treatment arm and a placebo-controlled comparator arm that uses a non-drug eluting hydrogel-based intracanalicular insert. There is not a requirement for either a timolol comparator or a validation arm. No eye drops, placebo or active, are administered in either the OTX-TP treatment arm or the placebo-controlled arm. The primary efficacy endpoint is superiority in the reduction of IOP from baseline in the OTX-TP treatment arm compared to the placebo arm at three diurnal time points at each of three measurement dates, 2, 6 and 12 weeks. We expect that the FDA will require that OTX-TP show both a statistically superior reduction of IOP, compared to the placebo and a clinically meaningful reduction of IOP prior to granting marketing approval. While enrollment in this first Phase 3 clinical trial has continued steadily, it has been slightly slower than projected. To address this issue, we are working closely with clinical sites to identify appropriate patients, and have added additional clinical sites to help complete enrollment. We expect topline efficacy data from the first Phase 3 clinical trial in the first half of 2019. We do not intend to initiate the second Phase 3 clinical trial until we receive data from the first Phase 3 clinical trial and may determine to discuss the results of this first Phase 3 clinical trial with the FDA prior to initiating a second Phase 3 clinical trial. Given the anticipated use of OTX-TP as a chronic therapy, we intend to generate six-month (300 patients) and one year (100 patients) safety data during the first Phase 3 clinical trial to support our product registration. In order to meet these targets, we expect to begin enrollment in an open-label one-year safety extension study in the second quarter of 2018 to support our product registration.

OTX-TIC (*intracameral travoprost implant****)***

OTX-TIC is our product candidate for glaucoma patients in need of a more significant reduction in IOP and ocular hypertension. OTX-TIC is a bioresorbable hydrogel implant incorporating travoprost that is designed to be administered by a physician as an intracameral injection with an initial target duration of drug release of four to six months. Preclinical studies to date have demonstrated reduction of IOP and pharmacokinetics in the aqueous humor that suggest a pharmacodynamic response of IOP lowering in humans. We initiated a Phase 1 clinical trial outside the United States in third quarter of 2017 to assess safety and obtain initial efficacy data, but we have not enrolled any patients in this trial as of April 30, 2018. The trial is a prospective, single-center study designed to evaluate the safety, efficacy, durability and tolerability of OTX-TIC compared to topical travoprost (eye drops) in up to 20 patients with open-angle glaucoma or ocular hypertension. Our U.S. investigational new drug application, or IND, became effective in the first quarter of 2018 and we have initiated a second Phase 1 trial in the United States in the second quarter of 2018. This trial is a multi-center, open-label, proof-of-concept clinical trial designed to evaluate the safety, durability, tolerability, and efficacy in patients with primary open-angle glaucoma or ocular hypertension. We dosed the first patient in this trial in May 2018 and expect a full data set in the first half of 2019.

Back-of-the-Eye Programs

We are engaged in the development of formulations of our hydrogel administered via intravitreal injection to address the large and growing markets for diseases and conditions of the back of the eye. Our initial development efforts are focused on the use of our extended-delivery hydrogel in combination with anti-angiogenic drugs, such as protein-based anti-VEGF drugs or small molecule drugs, such as TKIs, for the treatment of retinal diseases such as wet AMD, retinal vein occlusion and diabetic macular edema. Our initial goal for these programs is to provide extended delivery over a four to six month period thereby reducing the frequency of the current monthly or bi-monthly intravitreal injection regimen for wet AMD and other retinal diseases and providing a more consistent uniform release of drug over the treatment period.

OTX-TKI (intravitreal tyrosine kinase inhibitor implant)

OTX-TKI is a preformed, bioresorbable hydrogel fiber incorporating a small molecule TKI with anti-angiogenic properties delivered by intravitreal injection. TKIs have shown promise in the treatment of wet AMD. In May 2017, we reported data from preclinical studies evaluating the efficacy, tolerability and pharmacokinetics of OTX-TKI. In this study, OTX-TKI was well-tolerated, and high levels of drug were maintained in the tissue for up to twelve months in Dutch belted rabbits. We plan to initiate a Phase 1 clinical trial outside the United States in the second quarter of 2018. This clinical trial will be a multi-center, open-label, dose escalation study to test the safety, durability and tolerability of OTX-TKI. We also plan to evaluate biological activity by following visual acuity over time and measuring retinal thickness using standard optical coherence tomography, or OCT.

OTX-IVT (intravitreal afibercept implant) in Collaboration with Regeneron

In October 2016, we entered into a strategic collaboration, option and license agreement, or Collaboration Agreement, with Regeneron for the development and potential commercialization of products using our hydrogel in combination with Regeneron's large molecule VEGF-targeting compounds for the treatment of retinal diseases, with the initial focus on the VEGF trap aflibercept, currently marketed under the brand name Eylea. Under the terms of the agreement, we granted Regeneron an option, or the Option, to enter into an exclusive, worldwide license under our intellectual property to develop and commercialize products using our hydrogel in combination with Regeneron's large molecule VEGF-targeting compounds, or Licensed Products. The Collaboration Agreement does not cover the development of any products that deliver small molecule drugs, including TKIs, for any target including VEGF, or any products that deliver large molecule drugs other than those that target VEGF proteins. Under the terms of the Collaboration Agreement, we and Regeneron have agreed to conduct a joint research program with the aim of developing an extended-delivery formulation of aflibercept that is suitable for advancement into clinical development. We refer to the formulation we are developing with Regeneron as OTX-IVT.

Regeneron is responsible for funding an initial preclinical tolerability study, which it initiated in early 2018. If the Option is exercised, Regeneron will conduct further preclinical development and an initial clinical trial under a collaboration plan. We are obligated to reimburse Regeneron for certain development costs during the period through the completion of the initial clinical trial, subject to a cap of $25 million, which cap may be increased by up to $5 million

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

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

ReSure

Following our receipt of FDA approval for ReSure Sealant, we commercially launched this product in the United States in 2014. 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. While ReSure Sealant remains commercially available in the United States, there is no sales support provided to the product at this time.

Additional Potential Areas for Growth

In addition to our focus on formulating, developing and commercializing innovative therapies for diseases and conditions of the eye, we are also assessing the potential use of our hydrogel platform technology in new areas of the body. If we are to utilize our intellectual property, all of which we currently license from Incept, LLC, or Incept, for applications outside the field of ophthalmology, we will need to negotiate and enter into an amendment to our existing license agreement with Incept or a new license agreement with Incept covering one or more additional such fields of use.

Financial Position

We have generated limited revenue to date. All of our extended-delivery 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 $13.8 million and $16.0 million for the three months ended March 31, 2018 and 2017, respectively. As of March 31, 2018, we had an accumulated deficit of $251.0 million.

Our total cost and operating expenses were $13.8 million for the three months ended March 31, 2018, including $2.4 million in non-cash stock-based compensation expense and depreciation expense. Our operating expenses have grown as we continue to 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 formulation for the sustained delivery of protein-based or small molecule anti-angiogenic drugs, such as anti-VEGF drugs and TKIs 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. In August 2017, we updated our DEXTENZA commercial plans in light of the delayed regulatory process of DEXTENZA and realized savings in operating expenses, including reduced personnel costs, as a result of streamlining headcount, as part of an initiative to reduce expenses. As a result, we also expect to incur lower sales and marketing expenses for our product candidates until we obtain marketing approval of DEXTENZA or any of our other product candidates. In addition, we will continue to incur additional costs associated with operating as a public company.

We do not expect to generate significant revenue from sales of any product for several years, if at all. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. If we are unable to

access our borrowing capacity or 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 November 2016, we entered into an At-the-Market Sales Agreement, or the 2016 ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, under which we may offer and sell our common stock having aggregate proceeds of up to $40.0 million from time to time. During the three months ended March 31, 2018, we did not engage in any transactions under our 2016 ATM Agreement. Through April 30, 2018, we have sold an aggregate of 890,568 shares of common stock under the 2016 ATM Agreement, resulting in net proceeds of approximately $6.6 million after underwriting discounts, commission and other offering expenses. In January 2017, we completed a follow-on offering of our common stock at a public offering price of $7.00 per share. The offering consisted of 3,571,429 shares of common stock sold by us. We received net proceeds from the follow-on offering of approximately $23.3 million after deducting underwriting discounts and offering expenses. In January 2018, we completed a follow-on offering of our common stock at a public offering price of $5.00 per share. The offering consisted of 7,475,000 shares of common stock sold by us, including those shares sold in connection with the exercise by the underwriter of its option to purchase additional shares. We received net proceeds from the follow-on offering of approximately $34.7 million after deducting underwriting discounts and offering expenses.

Based on our current plans and forecasted expenses, we believe that our existing cash and cash equivalents, as of March 31, 2018, without giving effect to any potential payment under our Collaboration Agreement with Regeneron, will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements through the first quarter of 2019. 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. We have not reflected the full costs of building a sales force that we would build if DEXTENZA is approved for marketing in our current operating plan and will need to raise additional capital to support such an effort. See "—Liquidity and Capital Resources."

Financial Operations Overview

Revenue

From our inception through March 31, 2018, 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 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 2018. 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.

Operating Expenses

Research and Development Expenses

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

- employee-related expenses, including salaries, related benefits and payroll taxes, travel and stock-based compensation expense for employees engaged in research and development, clinical and regulatory and other related functions;
- expenses incurred in connection with the clinical trials of our product candidates, including with the investigative sites that conduct our clinical trials and under agreements with contract research organizations, or CROs;
- expenses relating to regulatory activities, including filing fees paid to the FDA for our submissions for product approvals;

- expenses associated with developing our pre-commercial manufacturing capabilities and manufacturing clinical study materials;
- ongoing research and development activities relating to our core bioresorbable hydrogel technology and improvements to this technology;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and supplies;
- costs relating to the supply and manufacturing of product inventory, prior to approval by the FDA or other regulatory agencies of our products; and
- expenses associated with preclinical development activities.

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

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

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

	Three Months Ended March 31,	
	2018	2017
ReSure Sealant	$ 15	$ 20
DEXTENZA for post-surgical ocular pain and inflammation	106	355
DEXTENZA for allergic conjunctivitis	14	146
DEXTENZA for dry eye disease	—	6
OTX-TP for glaucoma and ocular hypertension	1,309	1,027
Unallocated expenses	6,783	5,175
Total research and development expenses	$ 8,227	$ 6,729

We expect that our expenses will increase 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 timing, receipt and terms of any marketing approvals;
- 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; and
- significant and changing government regulation.

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, information technology 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 that we will 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. During the three months ended March 31, 2018 and 2017, we incurred selling and marketing expenses in connection with ReSure Sealant, which we began commercializing in 2014, and marketing expenses in preparation for a potential commercial launch of our product candidates.

In August 2017, we reorganized our DEXTENZA commercial plans and expect to realize savings in operating expenses, including personnel costs, as a result of streamlining headcount, as part of an initiative to enhance operations and reduce expenses. As a result, we expect our selling and marketing expenses to decrease until we obtain marketing approval of our product candidates.

Other Income (Expense)

Interest Income. In 2018, interest income consists primarily of interest income earned on cash and cash equivalents and to a lesser extent, marketable securities in 2017. In the three months ended March 31, 2018 and 2017, our interest income has not been significant due to the low rates of interest being earned on our invested balances.

Interest Expense. Interest expense is incurred on our debt. In March 2017, we amended our credit facility to increase the aggregate principal amount to $18.0 million and extend the maturity date to December 1, 2020.

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 amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued research and development expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. During the three months ended March 31, 2018, 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 8, 2018 and the notes to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

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

Accordingly, we believe the policies set forth in our Annual Report on Form 10-K filed with the SEC on March 8, 2018 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, 2018 and 2017

The following table summarizes our results of operations for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,		Increase (Decrease)
	2018	2017	
	(in thousands)		
Revenue:			
Product revenue	$ 340	$ 475	$ (135)
Total revenue	340	475	(135)
Costs and operating expenses:			
Cost of product revenue	80	115	(35)
Research and development	8,227	6,729	1,498
Selling and marketing	717	6,027	(5,310)
General and administrative	4,771	3,276	1,495
Total costs and operating expenses	13,795	16,147	(2,352)
Loss from operations	(13,455)	(15,672)	2,217
Other income (expense):			
Interest income	176	92	84
Interest expense	(486)	(443)	(43)
Total other expense, net	(310)	(351)	41
Net loss	$(13,765)	$(16,023)	$ 2,258

Revenue

We generated $0.3 million and $0.5 million of revenue during the three months ended March 31, 2018 and 2017, respectively, from sales of our ReSure Sealant product. The decrease in revenue is related to a fewer number of units shipped in 2018 as compared to 2017.

Research and Development Expenses

	Three Months Ended March 31,		Increase (Decrease)
	2018	2017	
	(in thousands)		
Direct research and development expenses by program:			
ReSure Sealant	$ 15	$ 20	$ (5)
DEXTENZA for post-surgical ocular pain and inflammation	106	355	(249)
DEXTENZA for allergic conjunctivitis	14	146	(132)
DEXTENZA for dry eye disease	—	6	(6)
OTX-TP for glaucoma and ocular hypertension	1,309	1,027	282
Unallocated expenses:			
Personnel costs	4,014	3,500	514
All other costs	2,769	1,675	1,094
Total research and development expenses.	$ 8,227	$ 6,729	$ 1,498

Research and development expenses were $8.2 million for the three months ended March 31, 2018, compared to $6.7 million for the three months ended March 31, 2017. Research and development costs increased by $1.5 million primarily due to an increase of $0.5 million in unallocated personnel costs and $1.1 million in unallocated all other costs, which was partially offset by a net decrease of $0.1 million in costs incurred in connection with the clinical trials of our DEXTENZA product candidate for the treatment of post-surgical ocular pain and inflammation, our DEXTENZA product candidate for the treatment of allergic conjunctivitis, our DEXTENZA product candidate for the treatment of dry eye disease and our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension.

For the three months ended March 31, 2018, we incurred $1.4 million in direct research and development expenses for our intracanalicular insert product candidates, including $0.1 million for our DEXTENZA product candidate for the treatment of post-surgical ocular pain and inflammation which was in Phase 3 clinical trials, and $1.3 million for our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension which was in a Phase 3 clinical trial. In comparison, for the three months ended March 31, 2017, we incurred $1.5 million in direct research and development expenses for our intracanalicular insert drug delivery product candidates for the front of the eye, including $0.4 million for our DEXTENZA product candidate for the treatment of post-surgical ocular pain and inflammation which was in Phase 3 clinical trials, $0.1 million for our DEXTENZA product candidate for the treatment of allergic conjunctivitis which was in a Phase 3 clinical trial, and $1.0 million for our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension which was in a Phase 3 clinical trial. Unallocated research and development expense increased $1.6 million for the three months ended March 31, 2018, compared to the three months ended March 31, 2017, due to an increase in personnel costs of $0.5 million due to additional hiring primarily in our clinical, regulatory and quality departments and an increase in stock-based compensation expense; $0.3 million in facility related costs and $0.3 million in depreciation expense.

Selling and Marketing Expenses

	Three Months Ended March 31,		Increase (Decrease)
	2018	2017	
	(in thousands)		
Personnel related (including stock-based compensation)	$ 384	$ 1,463	$(1,079)
Professional fees	196	3,805	(3,609)
Facility related and other	137	759	(622)
Total selling and marketing expenses	$ 717	$ 6,027	$(5,310)

Selling and marketing expenses were $0.7 million for the three months ended March 31, 2018, compared to $6.0 million for the three months ended March 31, 2017. The decrease of $5.3 million was primarily due to a decrease of $1.1 million reduction in personnel costs, $3.6 million in professional fees including consulting, trade shows and conferences and $0.6 million in facility related and other costs. In August 2017, we reorganized our DEXTENZA commercial plans streamlining headcount, as part of an initiative to enhance operations and reduce expenses in pre-commercialization activities.

General and Administrative Expenses

	Three Months Ended March 31,		Increase (Decrease)
	2018	2017	
	(in thousands)		
Personnel related (including stock-based compensation)	$ 2,061	$ 1,722	$ 339
Professional fees	2,317	1,200	1,117
Facility related and other	393	354	39
Total general and administrative expenses	$ 4,771	$ 3,276	$ 1,495

General and administrative expenses were $4.8 million for the three months ended March 31, 2018, compared to $3.3 million for the three months ended March 31, 2017. The increase of $1.5 million was primarily due to an increase of $0.3 million in personnel costs relating to additional hiring and stock-based compensation expense and an increase of $1.1 million in professional, insurance and consultant fees. Professional fees increased due to an increase in legal fees of $1.2 million related to the defense of the legal proceedings offset by a decrease in other professional services of $0.1 million.

Other Income (Expense), Net

Other expense, net was $0.3 million for the three months ended March 31, 2018, compared to $0.4 million for the three months ended March 31, 2017 as interest expense and interest income remained consistent.

Liquidity and Capital Resources

Since inception, we have incurred significant operating losses. As of March 31, 2018, we had an accumulated deficit of $251.0 million. We have generated limited revenue to date. In 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, 2018, 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 January 2017, we completed a follow-on offering of our common stock at a public offering price of $7.00 per share. The offering consisted of 3,571,429 shares of common stock sold by us. We received net proceeds from the follow-on offering of approximately $23.3 million after deducting underwriting discounts and offering expenses. In January 2018, we completed a follow-on offering of our common stock at a public offering price of $5.00 per share. The offering consisted of 7,475,000 shares of common stock sold by us, including those shares sold in connection with the exercise by the underwriter of its option to purchase additional shares. We received net proceeds from the follow-on offering of approximately $34.7 million after deducting underwriting discounts and offering expenses.

In November 2016, we entered into the 2016 ATM Agreement with Cantor, under which we may offer and sell our common stock having aggregate proceeds of up to $40.0 million from time to time. Through April 30, 2018, we have sold 890,568 shares of common stock under the 2016 ATM Agreement, resulting in net proceeds of approximately $6.6 million after underwriting discounts, commission and other offering expenses.

In March 2017, we amended our credit facility to increase the total indebtedness to $18.0 million. We have borrowings outstanding in the amount of $17.0 million, for which periodic principal and interest payments are due through 2020. See “—Contractual Obligations and Commitments” for additional information.

We may receive $10.0 million under its collaboration arrangement with Regeneron in the event Regeneron exercises its option to enter into an exclusive, worldwide license to develop and commercialize products containing our extended-delivery hydrogel formulation with us in combination with Regeneron’s large molecule VEGF-targeting compounds.

As of March 31, 2018, we had cash and cash equivalents of $62.9 million and outstanding debt of $17.0 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Based on our current plans and forecasted expenses, we believe that our existing cash and cash equivalents as of March 31, 2018, without giving effect to any potential payment under our Collaboration Agreement with Regeneron, will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements through the first quarter of 2019. 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. We have not reflected the full costs of building a sales force that we would build if DEXTENZA is approved for marketing in our current operating plan and will need to raise additional capital to support such an effort. These factors, and the factors described above, continue to raise substantial doubt about our ability to continue as a going concern.

Cash Flows

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

	Three Months Ended March 31,	
	2018	2017
Cash used in operating activities	$ (12,473)	$ (14,577)
Cash provided by investing activities	(381)	7,846
Cash provided by (used in) financing activities	34,227	28,477
Net increase in cash and cash equivalents	$ 21,373	$ 21,746

Operating activities. Net cash used in operating activities was $12.5 million for the three months ended March 31, 2018, primarily resulting from our net loss of $13.8 million partially offset by non-cash charges of $2.5 million. Our net loss was primarily attributed to research and development activities, selling and marketing expenses, and our general and administrative expenses. Our net non-cash charges during the three months ended March 31, 2018 consisted primarily of $2.4 million of stock-based compensation expense and depreciation expense. Net cash used by changes in our operating assets and liabilities during the three months ended March 31, 2018 consisted primarily of a decrease in accounts payable and accrued expenses of $1.4 million and a decrease 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 were due to increased product development activities and the timing of vendor invoicing and payments.

Net cash used in operating activities was $14.6 million for the three months ended March 31, 2017, primarily resulting from our net loss of $16.0 million partially offset by non-cash charges of $2.1 million. Our net loss was primarily attributed to research and development activities, selling and marketing expenses as we increased pre-commercialization activities in advance of the potential approval of DEXTENZA, and our general and administrative expenses. Our net non-cash charges during the three months ended March 31, 2017 consisted primarily of $2.0 million of stock-based compensation expense and depreciation expense. Net cash used by changes in our operating assets and liabilities during the three months ended March 31, 2017 consisted primarily of an increase in accounts payable and accrued expenses of $0.5 million and an increase in prepaid expenses and other current assets of $1.2 million. The changes in prepaid expenses and other current assets, accounts payable and accrued expenses were due to increased product development activities, pre-commercialization activities and the timing of vendor invoicing and payments.

Investing activities. Net cash used in investing activities for the three months ended March 31, 2018 totaled $0.4 million and net cash provided by investing activities for the three months ended March 31, 2017 totaled $7.8 million. For the three months ended March 31, 2018, net cash used in investing activities is due the purchases of property and equipment, primarily laboratory equipment was $0.4 million. For the three months ended March 31, 2017, net cash provided is primarily due to the sale of marketable securities of $12.5 million offset by the purchase of marketable securities of $3.0 million. For the three months ended March 31, 2017, the purchases of property and equipment, primarily laboratory equipment was $1.7 million.

Financing activities. Net cash provided by financing activities for the three months ended March 31, 2018 was $34.2 million and for the three months ended March 31, 2017 was $28.5 million. Net cash provided by financing activities for the three months ended March 31, 2018 consisted primarily of proceeds from our follow-on offering in January 2018 of $35.0 million, net of underwriting discounts and other offering expenses and excluding $0.3 of offering expenses which remain in accrued expenses and accounts payable as of the balance sheet date, $0.3 million from the

exercise of common stock options offset by $1.0 million for principal payments under our amended credit facility. Net cash provided by financing activities for the three months ended March 31, 2017 consisted primarily of proceeds from our follow-on offering in January 2017 and the 2016 ATM Agreement of $26.3 million, net of underwriting discounts and other offering expenses and $2.4 million (net) in borrowings under our amended credit facility offset by $0.2 million for insurance costs financed by a third party.

Funding Requirements

We expect to continue to incur losses in connection with our ongoing activities, particularly as we advance the clinical trials of our products in development and increase our sales and marketing resources focused on the potential launch of our product candidates, subject to receiving FDA approval.

We anticipate we will incur substantial expenses if and as we:

- continue to pursue the clinical development of our most advanced intracanalicular insert product candidates, DEXTENZA and OTX-TP;
- commence clinical trials of our product candidates OTX-TIC and OTX-TKI;
- conduct joint research and development under our strategic collaboration with Regeneron for the development and potential commercialization of products containing our extended-delivery hydrogel formulation in combination with Regeneron's large molecule VEGF targeting compounds to treat retinal diseases;
- continue the research and development of our other product candidates;
- seek to identify and develop additional product candidates, including through additional preclinical development activities associated with our back-of-the-eye program and glaucoma intracameral implant program;
- seek marketing approvals for any of our product candidates that successfully complete clinical development;
- develop and expand our sales, marketing and distribution capabilities for any of our product candidates, including DEXTENZA, for which we may obtain marketing approval;
- scale up our manufacturing processes and capabilities to support sales of commercial products, our ongoing clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval, and expand our facilities to accommodate this scale up and the expected growth in personnel;
- renovate our new facility including research and development laboratories, manufacturing space and office space;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts; and
- continue to operate as a public company.

Based on our current plans and forecasted expenses, we believe that our existing cash and cash equivalents, without giving effect to any potential payment under our Collaboration Agreement with Regeneron, will enable us to

fund our operating expenses, debt service obligations and capital expenditure requirements through the first quarter of 2019. 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. We have not reflected the full costs of building a sales force that we would build if DEXTENZA is approved for marketing in our current operating plan and will need to raise additional capital to support such an effort.

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

- the costs, timing and outcome of regulatory review of our product candidates by the FDA, the EMA or other regulatory authorities, including the resubmission of our NDA for DEXTENZA;
- the level of product sales from 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 any additional products for which we obtain marketing approval in the future;
- the costs of expanding our facilities to accommodate our manufacturing needs and expected growth in personnel;
- the progress, costs and outcome of the clinical trials of our extended-delivery drug delivery product candidates, in particular DEXTENZA and OTX-TP;
- the progress and status of our collaboration with Regeneron, including any development costs for which we reimburse Regeneron, the potential exercise by Regeneron of its option for a license for the development and potential commercialization of products containing our extended-delivery hydrogel formulation in combination with Regeneron's large molecule VEGF-targeting compounds, and our potential receipt of future milestone payments from Regeneron;
- the costs of advancing our internal development efforts for the back-of-the-eye small molecule TKI 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 amounts we receive, if any, from Regeneron for option exercise, development, regulatory and sales milestones and royalty payments under our collaboration;
- the extent to which we choose to establish additional collaboration, distribution or other marketing arrangements for our products and product candidates;
- the outcome of certain legal actions and proceedings, including the current lawsuits described under "Part II, Item 1 — Legal Proceedings";
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we acquire or invest in other businesses, products and technologies.

Until such time, if ever, as we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through equity offerings, debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. We do not have any committed external source of funds other than amounts we may receive from Regeneron for potential option exercise, development, regulatory and sales milestones and royalties under our collaboration and amounts we may be able to draw under our amended credit facility upon the achievement of regulatory and commercial milestones. To the extent that we raise additional capital through the sale of equity or convertible debt securities, each security holder's ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that

adversely affect each security holder's rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. The covenants under our existing credit facility, the pledge of our assets as collateral and the negative pledge of intellectual property limit our ability to obtain additional debt financing. If we raise additional funds through government or other third-party funding, collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

As discussed in Note 1 of the Notes to the Unaudited Condensed Consolidated Financial Statements, we have the responsibility to evaluate whether conditions or events raise substantial doubt about our ability to meet our future financial obligations as they become due within one year after the date the financial statements are issued. This evaluation initially cannot take into consideration the potential mitigating effects of plans that have not been fully implemented as of the date the financial statements are issued. Since we currently anticipate that our existing capital resources will enable us to meet our planned operational expenses, debt service obligations, and capital expenditures, based on our current operating plans, through the first quarter of calendar year 2019, we have concluded that there is substantial doubt about our ability to continue as a going concern within one year of the issuance date of these unaudited condensed consolidated financial statements. While we have plans in place to mitigate this risk, which primarily consist of raising additional capital through a combination of equity or debt financings, and, depending on the availability and level of additional financings, potentially new collaborations and reducing cash expenditures, there is no guarantee that we will be successful in these mitigation efforts.

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, 2017, we had federal net operating loss carryforwards of $126.2 million, which begin to expire in 2026, and state net operating loss carryforwards of $109.3 million, which begin to expire in 2026. As of December 31, 2017, we also had federal research and development tax credit carryforwards of $5.5 million and state research and development tax credit carryforwards $2.8 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

At March 31, 2018, there have been no material changes in our contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

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

Information regarding new accounting pronouncements is included in Note 2 – *Summary of Significant Accounting Policies* to the current period's financial statements.

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, 2018, we had cash and cash equivalents of $62.9 million, which consisted of money market funds. 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, 2018. 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, 2018, 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, 2018 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.

Securities Class Actions

On July 7, 2017, a putative class action lawsuit was filed against us and certain of our current and former executive officers in the United States District Court for the District of New Jersey, captioned *Thomas Gallagher v. Ocular Therapeutix, Inc, et al.*, Case No. 2:17-cv-05011. The complaint purports to be brought on behalf of shareholders who purchased our common stock between May 5, 2017 and July 6, 2017. The complaint generally alleges that we and certain of our current and former officers violated Sections 10(b) and/or 20(a) of the Securities Exchange Act of 1934, or the Exchange Act, and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning the Form 483 issued by the FDA related to DEXTENZA and our manufacturing operations for DEXTENZA. The complaint seeks unspecified damages, attorneys' fees, and other costs. On July 14, 2017, an amended complaint was filed; the amended complaint purports to be brought on behalf of shareholders who purchased our common stock between May 5, 2017 and July 11, 2017, and otherwise includes allegations similar to those made in the original complaint.

On July 12, 2017, a second putative class action lawsuit was filed against us and certain of our current and former executive officers in the United States District Court for the District of New Jersey, captioned *Dylan Caraker v. Ocular Therapeutix, Inc., et al.*, Case No. 2:17-cv-05095. The complaint purports to be brought on behalf of shareholders who purchased our common stock between May 5, 2017 and July 6, 2017. The complaint includes allegations similar to those made in the *Gallagher* complaint, and seeks similar relief.

On August 3, 2017, a third putative class action lawsuit was filed against us and certain of our current and former executive officers in the United States District Court for the District of New Jersey, captioned *Shawna Kim v. Ocular Therapeutix, Inc., et al.*, Case No. 2:17-cv-05704. The complaint purports to be brought on behalf of shareholders who purchased our common stock between March 10, 2016 and July 11, 2017. The complaint includes allegations similar to those made in the *Gallagher* complaint, and seeks similar relief.

On October 27, 2017, a magistrate judge for the United States District Court for the District of New Jersey granted the defendants' motion to transfer the above-referenced *Gallagher, Caraker*, and *Kim* litigations to the United States District Court for the District of Massachusetts. These matters were assigned the following docket numbers in the District of Massachusetts: 1:17-cv-12288 (*Gallagher*), 1:17-cv-12146 (*Caraker*), and 1:17-cv-12286 (*Kim*).

On March 9, 2018, the court granted plaintiffs' motion to consolidate the three actions and appointed co-lead plaintiffs and co-lead counsel for the consolidated action. On May 7, 2018, co-lead plaintiffs filed a consolidated amended class action complaint. The amended complaint makes allegations similar to those in the original complaints, against the same defendants, and seeks similar relief on behalf of shareholders who purchased our common stock between March 10, 2016 and July 11, 2017. The amended complaint generally alleges that defendants violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. Defendants' response to the consolidated amended complaint is due on July 6, 2018.

We deny any allegations of wrongdoing and intend to vigorously defend against these lawsuits.

Shareholder Derivative Litigation

On July 11, 2017, a purported shareholder derivative lawsuit was filed against certain of our current and former executive officers, certain current and former board members, and us as a nominal defendant, in the United States District Court for the District of Massachusetts, captioned *Robert Corwin v. Sawhney et al.*, Case No. 1:17-cv-11270. The complaint generally alleged that the individual defendants breached fiduciary duties owed to us by making allegedly false and/or misleading statements concerning the Form 483 related to DEXTENZA and our manufacturing operations for DEXTENZA. The complaint purported to assert claims against the individual defendants for breach of fiduciary duty, and sought to recover on behalf of us for any liability we incur as a result of the individual defendants' alleged misconduct. The complaint also sought contribution on behalf of us from all individual defendants for their alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. The complaint sought declaratory, equitable, and monetary relief, an unspecified amount of damages, with interest, and attorneys' fees

and costs. On September 20, 2017, counsel for the plaintiff filed a notice of voluntary dismissal, stating that the plaintiff wished to coordinate his efforts and proceed in a consolidated fashion with the plaintiff in a similar derivative suit that was pending in the Superior Court of Suffolk County of the Commonwealth of Massachusetts captioned *Angel Madera v. Sawhney et al.*, Case. No. 17-2273 (which is discussed in the paragraph immediately below) by filing an action in that court subsequent to the dismissal of this lawsuit. The *Corwin* lawsuit was dismissed without prejudice on September 21, 2017. On October 24, 2017, the plaintiff filed a new derivative complaint in Massachusetts Superior Court (Suffolk County), captioned *Robert Corwin v. Sawhney et al.*, Case No. 17-3425 (BLS2). The new *Corwin* complaint includes allegations similar to those made in the federal court complaint and asserts a derivative claim for breach of fiduciary duty against certain of our current and former officers and directors. The complaint also asserts an unjust enrichment claim against two additional defendants, SV Life Sciences Fund IV, LP and SV Life Sciences Fund IV Strategic Partners, LP. The complaint also names us as a nominal defendant.

On July 19, 2017, a second purported shareholder derivative lawsuit was filed against certain of our current and former executive officers, all current board members, one former board member, and us as a nominal defendant, in the Superior Court of Suffolk County of the Commonwealth of Massachusetts, captioned *Angel Madera v. Sawhney et al*., Case. No. 17-2273. The complaint included allegations similar to those made in the *Corwin* complaint. The complaint purported to assert derivative claims against the individual defendants for breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets, and sought to recover on behalf of us for any liability we incur as a result of the individual defendants' alleged misconduct. The complaint sought declaratory, equitable, and monetary relief, an unspecified amount of damages, with interest, and attorneys' fees and costs. On November 6, 2017, the court dismissed this action without prejudice due to plaintiff's failure to complete service of process within the time permitted under applicable court rules. On December 21, 2017, the same plaintiff filed a new derivative complaint in the same court, captioned *Angel Madera v. Sawhney et al.*, Case. No. 17-4126 (BLS2). The new *Madera* complaint is premised on substantially similar allegations as the previous complaint and purports to assert derivative claims against certain current and former executive officers and board members for breach of fiduciary duty, unjust enrichment, and waste of corporate assets, and names the Company as a nominal defendant. Like the new *Corwin* complaint, the new *Madera* complaint also asserts an unjust enrichment claim against two additional defendants, SV Life Sciences Fund IV, LP and SV Life Sciences Fund IV Strategic Partners, LP.

By order dated January 29, 2018, the court consolidated the state court *Corwin* and *Madera* complaints under the *Corwin* docket and appointed lead counsel for plaintiffs. On February 28, 2018, plaintiffs filed a consolidated amended complaint. The consolidated complaint names substantially the same defendants and is premised on substantially similar allegations as the previous *Corwin* and *Madera* complaints, asserting claims for breach of fiduciary duty against the individual defendants and unjust enrichment against the two SV entity defendants. On April 17, 2018, all defendants served a motion to dismiss the consolidated amended complaint. Pursuant to the briefing schedule the court set, plaintiffs will serve their opposition brief by June 1, 2018, and defendants will serve their reply within 21 days thereafter.

On January 31, 2018, a third purported shareholder derivative suit was filed against certain of our current and former executive officers, certain current and former board members, and us as a nominal defendant, in the United States District Court for the District of Massachusetts, captioned *Brian Robinson v. Sawhney et al.*, Case. No. 1:18-cv-10199. The complaint includes allegations similar to those made in the Corwin and Madera complaints. The complaint does not name either SV Life Sciences Fund, IV, LP or SV Life Sciences Fund IV Strategic Partners, LP as defendants, and adds two former officers as defendants. The complaint purports to assert derivative claims against the individual defendants for breach of fiduciary duty, waste of corporate assets, and unjust enrichment, and seeks to recover on behalf of us for any liability we incur as a result of the individual defendants' alleged misconduct. The complaint seeks declaratory, equitable, and monetary relief, an unspecified amount of damages, with interest, and attorneys' fees and costs. On April 30, 2018, we filed a motion to dismiss or stay the complaint. Pursuant to the briefing schedule the court set, plaintiffs will serve their opposition brief by June 11, and defendants will serve their reply within 20 days thereafter.

On February 16, 2018, a fourth purported shareholder derivative suit was filed against certain of our current and former executive officers, certain current and former board members, and us as a nominal defendant, in the United States District Court for the District of Delaware, captioned *Terry Kelly v. Sawhney et al.*, Case. No. 1:18-cv-00277. The complaint includes allegations similar to those made in the *Corwin* and *Madera* complaints. The complaint purports to assert derivative claims against the individual defendants for breach of fiduciary duty, unjust enrichment, and waste of corporate assets, and seeks to recover on behalf of us for any liability we incur as a result of the individual defendants' alleged misconduct. The complaint also asserts an unjust enrichment claim against SV Life Sciences Fund IV, LP and

SV Life Sciences Fund IV Strategic Partners, LP. The complaint seeks declaratory, equitable, and monetary relief, an unspecified amount of damages, with interest, and attorneys' fees and costs.

We deny any allegations of wrongdoing and intend to vigorously defend against these lawsuits.

In addition, we have received a subpoena from the SEC, dated December 15, 2017, requesting documents and information concerning DEXTENZA™ (dexamethasone insert) 0.4mg, including related communications with the U.S. Food and Drug Administration, investors and others. We intend to fully cooperate with the SEC regarding this non-public, fact-finding inquiry. The SEC has informed us that this inquiry should not be construed as an indication that any violations of law have occurred or that the SEC has any negative opinion of any person, entity or security.

We are unable to predict the outcome of these lawsuits or proceedings at this time. Moreover, any conclusion of these matters in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on our financial condition and business. In addition, the proceedings could adversely impact our reputation and divert management's attention and resources from other priorities, including the execution of business plans and strategies that are important to our ability to grow our business, any of which could have a material adverse effect on our business.

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 $44.7 million for the year ended December 31, 2016, $63.4 million for the year ended December 31, 2017 and $13.8 for the three months ended March 31, 2018. As of March 31, 2018, we had an accumulated deficit of $251.0 million. Through March 31, 2018, we have financed our operations primarily through private placements of our preferred stock, public offerings of our common stock and borrowings under credit facilities. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials, commercialization of ReSure Sealant and in preparation for a potential commercial launch of DEXTENZA. 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 we will incur substantial expenses if and as we:

- continue to pursue the clinical development of our most advanced intracanalicular insert product candidates, DEXTENZA and OTX-TP;
- commence clinical trials of our product candidates OTX-TIC and OTX-TKI;
- conduct joint research and development under our strategic collaboration with Regeneron, for the development and potential commercialization of products containing our extended-delivery hydrogel formulation in combination with Regeneron's large molecule, VEGF-targeting compounds to treat retinal diseases;
- continue the research and development of our other product candidates;

- seek to identify and develop additional product candidates, including through additional preclinical development activities associated with our back-of-the-eye program and glaucoma intracameral implant program;
- seek marketing approvals for any of our product candidates that successfully complete clinical development;
- develop and expand our sales, marketing and distribution capabilities for any of our product candidates, including DEXTENZA, for which we may obtain marketing approval;
- scale up our manufacturing processes and capabilities to support sales of commercial products, our ongoing clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval, and expand our facilities to accommodate this scale up and the expected growth in personnel;
- renovate our new facility including research and development laboratories, manufacturing space and office space;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts; and
- continue to operate as a public company.

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

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

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

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

- protecting our rights to our intellectual property portfolio.

We may never succeed in these activities and may never generate revenue that is sufficient or great enough to achieve profitability. In July 2016, we received a Complete Response Letter, or CRL, from the FDA regarding our new drug application, or NDA, for DEXTENZA for the treatment of post-surgical ocular pain. This 2016 CRL pertained to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of our manufacturing facility performed by the FDA New England District Office, or the District Office, in February 2016 that were documented on FDA Form 483. In November 2016, we received notice from the District Office accepting that our responses satisfactorily addressed the remaining corrective actions in the Form 483. Since receiving the CRL, we have also had ongoing communications with the FDA, including the New England District Office and offices within the Center for Drug Evaluation and Research, or CDER, including the Office of Process and Facilities, with regard to the manufacturing issues and our plan for a resubmission of our NDA. In January 2017, we resubmitted our NDA. Following a re-inspection of manufacturing operations by the FDA which was completed in May 2017, we received an FDA Form 483 containing inspectional observations focused on manufacturing processes and analytical testing related to the manufacture of drug product for commercial production. In July 2017, we received a second CRL from the FDA regarding our NDA for DEXTENZA for the treatment of post-surgical ocular pain, which states that the FDA has determined that it cannot approve the NDA in its present form. FDA concerns included deficiencies in manufacturing processes and analytical testing related to manufacturing of drug product identified during the May 2017 pre-NDA approval inspection. We have corresponded with the FDA regarding these inspectional observations and are working to resolve the issues that have been identified. In May 2017 we submitted our initial response to the Form 483 and in November 2017 we submitted our responses to the FDA's remaining inspectional observations in an effort to close out the items identified in the Form 483.

The remediation efforts we have undertaken in response to the FDA's inspectional observations and as a result of further internal review include upgrades to our manufacturing equipment and updates to our manufacturing processes and quality oversight. These changes are intended to resolve the FDA's outstanding concerns, including regarding the presence of particulate matter in certain manufactured lots of DEXTENZA, and enable us to consistently produce commercial lots and establish manufacturing processes sufficient for purposes of resubmission of our NDA. In December 2017, we requested a meeting with the FDA to describe our remediation efforts and NDA resubmission plans and to seek feedback. A meeting was granted in January 2018, and we believe that the preliminary written responses from the FDA to our questions fully addressed our meeting objectives. We decided that the meeting would no longer be necessary because of the completeness of the FDA's response and that the FDA's comments do not require substantial change in our manufacturing or regulatory plans. As a result, the correspondence with the FDA will represent the official record of that previously scheduled meeting. Subject to satisfactorily addressing the FDA inspectional observations and demonstrating consistency in our commercial stage manufacturing process, we plan to resubmit our NDA for DEXTENZA for the treatment of post-surgical ocular pain in the second quarter of 2018. Adequate resolution of the outstanding Form 483 inspectional observations and the final decision as to the adequacy of our manufacturing processes are determined by the FDA, with input from CDER's Office of Process and Facilities, as part of the NDA review process, and are necessary prior to NDA approval. If we are unable to resolve these inspectional observations in a timely manner or achieve consistency in our commercial stage manufacturing process, our resubmission of our NDA and its potential approval would be delayed or prevented.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

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

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct late stage clinical trials for our extended-delivery drug delivery product candidates, in particular DEXTENZA and OTX-TP, and seek marketing approval for any such product candidate for which we obtain favorable pivotal clinical results. We also expect to devote significant financial resources to conducting research and development and potentially seeking regulatory approval for our other product candidates. In addition, we plan to devote substantial financial resources to our commercialization efforts, including product manufacturing, sales, marketing and distribution for any of

our product candidates, including DEXTENZA, for which we may obtain marketing approval in the future. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

As of March 31, 2018, we had cash and cash equivalents of $62.9 million and outstanding debt of $17.0 million. Based on our current plans and forecasted expenses, we believe that our existing cash and cash equivalents, as of March 31, 2018, without giving effect to any potential payment under our Collaboration Agreement with Regeneron, will enable us to fund our operating expenses, debt service obligations and capital expenditure requirements through the first quarter of calendar year 2019. 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. We have not reflected the full costs of building a sales force that we would build if DEXTENZA is approved for marketing in our current operating plan and will need to raise additional capital to support such an effort. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcome of regulatory review of our product candidates by the FDA, the EMA or other regulatory authorities, including the resubmission of our NDA for DEXTENZA;
- the level of product sales from 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 any additional products for which we obtain marketing approval in the future;
- the costs of expanding our facilities to accommodate our manufacturing needs and expected growth in personnel;
- the progress, costs and outcome of the clinical trials of our extended-delivery drug delivery product candidates, in particular DEXTENZA and OTX-TP;
- the progress and status of our collaboration with Regeneron, including any development costs for which we reimburse Regeneron, the potential exercise by Regeneron of its option for a license for the development and potential commercialization of products containing our extended-delivery hydrogel formulation in combination with Regeneron's large molecule VEGF-targeting compounds, and our potential receipt of future milestone payments from Regeneron;
- the costs of advancing our internal development efforts for the back-of-the-eye small molecule TKI 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 amounts we receive, if any, from Regeneron for option exercise, development, regulatory and sales milestones and royalty payments under our collaboration;
- the extent to which we choose to establish additional collaboration, distribution or other marketing arrangements for our products and product candidates;
- the outcome of certain legal actions and proceedings, including the current lawsuits described under "Part II, Item 1—Legal Proceedings";
- 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 may not generate significant revenue from sales of any product for several years, if at all. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

We have included a paragraph relating to our ability to continue as a going concern in the footnotes of our audited financial statements included in our Annual Report on Form 10-K.

Our audited financial statements for the period ended December 31, 2017 include a paragraph stating that our losses from operations and need for additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

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 equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. We do not have any committed external source of funds other than the amounts we are entitled to receive from Regeneron for potential option exercise, development, regulatory and sales milestones and royalty payments under our collaboration. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights as holders of our common stock. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our pledge of our assets as collateral to secure our obligations under our credit facility may limit our ability to obtain additional debt financing.

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

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

We have a significant amount of indebtedness. Under our current credit facility, as amended, we had $17.0 million of outstanding principal amount of indebtedness as of March 31, 2018. 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, including by potentially amending our credit facility.

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

- requiring us to dedicate a substantial portion of cash and cash equivalents and marketable securities to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund

working capital, capital expenditures, product development efforts and other general corporate purposes;

- obligating us to negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions, encumbering our intellectual property, incurring indebtedness or liens, paying dividends, making investments and engaging in certain other business transactions;

- limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and

- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

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

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

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

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

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

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

Our management has broad discretion in the use of our available cash and other sources of funding and could spend those resources in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our available cash in a manner that does not produce income or that loses value.

Risks Related to Product Development

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

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

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

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

In certain cases, such as in our collaboration with Regeneron, many of these factors may be beyond our control, including clinical development and sales, marketing and distribution efforts. If we or our collaborators do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

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

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, including our intracanalicular insert product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, insert is 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, 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 pain and inflammation following cataract surgery, DEXTENZA did not meet the primary efficacy endpoint for inflammation with statistical significance at the pre-specified time point at day 8. However, we did achieve statistical significance for this inflammation endpoint at days 14 and 30. Accordingly, we measured the primary efficacy endpoint for inflammation in our completed Phase 3 clinical trials of DEXTENZA at day 14. In the first and third Phase 3 clinical trials, DEXTENZA met both primary endpoints for post-surgical ocular pain and inflammation following cataract surgery 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 the first two 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 pain and inflammation is applicable in connection with their review of our NDA seeking approval for DEXTENZA for an ocular pain indication. However, the FDA has also informed us that pain endpoints from the Phase 2 and first two Phase 3 trials, with respect to which we received favorable data, would support the NDA submission. Therefore, in September 2015, we submitted to the FDA an NDA for DEXTENZA for an ocular pain indication using the existing data from our completed Phase 2 and first two Phase 3 clinical trials notwithstanding the FDA's comment regarding the applicability of the hierarchy of the two primary endpoints in our completed Phase 2 and Phase 3 clinical trials. In July 2017, we received a CRL from the FDA regarding our resubmitted NDA for DEXTENZA stating that the FDA has determined that it cannot approve the NDA in its present form. FDA concerns included deficiencies in manufacturing process and analytical testing related to manufacturing of drug product identified during a pre-NDA approval inspection of our manufacturing facility. In our response to the FDA regarding these deficiencies, we also had to furnish a safety update regarding all completed trials of DEXTENZA, regardless of indication, dosage form or dose level.

We announced topline results from a third Phase 3 clinical trial of DEXTENZA for post-surgical ocular pain and inflammation in November 2016, which we plan to use to support the potential labeling expansion of DEXTENZA's indications for use to include inflammation. We modified the design of this third Phase 3 clinical trial compared to our two previous Phase 3 clinical trials of DEXTENZA based on our learnings from these trials. In this trial, DEXTENZA successfully met its two primary efficacy endpoints for pain and inflammation, achieving statistically significant differences between the treatment group and the placebo group for the absence of inflammatory cells on day 14 and the absence of pain on day 8, respectively. Secondary analyses on the primary efficacy measures have also been completed. DEXTENZA achieved each of the secondary endpoints related to absence of inflammatory cells, absence of pain, and absence of anterior chamber flare with statistical significance compared to placebo at each of the pre-specified

timepoints, with the exception of the endpoint for the absence of inflammatory cells at day 2 (which is the day following surgery). Based on the results of our third Phase 3 clinical trial of DEXTENZA, and subject to resubmitting and receiving approval for the pain indication pursuant to the initial NDA, we plan to submit an NDA supplement, or sNDA, for DEXTENZA for the treatment of post-surgical ocular inflammation. Although we believe our planned approach for seeking marketing approval of DEXTENZA is supported by our discussions with the FDA and by the absence of any efficacy or safety concerns identified by the FDA in the CRL with respect to the clinical data provided in the NDA, the FDA could nonetheless not grant marketing approval of DEXTENZA for the pain indication until we submit complete results from the third Phase 3 clinical trial, or at all.

In our first Phase 3 clinical trial of DEXTENZA for allergic conjunctivitis, for which we announced topline results in October 2015, 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 insert. The difference in the mean scores for ocular itching between the DEXTENZA group and the placebo group was greater than 0.5 units on a five point scale at all time points on day 7 post-insertion and was greater than 1.0 unit at a majority of the time points on day 7 post-insertion. The DEXTENZA group did not achieve these pre-specified endpoints on day 7 post-insertion with respect to conjunctival redness. In our second Phase 3 clinical trial of DEXTENZA for allergic conjunctivitis, for which we announced topline results in June 2016, DEXTENZA did not meet the sole primary endpoint for ocular itching. The single primary endpoint of the second Phase 3 clinical trial was the difference in the mean scores in ocular itching between the treatment group and the placebo comparator group at three time points on day 7 following insertion of the inserts. While mean ocular itching was seen to be numerically lower (more favorable) in the DEXTENZA treatment group compared to the placebo group measured at each of the three specified times on day 7 following insertion of the inserts, at 3, 5, and 7 minutes by -0.18, -0.29, and -0.29 units, respectively, on a five point scale, this difference did not reach statistical significance. In addition, the trial did not achieve the requirement of at least a 0.5 unit difference at all three time points on day 7 following insertion of the inserts and at least a 1.0 unit difference at the majority of the three time points between the treatment group and the placebo group on day 7 following insertion of the inserts. Further, in our prior Phase 2 clinical trial of DEXTENZA in which we were evaluating DEXTENZA for allergic conjunctivitis, DEXTENZA met one of the two primary efficacy measures. The DEXTENZA treatment group achieved a mean difference compared to the vehicle control group of more than 0.5 units on a five point scale on day 14 for all three time points measured in a day for both ocular itching and conjunctival redness. The DEXTENZA group did not achieve a mean difference compared to the vehicle control group of 1.0 unit for the majority of the three time points measured on day 14 for either ocular itching or conjunctival redness. Even if we obtain favorable clinical trial results in any additional Phase 3 clinical trials of DEXTENZA for allergic conjunctivitis, including meeting all primary efficacy measures, we may not obtain approval for DEXTENZA to treat allergic conjunctivitis or ocular itching associated with allergic conjunctivitis, or the FDA may require that we conduct additional clinical trials. Post-hoc analyses that we performed on the results of our completed Phase 3 clinical trials for allergic conjunctivitis may not be predictive of success in any future Phase 3 clinical trial. Although we believe that these analyses provide important information regarding DEXTENZA and are helpful in understanding the results of this trial and determining the appropriate criteria for future clinical trials, post-hoc analyses performed using an unlocked clinical trial database can result in the introduction of bias and are given less weight by regulatory authorities than pre-specified analyses.

We designed our Phase 2 clinical trials of OTX-TP for the treatment of glaucoma and ocular hypertension to assess clinically meaningful response to treatment, and did not power these trials to measure any efficacy endpoints with statistical significance. We reported topline efficacy results from our Phase 2b clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension in October 2015. OTX-TP did not achieve non-inferiority to timolol drops in our Phase 2b clinical trial. In this trial, on day 60 at the 8:00 a.m. time point, the OTX-TP group experienced a mean intraocular pressure, or IOP, lowering effect of 4.7 mmHg, compared with IOP 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 IOP lowering effect of 5.1 mmHg, compared with an IOP lowering effect of 7.2 mmHg in the timolol arm. Also in this trial, on day 60, the OTX-TP group experienced a mean diurnal IOP lowering effect of 3.3 mmHg compared to baseline 5.9 mmHg compared for the timolol group. On day 90, the OTX-TP group experienced a mean diurnal IOP, or IOP, lowering effect of 3.6 mmHg compared to baseline, versus 6.3 mmHg for the timolol group. We expect that our planned Phase 3 clinical trials for OTX-TP, one of which we initiated during the third quarter of 2016, will be powered with an appropriate number of patients to measure with statistical significance the superiority of OTX-TP as compared to a placebo vehicle intracanalicular insert in the reduction of mean IOP from baseline at all of the nine diurnal time points at week 2, week 6 and week 12 visits. We completed an End-of-Phase 2 review with the FDA in April 2016 and initiated the first of two planned Phase 3 clinical trials of OTX-TP in September 2016. Based on discussions with the FDA, the Phase 3 clinical trial design has

significant differences as compared to our completed Phase 2 clinical trials. In particular, the most notable changes from our first Phase 2 clinical trial to our first Phase 3 clinical trial are that our first Phase 3 clinical trial enrolls more subjects at a greater number of sites, has a different randomization, measures the primary efficacy endpoints on different days and at different timepoints, has a longer washout period, does not include a timolol active comparator and does not have eye drops, placebo or active, administered in either the treatment or the placebo-controlled arm. Despite these changes to our clinical trial protocol, we cannot be certain that our first Phase 3 clinical trial will be successful. We do not intend to initiate the second Phase 3 clinical trial until we receive data from the first Phase 3 clinical trial and may determine to discuss the results of this first Phase 3 clinical trial with the FDA prior to initiating a second Phase 3 clinical trial. If we do not achieve our primary endpoint in the Phase 3 clinical trials with statistical significance or do not achieve a clinically meaningful reduction in IOP, 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, including as a result of differences in trial design. Post-hoc analyses performed using an unlocked clinical trial database can result in the introduction of bias and are given less weight by regulatory authorities than pre-specified analyses.

The success of our intracanalicular insert product candidates is dependent upon retention during the course of intended therapy. As such, we may conduct non-significant risk investigational device exemption, or IDE, medical device, or NSR, studies in the United States for our extended-delivery intracanalicular insert in an effort to increase the rate of retention. All NSR studies that we have performed to date have involved placebo vehicle control intracanalicular inserts without active drug. If we determine to make any future changes to the design or composition of our inserts, such changes could affect the outcome of any subsequent clinical trials using these updated inserts. For example, in our Phase 2b clinical trial of OTX-TP, we used a different version of intracanalicular insert than either of the inserts that we used in our Phase 2a clinical trial of OTX-TP. Based on the results of our completed Phase 2a clinical trial, we designed the OTX-TP insert 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 insert used in the Phase 2a clinical trial. To achieve this, we modified the design of the OTX-TP insert to enlarge it in order to enable the insert 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 inserts could be visualized in approximately 88% of eyes by the day 60 visit. By the day 90 visit, the ability to visualize OTX-TP had declined to approximately 42% of eyes as the hydrogel softened, liquefied and had either advanced further down in the canaliculus or had cleared through the nasolacrimal duct. We are conducting additional NSR studies on additional modified insert designs, including a polyethylene glycol, or PEG, tip on the proximal end of the insert that have been incorporated into the design of the first Phase 3 trial of OTX-TP. If in our Phase 3 clinical trials the retention rates for our inserts are inadequate to ensure that the patient is receiving appropriate therapy, we may not be able to obtain regulatory approvals or, even if approved, achieve market acceptance of our extended-delivery drug delivery products.

The protocols for our clinical trials and other supporting information are subject to review by the FDA and regulatory authorities outside the United States. For our intracanalicular insert product candidates, we have typically conducted our initial and earlier stage clinical trials outside the United States. We generally plan to conduct our later stage and pivotal clinical trials of our intracanalicular insert product candidates in the United States. The FDA, however, could require us to conduct additional studies or require us to modify our planned pivotal clinical trials to receive clearance to initiate such trials in the United States or to continue such trials once initiated. The FDA is not obligated to comment on our trial protocols within any specified time period or at all or to affirmatively clear or approve our planned pivotal clinical trials. Subject to a waiting period of 30 days, we could choose to initiate our pivotal clinical trials in the United States without waiting for any additional period for comments from the FDA.

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

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

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately

represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates.

Other risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials
- administrative burdens of conducting clinical trials under multiple sets of foreign regulations;
- failure of enrolled patients to adhere to clinical protocols as a result of differences in healthcare services or cultural customs;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- political and economic risks relevant to foreign countries.

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

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

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

For example, we applied for a deferral from the FDA for the requirement to conduct pediatric studies for DEXTENZA for the treatment of post-surgical ocular pain and inflammation 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 extended-delivery drug delivery product candidates or our other product candidates that we may develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or similar regulatory authorities outside the United States. Although there is a significant prevalence of disease in the areas of ophthalmology in which we are focused, we may nonetheless experience unanticipated difficulty with patient enrollment. For example, in the third quarter of 2017 we initiated a Phase 1 clinical trial of OTX-TIC outside the United States, but we have not enrolled any patients in this trial as of April 30, 2018.

A variety of factors affect patient enrollment, 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 first Phase 3 clinical trial of OTX-TP is expected to enroll approximately 550 patients at approximately 50 sites in the United States and will be the largest clinical trial we will have conducted to date, and enrollment in this trial has been slower than projected. Patients randomized into the placebo control arm will not receive any glaucoma medications during the course of this trial. Our inability to enroll a sufficient number of patients in our first Phase 3 clinical trial or any of our other clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

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

If our extended-delivery drug delivery product candidates or any of our other product candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In each of our first two Phase 3 clinical trials of DEXTENZA for the treatment of post-surgical ocular pain and inflammation following cataract surgery, there were two subjects that experienced serious adverse events in the DEXTENZA group in each trial, none of which were ocular in nature or considered by the investigator to be related to the study treatment. In our third Phase 3 clinical trial of DEXTENZA for the treatment of post-surgical ocular pain and inflammation, there were three subjects that experienced serious adverse events in the DEXTENZA group, one of which was ocular in nature and none of which were considered by the investigator to be related to the study treatment. There was one ocular serious adverse event in the vehicle control group in the three completed Phase 3 clinical trials, which was hypopyon, or inflammatory cells in the anterior chamber. In our earlier Phase 2 clinical trial of DEXTENZA for the same indication, there were three serious adverse events, none of which was considered by the investigator to be related to the study treatment. In the DEXTENZA group of this Phase 2 clinical trial of DEXTENZA, the only adverse event that occurred more than once for the same subject was reduced visual acuity, which occurred twice but was not considered by the investigator to be related to the study treatment.

In our two pilot studies of OTX-TP for the treatment of glaucoma and ocular hypertension and our Phase 2a clinical trial of OTX-TP for the same indication, the most common adverse event was inflammatory reaction of the eyelids and ocular surface, which was noted in three patients in our pilot studies and in five patients in our Phase 2a clinical trial. No hyperemia-related adverse events were noted in any of the patients treated with OTX-TP in our Phase 2b clinical trial. There were no serious adverse events reported in our Phase 2b clinical trial; however, two OTX-TP subjects and two timolol subjects discontinued study participation due to ocular adverse events. Ocular adverse events were reported for 39.4% and 37.5% of subjects in the OTX-TP and timolol groups, respectively. The most frequently reported ocular adverse events were dacryocanaliculitis, or inflammation of the lacrimal ducts, acquired dacryostenosis, or closing of the tear ducts, and eyelid edema. In the Phase 2b clinical trial, inflammatory reaction at the administration site (punctal area) and lacrimal structure injury were each noted in one OTX-TP subject as compared to higher percentages in prior trials. In the Phase 2b trial, the majority of ocular adverse events, including the most frequently reported adverse events, were assessed by the investigators as treatment related. However, many compounds that initially showed promise in clinical or early stage testing for treating ophthalmic disease have later been found to cause side effects that prevented further development of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later be found to be caused by the study 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 diseases and conditions.

We are currently directing all of our development efforts towards applying our proprietary bioresorbable hydrogel technology platform to product candidates that are designed to provide extended delivery of therapeutic agents to the eye

using active pharmaceutical ingredients that are currently used in FDA-approved ophthalmic drugs. We have a number of product candidates at various stages of development based on our bioresorbable hydrogel technology platform and are exploring the potential use of our platform for other front-of-the-eye diseases and conditions. We are also developing hydrogel drug delivery implants designed to release therapeutic antibodies and small molecules such as TKIs, to modulate the biologic activity of VEGF over a sustained period following administration by an intravitreal injection for the treatment of diseases and conditions of the back of the eye, including wet age related macular degeneration, or wet AMD. In October 2016, we entered into a collaboration with Regeneron for the development and potential commercialization of products containing our extended-delivery hydrogel formulation in combination with Regeneron's large molecule VEGF-targeting compounds for the treatment of retinal diseases. Our existing product candidates and any other potential product candidates that we or our collaborators identify may not be suitable for continued preclinical or clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. We are also considering the future growth potential of the hydrogel platform technology in new areas of the body. If we do not successfully develop and commercialize our product candidates that we or our current or future collaborators develop based upon our technological approach, we will not be able to obtain substantial product revenues or revenue from collaboration agreements, including our collaboration with Regeneron, in future periods.

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

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

Risks Related to Manufacturing

We will need to upgrade and expand our manufacturing facility or relocate to another facility and to 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 facility located in Bedford, Massachusetts. In order to meet our business plan, which contemplates our scaling up manufacturing processes to support our product candidate development programs and the potential commercialization of these product candidates, we will need to upgrade and expand our existing manufacturing facility, or relocate to another manufacturing facility, add manufacturing personnel and ensure that validated processes are consistently implemented in our facility or facilities. The upgrade and expansion of our facility, or the relocation to an additional facility, will require additional regulatory approvals. In addition, it will be costly and time-consuming to expand our facility or relocate to another facility and recruit necessary additional personnel. If we are unable to expand our manufacturing facility or relocate to another 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 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 review of our NDA for

DEXTENZA, the FDA conducted a pre-NDA approval inspection of our manufacturing operations. As a result of this inspection, we received an FDA Form 483 containing inspectional observations focused on process controls, analytical testing and physical security procedures related to manufacture of our drug product for stability and commercial production purposes. We addressed some observations before the inspection was closed and responded to the FDA with a corrective action plan to complete the inspection process. In July 2016, we received a CRL from the FDA regarding our NDA for DEXTENZA. This CRL pertained to the deficiencies in manufacturing process and controls identified during the pre-NDA approval inspection of our manufacturing facility performed by the FDA New England District Office in February 2016 that were documented on the February Form 483. In January 2017, we resubmitted our NDA. Following a re-inspection of manufacturing operations by the FDA which was completed in May 2017, we received an FDA Form 483 containing inspectional observations focused on procedures for manufacturing processes and analytical testing related to the manufacture of drug product for commercial production. In July 2017, we received a second CRL from the FDA regarding our NDA for DEXTENZA for the treatment of post-surgical ocular pain, which states that the FDA has determined that it cannot approve the NDA in its present form. FDA concerns included deficiencies in manufacturing processes and analytical testing related to manufacturing of drug product identified during the May 2017 pre-NDA approval inspection. We have corresponded with the FDA regarding these inspectional deficiencies and are working to resolve the issues that have been identified. We have corresponded with the FDA regarding these inspectional observations and are working to resolve the issues that have been identified. In May 2017 we submitted our initial response to the Form 483 and in November 2017, we submitted our responses to the FDA's remaining inspectional observations in an effort to close out the items identified in the Form 483.

The remediation efforts we have undertaken in response to the FDA's inspectional observations and as a result of further internal review include upgrades to our manufacturing equipment and updates to our manufacturing processes and quality oversight. These changes are intended to resolve the FDA's outstanding concerns, including regarding the presence of particulate matter in certain manufactured lots of DEXTENZA, and enable us to consistently produce commercial lots and establish manufacturing processes sufficient for purposes of resubmission of our NDA. In December 2017, we requested a meeting with the FDA to describe our remediation efforts and NDA resubmission plans and to seek feedback. A meeting was granted in January 2018, and we believe that the preliminary written responses from the FDA to our questions fully addressed our meeting objectives. We decided that the meeting would no longer be necessary because of the completeness of the FDA's response and that the FDA's comments have not required any substantial change in our manufacturing or regulatory plans. As a result, the correspondence with the FDA will represent the official record of that previously scheduled meeting. Subject to satisfactorily addressing the FDA inspectional observations and demonstrating consistency in our commercial stage manufacturing process, we plan to resubmit our NDA for DEXTENZA for the treatment of post-surgical ocular pain in the second quarter of 2018. Adequate resolution of the outstanding Form 483 inspectional observations and the final decision as to the adequacy of our manufacturing processes are determined by the FDA with input from CDER's Office of Process and Facilities, as part of the NDA review process, and are necessary prior to NDA approval. If we are unable to resolve these inspectional observations in a timely manner or achieve consistency in our commercial stage manufacturing process, our resubmission of our NDA and its potential approval would be delayed or prevented.

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 the manufacture, packaging or testing of our products. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, product seizure or recall, imposition of a consent decree, or withdrawal of product approval, and would limit the availability of ReSure Sealant and our product candidates that we manufacture.

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

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

If our manufacturing facility 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 another facility or to a third party. Even if we could transfer our manufacturing to another facility or a third party, the shift would likely be expensive and time-consuming, particularly since any new facility would need to comply with the necessary regulatory requirements and to

be inspected and qualified. We would also need FDA approval before any products manufactured at that facility could be used for clinical or commercial supply. Such an event could delay our clinical trials or reduce our product sales.

Currently, we maintain insurance coverage against damage to our property and equipment in the amount of up to $15.3 million and to cover business interruption and research and development restoration expenses in the amount of up to $2.8 million. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for ReSure Sealant or any of our product candidates if there were a catastrophic event or failure of our current manufacturing facility or processes.

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

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

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

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

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

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

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

Risks Related to Commercialization

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

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

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

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

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

Our assessment of the potential market opportunity for ReSure Sealant and our product candidates is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of

such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. If the actual market for ReSure Sealant or any of our product candidates is smaller than we expect, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

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

We have limited experience in the sale, marketing and distribution of drug and device products. To achieve commercial success for ReSure Sealant and any product candidate for which we obtain marketing approval, we will need to establish and maintain adequate sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties. We commercially launched ReSure Sealant in February 2014 on a region by region basis in the United States through a network of independent distributors. In early 2017, we terminated these distributors and hired a contract sales force of four representatives to sell ReSure Sealant. We have subsequently terminated the agreement with the contract sales force to sell ReSure Sealant.

If DEXTENZA is approved for marketing, we are considering potential commercialization options for DEXTENZA in the United States, including building our own highly targeted, key account sales force that would focus on ambulatory surgical centers responsible for the largest volumes of cataract surgery. We would also expect to leverage such a sales force by selling ReSure Sealant alongside of DEXTENZA. If we decide to commercialize any of our products outside of the United States, we would expect to utilize a variety of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize any product that receives marketing approval. The building of such a sales force is not fully funded under the Company's current operating plan and is therefore subject to the risk of our ability to raise additional capital to support such an effort. We expect that a direct sales force will be required to effectively market and sell OTX-TP, if approved for marketing. We will also rely on Regeneron to commercialize our extended-delivery hydrogel formulation in combination with Regeneron's large molecule VEGF-targeting compounds. Because we have not historically evaluated whether to seek regulatory approval for any of our product candidates outside of the United States, pending potential receipt of regulatory approval for the applicable product candidate in the United States, at this time we cannot be certain when, if ever, we will recognize revenue from commercialization of our product candidates in any international markets. If we decide to commercialize our products outside of the United States, we expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with one or more third parties to commercialize any product of ours that receives marketing approval. These may include independent distributors, pharmaceutical companies or our own direct sales organization.

There are risks involved with both establishing our own sales, marketing and distribution capabilities and with entering into arrangements with third parties to perform these services. We may not be successful in entering into arrangements with third parties to sell, market and distribute our products or may be unable to do so on terms that are most beneficial to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to market, sell and distribute our products effectively. If a substantial number of independent distributors on whom we rely, or any significant independent distributor, were to cease to do business with us within a short period of time, our sales of products sold by such distributor or distributors could be adversely affected. In such a situation, we may need to seek alternative independent distributors. Because of the competition for their services, we may be unable to recruit additional qualified independent distributors to work with us. Our product revenues and our profitability, if any, under third-party collaboration including our collaboration with Regeneron, distribution or other marketing arrangements may also be lower than if we were to sell, market and distribute a product ourselves. On the other hand, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of any product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to use or prescribe our products;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

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

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

Because the active pharmaceutical ingredients in our product candidates, other than those developed under the Regeneron collaboration, are available on a generic basis, or are soon to be available on a generic basis, competitors will be able to offer and sell products with the same active pharmaceutical ingredient as our products so long as these competitors do not infringe the patents that we license. For example, our licensed patents related to our intracanalicular insert product candidates largely relate to the hydrogel composition of the intracanalicular inserts and certain drug-release features of the inserts. 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.

Icon Biosciences, Inc. received FDA approval of DEXYCU in February 2018. DEXYCU is an injection of dexamethasone into the anterior chamber of the eye to treat inflammation associated with cataract surgery. Other companies have also advanced into Phase 3 clinical development biodegradable, extended-delivery product candidates that could compete with our intracanalicular insert product candidates. ReSure Sealant is the first and only surgical sealant approved for ophthalmic use in the United States, but will compete with sutures as an alternative method for closing ophthalmic wounds. Multiple companies, including our collaborator Regeneron, are exploring in early stage development alternative means to deliver anti-VEGF and TKI products in an extended-delivery fashion to the back of the eye.

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

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

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

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

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

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

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

we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

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

Subject to the approval of the NDA resubmission we expect to file with the FDA for DEXTENZA for the treatment of post-surgical ocular pain, we will apply for a transitional pass-through reimbursement status, or C code, for DEXTENZA from the Centers for Medicare and Medicaid Services, or CMS, and expect pricing for DEXTENZA while in pass-through status to be approximately $450 to $500 per surgery. We expect pass-through status would remain in effect for up to three years depending on when we apply for and receive this reimbursement code. We have submitted an application to the CMS for a J code for DEXTENZA and expect to submit to the CMS for a standard J code for our OTX-TP product candidate, if our clinical trials are successful and if our NDA filings and sNDA 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 U.S. product liability insurance coverage in the aggregate, with a per incident limit of $10.0 million and approximately $15.0 million in product liability insurance in another jurisdiction in which we operate, with a per incident liability limit of approximately $15.0 million. These policies may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage as we expand our clinical trials and our sales of ReSure Sealant and any other product candidates for which we obtain marketing approval.

We will need to further increase our insurance coverage if we commence commercialization of any of our product candidates for which we obtain marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Dependence on Third Parties

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

In October 2016, we entered into a strategic collaboration, option and license agreement, or Collaboration Agreement, with Regeneron for the development and potential commercialization of products containing our extended-delivery hydrogel formulation in combination with Regeneron's large molecule VEGF-targeting compounds. Our ability to generate revenues from the Collaboration Agreement will depend on our and Regeneron's abilities to successfully perform the functions assigned to each of us under the Collaboration Agreement. We did not receive any upfront payment under the Collaboration Agreement, although Regeneron has an option to enter into an exclusive, worldwide license, with the right to sublicense, under our intellectual property to develop and commercialize products containing our extended-delivery hydrogel formulation in combination with Regeneron's large molecule VEGF-targeting compounds. Regeneron has agreed to pay us $10 million upon exercise of the option. The option is exclusive until 12 months after Regeneron has received a product candidate in accordance with a collaboration plan and non-exclusive for an additional six months following the end of the exclusive period. In December 2017, we delivered to Regeneron the final formulation for Regeneron's initial preclinical tolerability study. Under the Collaboration Agreement, we are obligated to reimburse Regeneron for certain development costs incurred by Regeneron under the collaboration plan during the period through the completion of the initial clinical trial, subject to a cap of $25 million, which cap may be increased by up to $5 million under certain circumstances. We are also entitled to receive under the terms of the Collaboration Agreement specified development, regulatory and sales milestone payments, as well as royalty payments.

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

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

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

We have in the past entered into collaboration agreements with third parties, including our collaboration with Regeneron, and expect to utilize a variety of types of collaboration, distribution and other marketing arrangements with third parties to commercialize ReSure Sealant or any of our product candidates for which we obtain marketing approval in markets outside the United States. We also may enter into arrangements with third parties to perform these services in

the United States if we do not establish our own sales, marketing and distribution capabilities in the United States for our product candidates or if we determine that such third-party arrangements are otherwise beneficial. We also may seek additional third-party collaborators for development and commercialization of other product candidates. Our likely collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Other than our collaboration with Regeneron, we are not currently party to any such arrangement. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Our collaboration with Regeneron poses, and any future collaborations likely will pose a number of risks, including the following:

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

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

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

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

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

We are currently conducting preclinical testing of protein-based anti-VEGF compounds in collaboration with Regeneron to explore the feasibility of delivering their drugs in combination with our hydrogel. The initial drug selected for preclinical testing under this collaboration is aflibercept, marketed under the brand name Eylea. We may explore broader collaborations for the development and potential commercialization of our hydrogel technology in combination with other large molecules with targets other than VEGF 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 pain and inflammation following cataract surgery. However, we have relied and may continue to rely on third parties, such as contract research organizations, or CROs, to conduct future clinical trials of our product candidates, including OTX-TP

for the treatment of glaucoma and ocular hypertension. If we deem necessary, we may engage third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct or assist in our clinical trials or other clinical development work. If we are unable to enter into an agreement with a CRO or other service provider when required, our product development activities would be delayed.

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

Risks Related to Our Intellectual Property

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

Our success depends in large part on our and our licensor's ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We and our licensor have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. Some of our licensed patents that we believe are integral to our hydrogel technology platform have terms that extend through at least 2024. However, other broader patents within our licensed patent portfolio expire between 2018 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 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, three of our licensed patents related to ReSure Sealant were recently invalidated and rendered unenforceable following their assertion by Integra LifeSciences Holdings Corporation, another licensee of Incept. 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 three issued patents outside of the United States that cover all three intracanalicular insert product candidates. We have three licensed patent families in Europe and certain other parts of the world for our intravitreal drug delivery product candidates, but only one patent issuance to date outside of the United States. Patents might not be issued and we may never obtain any patent protection or may only obtain substantially limited patent protection outside of the United States with respect to our products.

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

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

We may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in other contested proceedings such as opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability

to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products.

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

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

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

If we are not able to obtain patent term extensions 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 we have rights to 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, or we may incorrectly determine that a patent is invalid or does not cover a particular product or product candidate. Thus, we do not know with certainty that ReSure Sealant or any of our product candidates, or our commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property.

We are aware of a family of U.S. patent applications and issued patents that expired in approximately December 2015 and which have claims that ReSure Sealant could be considered as having infringed. We believe that the claims of this patent family are subject to a claim of invalidity. We are also aware of a U.S. patent with an expiration in 2020 with claims directed to formulations of hydrogels and which could be alleged to cover the hydrogel formulations used in our product candidates OTX-TP and OTX-MP. Based on the specifications and file history of that patent, we believe its claims should be construed with a scope that does not cover our product candidates. We also believe that such claims, if and to the extent they were asserted against our product candidates, would be subject to a claim of invalidity. Further, we are aware of a third-party patent relating to intracanalicular inserts that may relate to, and potentially could be asserted against our intracanalicular insert product candidates, including DEXTENZA and OTX-TP. We believe that the claims of this patent are 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. In particular, if we determine to pursue a strategy of expanding the use of the hydrogel technology outside of the field of ophthalmology, we would need to negotiate and enter into an amendment to our existing license agreement with Incept or a new license agreement with Incept covering one or more additional such fields of use. We may not be able to obtain any such required amendment or new license on commercially reasonable terms or at all.

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

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

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, especially if additional clinical trials are required, if approval is obtained at all. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory

authorities for each therapeutic indication to establish the product candidate's safety and purity. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, the EMA or other regulatory authorities may determine that our product candidates are not safe or effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. In addition, while we have had general discussions with the FDA concerning the design of some of our clinical trials, we have not discussed with the FDA the specifics of the regulatory pathways for our product candidates.

As part of its review to date 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.

The FDA has also completed two inspections of our manufacturing facility in connection with our NDA for DEXTENZA for the treatment of post-surgical ocular pain. After each inspection, we received a Form 483 from the FDA pertaining to deficiencies in our manufacturing processes identified during such inspection. After we responded to the issues which had been identified with corrective action plans, we subsequently received a CRL from the FDA. Following the July 2016 CRL, we resubmitted our NDA to the FDA in January 2017. After the May 2017 inspection, we received a Form 483 from the FDA focused on procedures from manufacturing processes and analytical testing related to the manufacture of drug product for commercial production. We received a CRL regarding these and other matters in July 2017. We have corresponded with the FDA regarding these inspectional observations and are working to resolve the issues that have been identified in the Form 483, including the presence of particulate matter in certain manufactured lots of DEXTENZA. In November 2017, we submitted our complete responses to the FDA in an effort to close out the Form 483 deficiencies. Subject to satisfactorily addressing the FDA inspectional observations, we plan to resubmit our NDA for DEXTENZA for the treatment of post-surgical ocular pain in the second quarter of 2018. However, if we are unable to address such issues successfully or if the FDA determines that the actions we have taken or will take to remediate such issues to be inadequate, our ability to commercialize any products could be limited, which could adversely affect our ability to achieve or sustain profitability.

Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA, the EMA and regulatory authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we or any current or future collaborator of ours ultimately obtains may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Accordingly, if we or any current or future collaborator of ours experiences delays in obtaining approval or if we or they fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

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

In order to market and sell ReSure Sealant or our product candidates in the European Union and many other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous

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

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

Even if we, or any current or future collaborators, obtain marketing approvals for our product candidates, the terms of approvals, ongoing regulations and post-marketing restrictions for our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any current or future collaborators, must therefore comply with requirements concerning advertising and promotion for any of our products for which we or our collaborators obtain marketing approval. Promotional communications with respect to drug products, biologics, 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, was to confirm that ReSure Sealant can be used safely by physicians in a standard cataract surgery practice and to confirm the incidence of the most prevalent adverse ocular events identified in our pivotal study of ReSure Sealant in eyes treated with ReSure Sealant. We submitted the final study report of the Clinical PAS to the FDA in June 2016 and the FDA has confirmed the Clinical PAS has been completed. The second post-approval study, identified as the Device Exposure Registry, is intended to link to the Medicare database to ascertain if patients are diagnosed or treated for endophthalmitis within 30 days following cataract surgery and application of ReSure Sealant. In December 2015, the CMS denied our application for a tracking or research code for ReSure Sealant commercial use. In cooperation with the FDA, we have identified another option for conducting this registry study while maintaining the objective for linking ReSure Sealant use to the Medicare database through a partnership with a third party. In July 2016, the FDA approved the Device Exposure Registry protocol, which should allow us to complete the study in one to two years. We are required to provide periodic reports to the FDA on the progress of this post-approval study until it is completed. We initiated enrollment in this study in December 2016 and submitted our first progress report to FDA in January 2017. Following review of the results from these post-approval studies, or if we are unable to complete the Device Exposure Registry, any concerns with respect to endophthalmitis that we are unable to address due to the lack of completion of the study. This would negatively affect our ability to commercialize ReSure Sealant.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug and biologic manufacturers or quality assurance standards applicable to medical device manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding

maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our current or future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to physicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals, with data collection beginning in August 2013; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

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

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Under the CURES Act and the Trump Administration's regulatory reform initiatives, the FDA's policies, regulations and guidance may be revised or revoked in a manner that could prevent, limit or delay regulatory approval of our product candidates, which would impact our ability to generate revenue.

In December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. An under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the

FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Current and future legislation may increase the difficulty and cost for us and any current or future collaborators to obtain marketing approval of and commercialize our 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 drug candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any drugs 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 future collaborators, may receive for any approved drugs.

Among the provisions of the Patient Protection and Affordable Care Act, or ACA, of potential importance to our business and our drug candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- 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 to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability;
- 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 drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted since the ACA 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 will stay in effect through 2024 unless additional Congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient

programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

We expect that these healthcare reforms, 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 additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a “skinny” version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures was passed by the U.S. Senate.

The Trump Administration has also taken executive actions to undermine or delay implementation of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Administration announced that it will discontinue the payment of cost-sharing reduction, or CSR, payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain.

More recently, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Further, each chamber of the Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. The Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session.

We will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on our business. It is possible that repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While the timing and scope of any potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, it is also possible that some of the ACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop commercialize product candidates.

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

Moreover, legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical drugs. 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 drug 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 future collaborators to more stringent drug labeling and post-marketing testing and other requirements.

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

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

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

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

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

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

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with

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

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

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

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

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

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

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), the limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), the one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modification or repeal many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain

and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2017, we had federal and state net operating loss carryforwards of $126.2 million, which begin to expire in 2026, and state net operating loss carryforwards of $109.3 million, which begin to expire in 2026. As of December 31, 2017, we also had federal research and development tax credit carryforwards of $5.5 million and state research and development tax credit carryforwards $2.8 million, which begin to expire in 2026 and 2025, respectively. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset our future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain how various states will respond to the newly enacted federal tax law. If our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

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 remain highly dependent on the research and development, clinical and business development expertise of Amar Sawhney, Ph.D., our Executive Chairman of the Board of Directors and former President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical team, including Antony Mattessich, our President and Chief Executive Officer. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our 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.

Although we had a reduction in workforce in 2017 primarily related to sales and marketing personnel, we expect our drug development, clinical, regulatory affairs, and manufacturing teams to grow in the short-term and may regrow our sales and marketing capabilities in the longer term following the planned resubmission of our NDA for DEXTENZA. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. In 2016, we entered into a lease agreement for new general office research and development and manufacturing space. We relocated our corporate headquarters to the new leased premises during June 2017 and are evaluating the relocation

of our manufacturing operations to the new leased premises. 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.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

Risks Related to Our Common Stock

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

Our executive officers, directors and principal stockholders, in the aggregate, beneficially own a significant portion of our capital stock. As a result, if these stockholders were to choose to act together, they could 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, could 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. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price at which they purchased it. The market price for our common stock may be influenced by many factors, including:

- our success in commercializing ReSure Sealant and any product candidates, including potentially DEXTENZA, for which we obtain marketing approval;
- the outcome of our NDA filing for DEXTENZA for the treatment of post-surgical ocular pain;
- the success of competitive products or technologies;
- results of clinical trials of our product candidates;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;

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

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation has often been instituted against that company. We also may face securities class-action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to commercialize DEXTENZA, OTX-TP or our other product candidates. As described in “Part II, Item 1— Legal Proceedings,” we and certain of our current and former executive officers and current and former board members have been named as defendants in purported class action lawsuits and derivative lawsuits. These proceedings and other similar litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources.

We are currently subject to legal actions and proceedings related to the decline in our stock price, which could distract our management and could result in substantial costs or large judgments against us.

In July 2017, we experienced a decline in our stock price following our announcement that we had received notice of the FDA’s determination that it could not approve our NDA for DEXTENZA in its present form. In addition, the market prices of securities of companies in the biotechnology and pharmaceutical industry have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These fluctuations could adversely affect the market price of our common stock. In the past, securities class action litigation has often been brought against companies following periods of volatility in the market prices of their securities. In July 2017, class action lawsuits were filed against us and certain of our current and former executive officers in the United States District Court for the District of New Jersey, which have subsequently been transferred to the United States District Court for the District of Massachusetts at our request. In addition, in July 2017, shareholder derivative actions were filed against certain of our current and former executive officers, certain of our current and former board members, and two of our investors and against the company as a nominal defendant, in the United States District Court for the District of Massachusetts and in Massachusetts Superior Court (Suffolk County). These actions were re-filed in October and December 2017, were consolidated by court order in January 2018, and are now pending under one docket in Massachusetts Superior Court (Suffolk County). In January 2018, a third shareholder derivative action was filed against us, certain of our current and former executive officers, and certain of our current and former board members in the United States District Court for the District of Massachusetts. In February 2018, a fourth shareholder derivative action was filed against us, certain of our current and former executive officers, certain of our current and former board members, and two of our investors in the United States District Court for the District of Delaware. Due to the volatility in our stock price, we may be the target of similar litigation in the future.

In addition, we received a subpoena from the SEC in December 2017, requesting documents and information concerning DEXTENZA, including related communications with the FDA, investors and others. We intend to fully cooperate with the SEC regarding this non-public, fact-finding inquiry.

In connection with such legal proceedings, we could incur substantial costs and such costs and any related settlements or judgments may not be covered by insurance. We could also suffer an adverse impact on our reputation and a diversion of management's attention and resources, which could cause serious harm to our business, operating results and financial condition.

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

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

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

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

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until December 31, 2019, provided that, if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30 before that time or if we have annual gross revenues of $1.07 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than $1 billion of non-convertible debt over a three-year period. As an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

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

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

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

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

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

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

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

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

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

Recent Sales of Unregistered Securities

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

Purchase of Equity Securities

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

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the following Exhibit Index.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File Number	Date of Filing	Exhibit Number	
10.1+	Employment Agreement, by and between Ocular Therapeutix, Inc. and Kevin Hanley, dated as of January 5, 2018	10-K	001-36554	3/8/2018	10.31	
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					X
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					X
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					X
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					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Database					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X

+ Management contract or compensatory plan or arrangement.

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 8, 2018

By: /s/ Donald Notman
Donald Notman
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATIONS

I, Antony Mattessich, 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 8, 2018

By: /s/ Antony Mattessich
Antony Mattessich
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Donald Notman, 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 8, 2018

By: /s/ Donald Notman
Donald Notman
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Antony Mattessich, 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 8, 2018

By: /s/ Antony Mattessich
Antony Mattessich
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Donald Notman, 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 8, 2018

By: /s/ Donald Notman
Donald Notman
Chief Financial Officer
(Principal Financial and Accounting Officer)