UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

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)**
24 Crosby Drive Bedford, MA	**01730**
(Address of principal executive offices)	**(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, $0.0001 par value per share	OCUL	The Nasdaq Global Select Market

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 every Interactive Data File required to be submitted 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 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	☐	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 November 7, 2019, there were 48,079,615 shares of Common Stock, $0.0001 par value per share, outstanding.

Ocular Therapeutix, Inc.

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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 commercialization efforts for our product DEXTENZA®;
- our plans to develop and commercialize DEXTENZA® for additional indications and our other product candidates based on our proprietary bioresorbable hydrogel technology platform;
- our ability to manufacture DEXTENZA in compliance with current Good Manufacturing Practices, or cGMP;
- our ability to build and manage a sales, marketing and distribution infrastructure to support the commercialization of DEXTENZA;
- the timing of and our ability to submit applications and obtain and maintain regulatory approvals for DEXTENZA and our other product candidates;
- our estimates regarding expenses, future revenue, the sufficiency of our cash resources, our ability to fund our operating expenses, debt service obligations and capital expenditure requirements and needs for additional financing;
- our plans to raise additional capital, including through equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements and marketing and distribution arrangements;
- our ongoing and planned clinical trials, including our Phase 3 clinical trial of DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis, our Phase 1 clinical trial of OTX-TIC for the reduction of intraocular pressure in patients with glaucoma and ocular hypertension and our Phase 1 clinical trial of OTX-TKI for the treatment of wet age-related macular degeneration, or wet AMD;
- our ability to resolve the U.S. Food and Drug Administration warning letter received with respect to ReSure® Sealant on October 18, 2018;
- the potential advantages of DEXTENZA, 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;
- our estimates regarding the potential market opportunity for DEXTENZA, ReSure Sealant, and our other product candidates;
- the preclinical and clinical development of our intravitreal depot with protein-based or small molecule drugs, including tyrosine kinase inhibitors, for the treatment of wet AMD and other retinal diseases;

- the preclinical and clinical development of our intracameral injection for the treatment of glaucoma and ocular hypertension;
- 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 capabilities and strategy, and the costs and timing of manufacturing, sales, marketing, distribution and other commercialization efforts, with respect to DEXTENZA, ReSure Sealant and any additional products 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, including potential opportunities outside the field of ophthalmology;
- the impact of government laws and regulations;
- the costs and outcomes of legal actions and 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.

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 65,414	$ 54,062
Accounts receivable	1,114	201
Inventory	895	217
Prepaid expenses and other current assets	2,213	1,713
Total current assets	69,636	56,193
Property and equipment, net	10,474	10,236
Restricted cash	1,764	6,614
Operating lease assets	6,836	—
Total assets	$ 88,710	$ 73,043
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,461	$ 2,965
Accrued expenses and other current liabilities	6,471	6,194
Operating lease liabilities	1,073	—
Total current liabilities	11,005	9,159
Other liabilities	—	3,221
Operating lease liabilities, net of current portion	9,206	—
Derivative liability	9,100	—
Notes payable, net of discount	24,952	24,788
2026 convertible notes, net	23,146	—
Total liabilities	77,409	37,168
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at September 30, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized and 48,079,615 and 41,518,091 shares issued and outstanding at September 30, 2019 and December 31, 2018	5	4
Additional paid-in capital	368,894	333,114
Accumulated deficit	(357,598)	(297,243)
Total stockholders' equity	11,301	35,875
Total liabilities and stockholders' equity	$ 88,710	$ 73,043

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

Ocular Therapeutix, Inc.

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Product revenue, net	$ 829	$ 498	$ 1,971	$ 1,486
Total revenue, net	829	498	1,971	1,486
Costs and operating expenses:				
Cost of product revenue	806	115	1,486	348
Research and development	10,235	9,685	30,966	26,657
Selling and marketing	6,777	1,067	17,349	2,651
General and administrative	6,155	4,447	16,571	13,665
Total costs and operating expenses	23,973	15,314	66,372	43,321
Loss from operations	(23,144)	(14,816)	(64,401)	(41,835)
Other income (expense):				
Interest income	308	230	1,016	621
Interest expense	(1,651)	(424)	(4,296)	(1,365)
Change in fair value of derivative liability	5,717	—	7,334	—
Other income (expense), net	(8)	—	(8)	—
Total other income (expense), net	4,366	(194)	4,046	(744)
Net loss and comprehensive loss	$ (18,778)	$ (15,010)	$ (60,355)	$ (42,579)
Net loss per share, basic	$ (0.40)	$ (0.38)	$ (1.37)	$ (1.15)
Weighted average common shares outstanding, basic	46,944,536	39,017,922	44,052,470	37,111,200
Net loss per share, diluted	$ (0.45)	$ (0.38)	$ (1.37)	$ (1.15)
Weighted average common shares outstanding, diluted	52,713,768	39,017,922	44,052,470	37,111,200

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

Ocular Therapeutix, Inc.

Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (60,355)	$ (42,579)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	6,806	5,534
Non-cash interest expense	2,469	265
Change in fair value of derivative liability	(7,334)	—
Depreciation and amortization expense	1,856	1,704
(Gain)/loss on disposal of property and equipment	7	—
Changes in operating assets and liabilities:		
Accounts receivable	(913)	(14)
Prepaid expenses and other current assets	(500)	382
Inventory	(678)	20
Operating lease assets	552	—
Accounts payable	32	(1,003)
Accrued expenses and deferred rent	543	112
Operating lease liabilities	(596)	—
Net cash used in operating activities	(58,111)	(35,579)
Cash flows from investing activities:		
Purchases of property and equipment	(1,637)	(1,410)
Net cash used in investing activities	(1,637)	(1,410)
Cash flows from financing activities:		
Proceeds from issuance of 2026 convertible notes, net of issuance costs	37,275	—
Proceeds from exercise of stock options	34	346
Proceeds from issuance of common stock pursuant to employee stock purchase plan	294	119
Proceeds from issuance of common stock offering, net	28,647	55,961
Repayment of notes payable	—	(4,114)
Net cash provided by financing activities	66,250	52,312
Net increase in cash, cash equivalents and restricted cash	6,502	15,323
Cash, cash equivalents and restricted cash at beginning of period	60,676	43,152
Cash, cash equivalents and restricted cash at end of period	$ 67,178	$ 58,475
Supplemental disclosure of non-cash investing and financing activities:		
Additional right of use asset and related lease liability	$ 2,044	$ —
Additions to property and equipment included in accounts payable and accrued expenses at balance sheet dates	$ 464	$ 198
Derivative liability in connection with issuance of 2026 convertible notes	$ 16,434	$ —
Public offering costs included in accounts payable and accrued expenses at balance sheet dates	$ —	$ 11

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

Ocular Therapeutix, Inc.

Consolidated Statements of Stockholders' Equity
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value			
Balances at December 31, 2018	41,518,091	$ 4	$ 333,114	$ (297,243)	$ 35,875
Issuance of common stock upon exercise of stock options	406	—	1	—	1
Issuance of common stock upon public offering, net of issuance costs	1,318,481	—	4,954	—	4,954
Stock-based compensation expense	—	—	1,942	—	1,942
Net loss	—	—	—	(17,124)	(17,124)
Balances at March 31, 2019	42,836,978	$ 4	$ 340,011	$ (314,367)	$ 25,648
Issuance of common stock in connection with employee stock purchase plan	84,238	—	294	—	294
Issuance of common stock upon public offering, net of issuance costs	1,180,367	—	5,074	—	5,074
Stock-based compensation expense	—	—	1,695	—	1,695
Net loss	—	—	—	(24,453)	(24,453)
Balances at June 30, 2019	44,101,583	$ 4	$ 347,074	$ (338,820)	$ 8,258
Issuance of common stock upon exercise of stock options	16,389	—	33	—	33
Issuance of common stock upon public offering, net of issuance costs	3,961,643	1	18,618	—	18,619
Stock-based compensation expense	—	—	3,169	—	3,169
Net loss	—	—	—	(18,778)	(18,778)
Balances at September 30, 2019	48,079,615	$ 5	$ 368,894	$ (357,598)	$ 11,301

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

Ocular Therapeutix, Inc.

Consolidated Statements of Stockholders' Equity
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value			
Balances at December 31, 2017	29,658,202	$ 3	$ 263,409	$ (237,265)	$ 26,147
Issuance of common stock upon exercise of stock options	146,852	—	266	—	266
Issuance of common stock upon public offering, net of issuance costs	7,475,000	1	34,704	—	34,705
Stock-based compensation expense	—	—	1,831	—	1,831
Net loss	—	—	—	(13,765)	(13,765)
Balances at March 31, 2018	37,280,054	$ 4	$ 300,210	$ (251,030)	$ 49,184
Issuance of common stock upon exercise of stock options	1,207	—	7	—	7
Issuance of common stock in connection with employee stock purchase plan	29,141	—	119	—	119
Issuance of common stock upon public offering, net of issuance costs	1,166,535	—	8,393	—	8,393
Stock-based compensation expense	—	—	1,830	—	1,830
Net loss	—	—	—	(13,804)	(13,804)
Balances at June 30, 2018	38,476,937	$ 4	$ 310,559	$ (264,834)	$ 45,729
Issuance of common stock upon exercise of stock options	21,367	—	73	—	73
Issuance of common stock upon public offering, net of issuance costs	2,026,031	—	12,852	—	12,852
Stock-based compensation expense	—	—	1,873	—	1,873
Net loss	—	—	—	(15,010)	(15,010)
Balances at September 30, 2018	40,524,335	$ 4	$ 325,357	$ (279,844)	$ 45,517

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

Ocular Therapeutix, Inc.

Notes to the Consolidated 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 product pipeline candidates provide differentiated drug delivery solutions that reduce the complexity and burden of the current standard of care (eye drops) by creating local programmed-release alternatives. 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 products 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 and compliance, reimbursement, uncertainty of market acceptance of products and the need to obtain additional financing. Recently approved products will require significant sales, marketing and distribution support up to and including upon their launch. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization.

As of September 30, 2019, the Company's lead product candidate DEXTENZA® (dexamethasone insert) 0.4mg, has been approved by the FDA and the Company's other product candidates are 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 rapidly changing 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 commercial launch of DEXTENZA.

Based on the Company's current forecasted operating plan, which includes estimates related to anticipated cash inflows from DEXTENZA product sales, and cash outflows for operating expenses, the Company believes that its existing cash and cash equivalents of $65.4 million, as of September 30, 2019 along with the expected cost savings from the operational restructuring announced in early November 2019, will enable it to fund its planned operating expenses, debt service obligations and capital expenditure requirements through the fourth quarter of 2020. The Company has a limited history of commercialization of DEXTENZA, and management does not yet have sufficient historical evidence to assert that it is probable that the Company will receive sufficient revenues from its sales of DEXTENZA to fund operations. The Company does not expect that DEXTENZA revenue will be substantial in 2019. Therefore, 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 September 30, 2019, the Company had an accumulated deficit of $357,598.

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, 2018 was derived from audited financial statements, but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of September 30, 2019 and for the three and nine months ended September 30, 2019 and 2018 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, 2018 included in the Company's Annual Report on Form 10-K on file with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of September 30, 2019 and results of operations and cash flows for the three and nine months ended September 30, 2019 and 2018 have been made. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2019.

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 and the fair value of derivatives. 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 September 30, 2019 and December 31, 2018, were carried at fair value determined according to the fair value hierarchy described above (Note 3). The Company's derivative liability at September 30, 2019 was carried at fair value determined according to the fair value hierarchy described above and classified as a Level 3 measurement. 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 variable interest rate notes payable (Note 8) are recorded at amortized costs, which approximates fair value due to their short-term nature.

On March 1, 2019, the Company issued $37,500 aggregate principal amount of unsecured senior subordinated convertible notes (the "2026 Convertible Notes") (Note 5) and is carried, net of derivative liability, at its amortized cost of $23,146 at September 30, 2019. The estimated fair value of the 2026 Convertible Notes was $33,001 at September 30, 2019. The fair value of the 2026 Convertible Notes was estimated utilizing a binomial lattice model which requires the use of Level 3 unobservable inputs. The main input when determining the fair value for disclosure purposes is the bond yield which is updated each period to reflect the yield of a comparable instrument issued as of the valuation date. The estimated fair value presented is not necessarily indicative of an amount that could be realized in a current market exchange. The use of alternative inputs and estimation methodologies could have a material effect on these estimates of fair value.

Revenue Recognition

The Company recognizes product revenue from DEXTENZA for the treatment of post-surgical ocular inflammation and pain, which it began selling to customers in June 2019, and ReSure Sealant. The Company has generated limited revenues from ReSure Sealant to date and does not expect significant future sales.

In November 2018, the FDA approved DEXTENZA for the treatment of ocular pain following ophthalmic surgery. The Company entered into a limited number of arrangements with specialty distributors in the United States to distribute DEXTENZA. Topic 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services.

To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract with a customer under Topic 606, including when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for product revenue, see Product Revenue, Net (below).

Product Revenue, Net— The Company derives its product revenues from the sale of DEXTENZA in the United States to customers, which includes a limited number of specialty distributors, who then subsequently resell DEXTENZA to physicians, clinics and certain medical centers or hospitals. In addition to distribution agreements with customers, the Company enters into arrangements with government payers that provide for government mandated rebates and chargebacks with respect to the purchase of DEXTENZA.

The Company recognizes revenue on product sales when the customer obtains control of the Company's product, which occurs at a point in time (upon delivery to the customer). The Company has determined that the delivery of

DEXTENZA to its customers constitutes a single performance obligation. There are no other promises to deliver goods or services beyond what is specified in each accepted customer order. The Company has assessed the existence of a significant financing component in the agreements with its customers. The trade payment terms with our customers do not exceed one year and therefore the Company has elected to apply the practical expedient and no amount of consideration has been allocated as a financing component. Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

Transaction Price, including Variable Consideration— Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, government chargebacks, discounts and rebates, and other incentives, such as voluntary patient assistance, and other fee-for-service amounts that are detailed within contracts between the Company and its customers relating to the Company's sale of DEXTENZA. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). These estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price, only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's original estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances—The Company compensates (through trade discounts and allowances) its customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the customer and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and comprehensive loss through September 30, 2019, as well as a reduction to trade receivables, net on the consolidated balance sheets.

Product Returns— Consistent with industry practice, the Company generally offers customers a limited right of return for product that has been purchased from the Company in certain circumstances as further discussed below. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as within accrued expenses and other current liabilities, in the accompanying consolidated balance sheets. The Company currently estimates product return reserves using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has received no returns to date and believes the returns of DEXTENZA will be minimal.

The Company's limited right of return allows for eligible returns of DEXTENZA in the following circumstances:

- Shipment errors that were the result of an error by the Company;
- Quantity delivered that is greater or less than the quantity ordered;
- Product distributed by the Company that is damaged in transit prior to receipt by the customer;
- Product from physicians, clinics, medical centers and hospitals that was not administered to the patient that is rendered non-unusable due to spoilage or mishandling
- Expired product, previously purchased directly from the Company, that is returned during the period beginning six months prior to the product's expiration date and ending twelve months after the product's expiration date;
- Product subject to a recall; and
- Product that the Company, at its sole discretion, has specified to be returned.

Government Chargebacks— Chargebacks for fees and discounts to qualified government healthcare providers represent the estimated obligations resulting from contractual commitments to sell products to qualified U.S. Department of Veterans Affairs hospitals and 340B entities at prices lower than the list prices charged to customers who directly purchase the product from the Company. The 340B Drug Discount Program is a U.S. federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. Customers charge the Company for the difference between what they pay for the product and the statutory selling price to the qualified government entity. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and trade receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified government healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that customers have claimed, but for which the Company has not yet issued a credit.

Government Rebates— The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. For Medicaid programs, the Company estimates the portion of sales attributed to Medicaid patients and records a liability for the rebates to be paid to the respective state Medicaid programs. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Other Incentives— Other incentives which the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as an accrued expenses and other current liabilities on the consolidated balance sheets.

Inventory

The Company values its inventories at the lower of cost or estimated net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within cost of product revenue. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as a cost of product revenue in the consolidated statements of operations and comprehensive loss.

The Company capitalizes inventory costs associated with the Company's products after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory acquired prior to receipt of marketing approval of a product candidate is expensed as research and development expense as incurred. Inventory that can be used in either the production of clinical or commercial product is expensed as research and development expense when selected for use in a clinical manufacturing campaign. Inventory produced that will be used in promotional marketing campaigns is expensed to selling, general and administrative expense when it is selected for use in a marketing program.

Derivative Liability

The 2026 Convertible Notes allow the holders to convert all or part of the outstanding principal of their 2026 Convertible Notes into shares of the Company's common stock provided that no conversion results in a holder beneficially owning more than 19.99% of the issued and outstanding common stock of the Company. The entire embedded conversion option is required to be separated from the 2026 Convertible Notes and accounted for as a freestanding derivative instrument subject to derivative accounting. Therefore, the entire conversion option is bifurcated from the underlying debt instrument and accounted for and valued separately from the host instrument. The Company measures the value of the embedded conversion option at its estimated fair value and recognizes changes in the estimated fair value in other income (expense), net in the consolidated statements of operations and comprehensive loss during the period of change. The embedded conversion is recognized as a derivative liability in the Company's consolidated balance sheet.

Restricted Cash

The Company held restricted cash of $1,764 and $6,614 at September 30, 2019 and December 31, 2018, respectively, on its consolidated balance sheet. The Company held restricted cash as security deposits for the lease of its manufacturing space and its former corporate headquarters and a financial covenant associated with the terms of its existing debt with lenders for total indebtedness of $25,000, which restricted the Company's withdrawal or usage of $5,000. On August 2, 2019, the Company entered into a second amendment to the Credit Agreement (Note 8) in which the lenders agreed to remove the financial covenant requiring the Company to maintain a minimum of $5,000 of cash on hand.

The Company's statements of cash flows include 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 is as follows:

	September 30, 2019	September 30, 2018	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 65,414	$ 56,861	$ 54,062	$ 41,538
Restricted cash	1,764	1,614	6,614	1,614
Total cash, cash equivalents and restricted cash as shown on the statements of cash flows	$ 67,178	$ 58,475	$ 60,676	$ 43,152

Net Loss Per Share

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based on their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities, including the assumed conversion of our 2026 Convertible Notes, outstanding stock options and common stock warrants, except where the result would be anti-dilutive. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of the conversion of the 2026 Convertible Notes, the exercise of outstanding stock options and common stock warrants. In the diluted net loss per share calculation, net loss would also be adjusted for the elimination of interest expense on the 2026 Convertible Notes (which includes amortization of the discount created upon bifurcation of the conversion option from the debt) and, the mark-to-market gain or loss each period to the bifurcated conversion option, if the impact was not anti-dilutive.

Recently Issued and Adopted Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), a new standard issued to increase transparency and comparability among organizations related to their leasing activities. This standard established a right-of-use model that requires all lessees to recognize right-of-use assets and lease liabilities on their balance sheet that arise from leases as well as provide disclosures with respect to certain qualitative and quantitative information related to a company's leasing arrangements to meet the objective of allowing users of financial statements to assess the amount, timing and uncertainty of cash flows arising from leases.

The FASB subsequently issued the following amendments to ASU 2016-02 that have the same effective date and transition date: ASU No. 2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842, ASU No. 2018-10, Codification Improvements to Topic 842, Leases, ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, ASU No. 2018-20, Narrow-Scope Improvement for Lessors, and ASU No. 2019-01, Leases (Topic 842): Codification Improvements. The Company adopted these amendments with ASU 2016-02 (collectively, the "New Leasing Standards") effective January 1, 2019.

The Company adopted the New Leasing Standards using the modified retrospective transition approach, as of January 1, 2019, with no restatement of prior periods or cumulative adjustment to accumulated deficit. Upon adoption, the Company elected the package of transition practical expedients, which allowed the Company to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. The Company made an accounting policy election to not recognize leases with an initial term of 12 months or less within its consolidated balance sheets and to recognize those lease payments on a straight-line basis in its consolidated statements of operations and comprehensive loss over the lease term.

Upon adoption of the New Leasing Standards the Company recognized operating lease assets of approximately $5,300 and corresponding operating lease liabilities of approximately $8,800, which are included in the Company's consolidated balance sheet. The adoption of the New Leasing Standards did not have an impact on the Company's consolidated statements of operations and comprehensive loss.

The Company determines if an arrangement is a lease at contract inception. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company uses its incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments.

The Company's operating leases are reflected in operating lease assets, current portion of operating lease liabilities and operating lease liabilities, net of current portion and in the Company's consolidated balance sheets. The right of use asset was determined using the present value of the future minimum lease payments over the term of the lease, any lease payments made to the lessor at or before the commencement date, reduced by lease incentives, and initial direct costs incurred by the Company. The liabilities are determined using the present value of the future minimum lease payments.

For additional information on the adoption of the New Leasing Standards, see Note 14 - Leases, to these consolidated financial statements.

On March 31, 2019, the FASB issued ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). The new standard simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company adopted ASU 2018-07 as required on January 1, 2019, and its adoption did not have any material impact on the Company's consolidated results of operations.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2019 and December 31, 2018 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of September 30, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ —	$ 59,906	$ —	$ 59,906
Liability:				
Derivative liability (Note 4)	—	—	9,100	9,100
Total	$ —	$ 59,906	$ 9,100	$ 69,006

	Fair Value Measurements as of December 31, 2018 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ —	$ 50,906	$ —	$ 50,906
Total	$ —	$ 50,906	$ —	$ 50,906

During the nine months ended September 30, 2019 there were no transfers between Level 1, Level 2 and Level 3.

4. Derivative Liability

The 2026 Convertible Notes (Note 5) contained an embedded conversion option that met the criteria to be bifurcated and accounted for separately from the 2026 Convertible Notes (the "Derivative Liability"). The Derivative Liability was recorded at fair value upon the issuance of the 2026 Convertible Notes and is subsequently remeasured to fair value at each reporting period. The Derivative Liability was initially valued and remeasured using a "with-and-without" method. The "with-and-without" methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the embedded conversion option. The difference between the entire instrument with the embedded conversion option compared to the instrument without the embedded conversion option is the fair value of the derivative, recorded as the Derivative Liability.

The fair value of the 2026 Convertible Notes with and without the conversion option is estimated using a binomial lattice approach. The main inputs to valuing the 2026 Convertible Notes with the conversion option as of September 30, 2019 include the Company's stock price on the valuation date ($3.04 on September 30, 2019); the expected annual volatility of the Company's stock (88%) and the bond yield (13.1%), which was derived by making the fair value of the 2026 Convertible Notes equal to the face value on the issuance date. Fair value measurements are highly sensitive to changes in these inputs and significant changes in these inputs would result in a significantly higher or lower fair value.

A roll forward of the derivative liability is as follows:

	As of September 30, 2019
Balance at December 31, 2018	$ —
Initial value	16,434
Change in fair value	(7,334)
Balance at September 30, 2019	$ 9,100

5. Convertible Notes

On March 1, 2019, the Company issued $37,500 of 2026 Convertible Notes. Each 2026 Convertible Note accrues interest at an annual rate of 6% of its outstanding principal amount, which is payable, along with the principal amount at

maturity, on March 1, 2026, unless earlier converted, repurchased or redeemed. The Company includes the deferred interest in the balance of the 2026 Convertible Notes on its consolidated balance sheet. The effective annual interest rate for the 2026 Convertible Notes was 13.5% through September 30, 2019.

The holders of the 2026 Convertible Notes may convert all or part of the outstanding principal amount of their 2026 Convertible Notes into shares of the Company's common stock, par value $0.0001 per share, prior to maturity and provided that no conversion results in a holder beneficially owning more than 19.99% of the issued and outstanding common stock of the Company. The conversion rate is initially 153.8462 shares of the Company's common stock per $1,000 principal amount of the 2026 Convertible Notes, which is equivalent to an initial conversion price of $6.50 per share. The conversion rate is subject to adjustment in customary circumstances such as stock splits or similar changes to the Company's capitalization.

At its election, the Company may choose to make such conversion payment in cash, in shares of common stock, or a combination thereof. Upon any conversion of any 2026 Convertible Note, the Company is obligated to make a cash payment to the holder of such 2026 Convertible Note for any interest accrued but unpaid on the principal amount converted. Upon the occurrence of a Corporate Transaction (as defined below), each holder has the option to require the Company to repurchase all or part of the outstanding principal amount of such note at a repurchase price equal to 100% of the outstanding principal amount of the 2026 Convertible Note to be repurchased, plus accrued and unpaid interest to, but excluding the repurchase date. In addition, each holder is entitled to receive an additional make-whole cash payment in accordance with a table set forth in each 2026 Convertible Note.

Upon conversion by the holder, the Company has the right to select the settlement of the conversion in either shares of common stock, cash, or in a combination thereof. In addition, the Company is obligated to make a cash payment to the holder of such 2026 Convertible Note for any interest accrued but unpaid on the principal amount converted.

- If the Company elects to satisfy such conversion by shares of common stock, the Company shall deliver to the converting holder in respect of each $1,000 principal amount of 2026 Convertible Notes being converted a number of common shares equal to the conversion rate in effect on the conversion date;

- If the Company elects to satisfy such conversion by cash settlement, the Company shall pay to the converting holder in respect of each $1,000 principal amount of 2026 Convertible Notes being converted cash in an amount equal to the sum of the Daily Conversion Values (as defined below) for each of the twenty (20) consecutive trading days during a specified period. The "Daily Conversion Values" is defined as each of the 20 consecutive trading days during the specified period, 5.0% of the product of (a) the conversion rate on such trading day and (b) the Daily VWAP on such trading day. The Daily VWAP is defined as each of the 20 consecutive trading days during the applicable Observation Period, the per share volume-weighted average price as displayed under the heading "Bloomberg VWAP" on the Bloomberg page for the Company.

- If the Company elects to satisfy such conversion by combination, the Company shall pay or deliver, as the case may be, in respect of each $1,000 principal amount of 2026 Convertible Notes being converted, a settlement amount equal to the sum of the Daily Settlement Amounts (as defined below) for each of the twenty (20) consecutive trading days during the specified period. The "Daily Settlement Amount" is defined as, for each of the 20 consecutive trading days during the specified period: (a) cash in an amount equal to the lesser of (i) the Daily Measurement Value (as defined below) and (ii) the Daily Conversion Value on such Trading Day; and (b) if the Daily Conversion Value on such trading day exceeds the Daily Measurement Value, a number of Shares equal to (i) the difference between the Daily Conversion Value and the Daily Measurement Value, divided by (ii) the Daily VWAP for such Trading Day. The "Daily Measurement Value" is defined as the Specified Dollar Amount (as defined below), if any, divided by 20. The "Specified Dollar Amount" is defined as the maximum cash amount per $1,000 principal amount of Notes to be received upon conversion as specified in the notice specifying the Company's chosen settlement method.

In the event of a Corporate Transaction, the noteholder shall have the right to either (a) convert all of the unpaid principal at the conversion rate and receive a cash payment equal to (i) the outstanding accrued but unpaid interest under the 2026 Convertible Note to, but excluding, the corporate transaction conversion date (to the extent such date occurs

prior to March 1, 2026, the maturity date of the 2026 Convertible Notes) plus (ii) and an additional amount of consideration based on a sliding scale depending on the date of such as Corporate transaction or (b) require the Company to repurchase all or part of the outstanding principal amount of such 2026 Convertible Note at a repurchase price equal to 100% of the outstanding principal amount of the 2026 Convertible Note to be repurchased, plus accrued and unpaid interest to, but excluding, the repurchase date.

A corporate transaction includes (i) a merger or consolidation executed through a tender offer or change of control (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation); (ii) a sale, lease, transfer, of all or substantially all of the assets of the Company; or (iii) if the Company's common stock ceases to be listed or quoted on any of the New York Stock Exchange, the Nasdaq Global Select Market, the Nasdaq Global Market or the Nasdaq Capital Market (the "Corporate Transaction").

On or after March 1, 2022, if the last reported sale price of the common stock has been at least 130% of the conversion rate then in effect for 20 of the preceding 30 trading days (including the last trading day of such period), the Company is entitled, at its option, to redeem all or part of the outstanding principal amount of the 2026 Convertible Notes, on a pro rata basis, at an optional redemption price equal to 100% of the outstanding principal amount of the 2026 Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the optional redemption date.

The 2026 Convertible Notes are subject to acceleration upon the occurrence of specified events of default, including a default or breach of certain contracts material to the Company and the delisting and deregistration of the Company's common stock.

As discussed in Note 4, the Company determined that the embedded conversion option is required to be separated from the 2026 Convertible Notes and accounted for as a freestanding derivative instrument subject to derivative accounting. The allocation of proceeds to the conversion option results in a discount on the 2026 Convertible Notes. The Company is amortizing the discount to interest expense over the term of the 2026 Convertible Notes using the effective interest method.

A summary of the 2026 Convertible Notes at September 30, 2019 is as follows:

	September 30, 2019
2026 Convertible Notes	$ 37,500
Less: unamortized discount	(15,684)
	21,816
Interest	1,330
Total	$ 23,146

6. Income Taxes

The Company did not provide for any income taxes in its consolidated statement of operations and comprehensive loss for the three and nine-month periods ended September 30, 2019 or 2018. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at September 30, 2019 and December 31, 2018, it was more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized.

The Company has not recorded any amounts for unrecognized tax benefits as of September 30, 2019 or December 31, 2018. As of September 30, 2019 and December 31, 2018, 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, 2015 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.

7. Collaboration Agreement

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.

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. Through September 30, 2019, the Option has not been exercised, and no payments have been made.

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.

In December 2017, the Company delivered to Regeneron a proposed final formulation for the initial preclinical tolerability study. Regeneron initiated the preclinical study in early 2018. The Company and Regeneron have subsequently reached an understanding that the proposed formulation was not final and have ceased development of it. The Company is currently in discussions with Regeneron, in accordance with the terms of the Collaboration Agreement, regarding the development of an alternative formulation.

8. Notes Payable

The Company entered into a credit and security agreement in 2014 (as amended to date, the "Credit Agreement") establishing the Company's credit facility (the "Credit Facility"). The Company has a total borrowing capacity of $25,000 under the Credit Facility which has been fully drawn down as of September 30, 2019.

In December 2018, the Company amended the terms of the Credit Agreement to increase total indebtedness under the Credit Facility to $25,000, which was used primarily to pay-off outstanding balances as of the closing date. The Company is required to make interest-only payments under the Credit Facility until December 2020. Commencing in January 2021, the Company is required to make 36 equal monthly installments of principal in the amount of $694, plus interest, through December 2023. In the event the Company achieves certain milestones under the Credit Agreement, the Company has the right to extend the interest-only payments through December 21, 2021 and make 24 equal monthly installments of principal in the amount of $1,042, plus interest. The Company has not assumed the achievement of these milestones for purposes of disclosures herein.

Amounts borrowed under the Credit Facility are at LIBOR base rate, subject to 2.00% floor, plus 7.25%. The interest rate on the date of the amendment was 9.76%. In addition, a final payment (exit fee) equal to 3.5% of amounts drawn under the Credit Facility, or $875 based on borrowings of $25,000, is due upon the maturity date of December 21, 2023. The Company is accruing the exit fee through December 21, 2023.

On August 2, 2019, the Company entered into a second amendment to the Credit Agreement in which the lenders agreed to remove the financial covenant requiring the Company to maintain a minimum of $5,000 of cash on hand. Prior to this amendment, the Company was required to maintain a minimum of $5,000 of cash on hand as a financial covenant to the borrowing arrangement, which the Company had included in long-term restricted cash.

There are no financial covenants associated with the Credit Agreement. However, the Credit Agreement does contain 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 Company is not in violation of any of the covenants. The obligations under the Credit Agreement 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 debt is collateralized by substantially all of the Company's assets, including its intellectual property.

In accordance with the Credit Agreement, in connection with the Company's desire to issue and sell the 2026 Convertible Notes, the Company amended the terms of its debt with existing lenders in February 2019. The amendment added to the Credit Agreement, among other provisions, a negative covenant restricting the Company from paying the holders of the 2026 Convertible Notes ahead in priority to the existing lenders, for so long as indebtedness remains outstanding under the Credit Facility, and a cross-default provision to establish that an event of default under the purchase agreement for the 2026 Convertible Notes also constitutes an event of default under the Credit Agreement.

Borrowings outstanding are as follows:

	September 30, 2019	December 31, 2018
Borrowings outstanding	$ 25,000	$ 25,000
Accrued exit fee	136	5
Unamortized discount	(184)	(217)
	$ 24,952	$ 24,788

As of September 30, 2019, the annual repayment requirements for the Credit Facility, inclusive of the final payment of $875 due at expiration, were as follows:

Year Ending December 31,	Principal	Interest and Final Payment	Total
Remainder of 2019	$ —	$ 624	$ 624
2020	—	2,481	2,481
2021	8,333	2,094	10,427
2022	8,333	1,270	9,603
2023	8,334	1,320	9,654
	$ 25,000	$ 7,789	$ 32,789

Interest paid amounted to $1,850 and $1,131 for the nine months ended September 30, 2019 and 2018, respectively.

9. Common Stock

On April 5, 2019, the Company entered into an Open Market Sale Agreement℠ (the "2019 Sales Agreement") with Jefferies, LLC ("Jefferies"), under which the Company may offer and sell its common stock having aggregate proceeds of up to $50,000 from time to time through Jefferies, acting as agent. In the three and nine months ended September 30, 2019, the Company sold 3,961,643 and 5,142,010 shares of common stock at-the-market under the 2019 Sales Agreement, resulting in net proceeds of approximately $18,618 and $23,692, respectively, after underwriting discounts and commissions and expenses.

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 and commissions and expenses.

In November 2016, the Company entered into a controlled equity offering sales agreement (the "2016 Sales Agreement") with Cantor Fitzgerald & Co., under which the Company could offer and sell its common stock having aggregate proceeds of up to $40,000 from time to time. In the three months ended March 31, 2019, the Company sold 1,318,481 shares of common stock at-the-market under the 2016 Sales Agreement, resulting in net proceeds of approximately $4,954 after underwriting discounts and commissions and expenses. Through March 31, 2019, the Company sold 6,330,222 shares of common stock at-the-market under the 2016 Sales Agreement, resulting in net proceeds of approximately $38,381 after underwriting discounts and commissions and expenses. As of February 25, 2019, the Company had no amounts remaining available for future sale under the 2016 Sales Agreement. On February 28, 2019, pursuant to the 2016 Sales Agreement, the Company delivered a termination notice to Cantor, terminating the 2016 Sales Agreement.

10. Net Loss Per Share

Basic net loss per share was calculated as follows for the three and the nine months ended September 30, 2019 and 2018.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss attributable to common stockholders	$ (18,778)	$ (15,010)	$ (60,355)	$ (42,579)
Denominator:				
Weighted average common shares outstanding, basic	46,944,536	39,017,922	44,052,470	37,111,200
Net loss per share attributable to common stockholders, basic	$ (0.40)	$ (0.38)	$ (1.37)	$ (1.15)

For the three months ended September 30, 2018 and the nine months ended September 30, 2019 and 2018 there is no dilutive impact. Therefore, diluted net loss per share is the same as basic net loss per share. Diluted net loss per share was calculated as follows for the three months ended September 30, 2019:

	Three Months Ended September 30, 2019
Net loss attributable to common stockholders, basic	$ (18,778)
Interest expense on 2026 Convertible Notes	998
Change in fair value of derivative liability	(5,717)
Net loss attributable to common stockholders, diluted	$ (23,497)
Weighted average common shares outstanding, basic	46,944,536
Shares issuable upon conversion of 2026 Convertible Notes, as if converted	5,769,232
Weighted average common shares outstanding, diluted	52,713,768
Net loss per share attributable to common stockholders, diluted	$ (0.45)

The Company excluded the following common stock equivalents, outstanding as of September 30, 2019 and 2018, from the computation of diluted net loss per share for the three and nine months ended September 30, 2019 and the three and nine months ended September 30, 2018 because they had an anti-dilutive impact. The Company also excluded the shares issuable upon conversion of the 2026 Convertible notes from the computation of diluted net loss per share for the nine months ended September 30, 2019 because they had an anti-dilutive impact.

	As of September 30,	
	2019	2018
Options to purchase common stock	7,621,722	5,175,803
Warrants for the purchase of common stock	18,939	18,939
	7,640,661	5,194,742

11. 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, 2019, the number of shares available for issuance under the 2014 Plan was increased by 1,659,218. During the three and nine months ended September 30, 2019, the Company granted options to purchase 266,450 and 2,976,450 shares of common stock, respectively, at a weighted exercise price of $4.59 and $4.11 per share, respectively. As of September 30, 2019, 893,066 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, 2019, the number of shares available for issuance under the 2014 Plan was increased by 207,402. During the three and nine months ended September 30, 2019, no shares and 84,238 shares, respectively, of common stock were issued. As of September 30, 2019, 524,674 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).

On July 9, 2019, the Company issued to the Senior Vice President, Head of Business Development, a non-statutory stock option to purchase an aggregate of 60,000 shares of our common stock at an exercise price of $5.13 per share. Subject to Senior Vice President, Head of Business Development 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 Stock Incentive Plan as an inducement material to Senior Vice President, Head of Business Development's acceptance of entering into employment with us in accordance with Nasdaq Listing Rule 5635(c)(4).

Stock-based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 543	$ 627	$ 1,756	$ 1,853
Selling and marketing	260	116	718	343
General and administrative	2,366	1,130	4,332	3,338
	$ 3,169	$ 1,873	$ 6,806	$ 5,534

As of September 30, 2019, the Company had an aggregate of $12,109 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.5 years.

As of September 30, 2019, there were no outstanding unvested service-based stock options held by nonemployees for the purchase of common stock.

12. Commitments and Contingencies

Intellectual Property Licenses

The Company entered into a license agreement with Incept LLC ("Incept") to use and develop certain intellectual property rights in 2007. The Company and Incept amended and restated the agreement in January 2012 (such amended and restated agreement, the "Prior Agreement"). Under the Prior Agreement, 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. On September 13, 2018 (the "Effective Date"), the Company and Incept further amended and restated the license agreement in full (the "Second Amended Agreement") to expand the scope of the Company's intellectual property license and modify future intellectual property ownership and other rights thereunder.

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 Prior Agreement. Through September 30, 2019, royalties paid under this agreement related to product sales were $244 and have been charged to cost of product revenue.

License Rights; Ownership of Intellectual Property

In the Second Amended Agreement, the parties have agreed to expand the field of use of the exclusive, worldwide, perpetual, irrevocable license held by the Company under the Prior Agreement to include specified intellectual property rights and technology owned or controlled by Incept to make, have made, use, offer for sale, sell, sublicense, have sublicensed, offer for sublicense and import, (i) consistent with the Prior Agreement, products delivered to or around the human eye for diagnostic, therapeutic or prophylactic purposes relating to all human ophthalmic diseases or conditions (the "Ophthalmic Field of Use") and (ii) as a result of the expansion of the scope of the license pursuant to the Prior Agreement, products delivered for the treatment of acute post-surgical pain or for the treatment of ear, nose and/or throat diseases or conditions, subject to specified exceptions (the "Additional Field of Use"). The parties have further agreed to expand the field of use of the license for certain patents, patent applications and other rights pertaining to shape-changing hydrogel formulations thereunder (the "Shape-Changing IP") to include all fields except those involving the nerves and associated tissues specified in the Second Amended Agreement.

The Company will solely own, without a license to Incept, all intellectual property rights conceived solely by one or more individuals from the Company ("Company Individuals") after the Effective Date, subject to exceptions specified therein. Subject to certain exceptions specified in the Second Amended Agreement, Incept will own and license to the Company (i) all intellectual property rights included in the Prior Agreement ("Original IP") in the Ophthalmic Field of Use and the Additional Field of Use, (ii) intellectual property rights in the field of drug delivery conceived by one or more Company Individuals on or before the Effective Date ("Incept IP"), and (iii) intellectual property rights in the field of drug delivery conceived by one or more Company Individuals jointly with one or more individuals from Incept, including Dr. Sawhney ("Incept Individuals"), after the Effective Date ("Joint IP" and, collectively with the Original IP and the Incept IP, the "Licensed IP").

Financial Terms

The Company and any of its sublicensees are obligated to pay Incept royalties as follows under the Second Amended Agreement: (i) consistent with the Prior Agreement, a royalty equal to a low single-digit percentage of net sales by the Company or its affiliates of products, devices, materials, or components thereof ("Licensed Products"), including or covered by Original IP, excluding the Shape-Changing IP, in the Ophthalmic Field of Use; (ii) a royalty equal to a mid-single-digit percentage of net sales by the Company or its affiliates of Licensed Products including or covered by Original IP, excluding the Shape-Changing IP, in the Additional Field of Use; and (iii) a royalty equal to a low single-digit percentage of net sales by the Company or its affiliates of Licensed Products including or covered by Incept IP or Joint IP in the field of drug delivery. Royalty obligations under the Second Amended Agreement commence with the first commercial sale of a Licensed Product described above and terminate upon the expiration of the last-to-expire patents included in the Licensed IP, as applicable. Any sublicensee of the Company also will be obligated to pay Incept royalties on net sales of Licensed Products made by it and will be bound by the terms of the Second Amended Agreement to the same extent as the Company. Additionally, at its sole discretion, Incept may require, as a condition of any sublicense by the Company in the Additional Field of Use and in exchange for a reduction in the royalties owed on net sales of Licensed Products described above, payments equal to a mid-teen percentage of any upfront payment and, subject to certain conditions, other payments received by the Company from the sublicensee.

Patent Prosecution and Litigation

Incept will continue to have sole control and responsibility for ongoing prosecution of patents included in the Original IP, and the Company will have sole control and responsibility for ongoing prosecution of patents and patent applications included in or arising under the Incept IP or Joint IP. The parties have agreed to work together in good faith to enter into a separate agreement under which, subject to certain limitations, the Company would assume control of the prosecution of patents and patent applications included in or arising under the Shape-Changing IP. The Company has the right, subject to certain conditions, to bring suit against third parties who infringe the patents included in the Original IP in the Ophthalmic Field of Use or the Additional Field of Use, patents included in the Incept IP in the drug delivery filed, patents included in the Joint IP in the drug delivery field, and patents included in the Shape-Changing IP in all

fields except as described above. The Company has also agreed, if requested by Incept, to enter into a joint defense and prosecution agreement for the purpose of allowing the parties to share confidential and attorney-client privileged information regarding the possible infringement of one or more patents covered by the Second Amended Agreement. The Company is responsible for all costs incurred in prosecuting any infringement action it brings.

Term and Termination

The Second Amended Agreement will expire on the later of (i) the expiration or disclaimer by the Company of the last valid claim of an issued and unexpired patent included in the Licensed IP or (ii) the final unappealable rejection or abandonment of the last pending patent application arising under the Licensed IP. Either party may terminate the Second Amended Agreement in the event of the other party's insolvency, bankruptcy or comparable proceedings, or if the other party materially breaches the agreement and does not cure such breach during a specified cure period.

Collaboration Agreement

In October 2016, the Company entered into the Collaboration Agreement with Regeneron as described in Note 7. Under the terms of the Collaboration Agreement, the Company has granted Regeneron an 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. If the Option is exercised, the Company is obligated to reimburse Regeneron for certain development costs incurred 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. Through September 30, 2019, 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 consolidated 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. On July 6, 2018, defendants filed a motion to dismiss the consolidated amended complaint. Plaintiffs filed an opposition to the motion to dismiss on September 4, 2018, and defendants filed a reply on October 4, 2018. The court held oral argument on the motion to dismiss on February 6, 2019. By order dated April 30, 2019, the court granted defendants' motion to dismiss. On May 31, 2019, the plaintiffs filed a notice of appeal to the United States Court of Appeals for the First Circuit regarding the District Court's opinion and order of dismissal of the Complaint. The plaintiffs/appellants filed their opening brief on the appeal on October 23, 2019. Defendants'/appellees' response brief is due on November 22, 2019, and plaintiffs'/appellants' reply brief is due on December 13, 2019.

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/or 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. On June 22, 2018, plaintiffs served their opposition to the motion to dismiss and a cross-motion to stay the proceedings pending a decision on the motion to dismiss in the above-referenced securities class action in the District of Massachusetts. On July 30, 2018, the parties filed a joint motion to stay the proceedings pending a decision on the motion to dismiss in the above-referenced securities class action in the District of Massachusetts. On August 3, 2018, the court granted the motion to stay.

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, all defendants filed a motion to dismiss or stay the complaint. Plaintiff filed his opposition on June 22, 2018. On July 26, 2018, the parties filed a joint motion to extend the deadline for defendants to file their reply brief pending the potential substitution of the named shareholder plaintiff. On August 20, 2018, the parties filed a joint stipulation and proposed order regarding plaintiff's unopposed request to substitute a new shareholder plaintiff and the parties' joint request that the court stay the proceedings pending a decision on the motion to dismiss in the above-referenced securities class action in the District of Massachusetts. On September 4, 2018, the court entered the requested order substituting the named plaintiff and staying the matter.

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. On June 11, 2018, the parties filed a stipulation staying the lawsuit pending final judgment in the consolidated derivative action pending in Massachusetts state court under the *Corwin* docket, described above. The court entered an order staying the case on June 12, 2018.

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

In addition, the Company 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 received a second subpoena from the SEC on August 21, 2018, requesting documents and information concerning its participation in two investor conferences in June 2017. By letter dated May 2, 2019, the SEC notified the Company that the SEC had concluded its investigation and did not intend to recommend an enforcement action against the Company or any individuals.

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.

13. Related Party Transactions

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. Mr. Jonathan M. Sparks, Ph.D., a partner at McCarter & English, has also served in the capacity as the Company's in-house counsel since October 2017. The Company incurred fees for legal services rendered by McCarter of $209 and $155 and $672 and $376 for the three and nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, there was $62 recorded in accounts payable and $55 recorded in accrued expenses for McCarter.

14. Leases

The Company leases real estate, including laboratory, manufacturing and office space, and certain equipment. The Company's leases have remaining lease terms ranging from less than 1 year to 9 years. Certain leases include one or more options to renew, exercised at our sole discretion, with renewal terms that can extend the lease term from one year to six years. All of the Company's leases qualify as operating leases.

On April 4, 2019, the Company entered into a non-cancelable lease for 30,036 square feet of space located at 24 Crosby Street in Bedford, Massachusetts to be used for office space. The five-year lease commenced on April 18, 2019 and terminates on March 24, 2024 and does not include any lease renewal options. The Company recorded an operating lease asset and liability of $2,044 on its consolidated balance sheet in connection with this lease.

The following table summarizes the presentation in the Company's consolidated balance sheet of its operating leases:

	Balance sheet location	September 30, 2019
Assets:		
Operating lease assets	Operating lease assets	$ 6,836
Liability:		
Current operating lease liabilities	Operating lease liabilities	$ 1,073
Non-current operating lease liabilities	Operating lease liabilities, net of current portion	9,206
Total Operating lease liabilities:		$ 10,279

The following table summarizes the effect of lease costs in the Company's consolidated statements of operations and comprehensive loss:

	Statement of operations and comprehensive loss location	For the Three Months Ended September 30, 2019	For the Nine Months Ended September 30, 2019
Operating lease costs	Research and development	$ 423	$ 1,215
	Selling and marketing	79	183
	General and administrative	89	226
		$ 591	$ 1,624

The minimum lease payments for the next five years and thereafter is expected to be as follows:

Year Ending December 31,	September 30, 2019
2019 (remaining three months)	592
2020	2,418
2021	2,483
2022	2,548
2023	2,358
Thereafter	5,383
Total lease payments	$ 15,782
Less: interest	5,503
Present value of operating lease liabilities	$ 10,279

Under the prior lease guidance minimum rental commitments under non-cancelable leases for each of the next five years and total thereafter as of December 31, 2018, were as follows:

	2019	2020	2021	2022	2023	Thereafter	Total
Minimum lease payments	$ 1,809	1,850	1,886	1,936	1,730	5,224	$ 14,435

The weighted average remaining lease term and weighted average discount rate of our operating leases are as follows:

	September 30, 2019
Weighted average remaining lease term in years	6.7
Weighted average discount rate	13.55 %

Supplemental disclosure of cash flow information related to our operating leases included in cash flows provided by operating activities in our consolidated statements of cash flows is as follows:

	For the Three Months Ended September 30, 2019	For the Nine Months Ended September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities	$ 591	$ 1,478

15. Subsequent Events

Inducement Stock Option Awards

On October 29, 2019, the 2019 Inducement Stock Incentive Plan (the "2019 Plan") was approved by the Board of Directors of the Company. Awards under the Plan may only be granted to persons who (a) were not previously an employee or director of the Company or (b) are commencing employment with the Company following a bona fide period of non-employment, in either case as an inducement material to the individual's entering into employment with the Company and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). For the avoidance of doubt, neither consultants nor advisors shall be eligible to participate in the Plan. Each person who is granted an Award under the 2019 Plan is deemed a "Participant." The Plan provides for the following types of awards, each of which is referred to as an "Award": non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards. The number of shares of common stock that may be issued under the 2019 Plan is 500,000.

November 2019 Reduction in Force

On November 6, 2019, the Board of Directors approved an operational restructuring to eliminate a portion of the Company's workforce to reduce expenses. As part of this operational restructuring, the Company reduced headcount by approximately 22%. The Company expects to substantially complete the restructuring in the fourth quarter of 2019. The Company estimates total restructuring costs of approximately $0.7 million. The Company expects that approximately $0.6 million would be paid during the three months ended December 31, 2019 and approximately $0.1 million would be paid during 2020.

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 consolidated 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 7, 2019. 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 local programmed-release of drug to the eye. We believe that our local programmed-release drug delivery technology has the potential 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 products and product candidates in early commercial, clinical and preclinical development applying this technology to treat post-surgical ocular inflammation and pain, allergic conjunctivitis, glaucoma and ocular hypertension, and wet age-related macular degeneration, or wet AMD, among other conditions.

In November 2018, the FDA approved our new drug application, or NDA, for DEXTENZA® (dexamethasone ophthalmic insert) 0.4mg for intracanalicular use for the treatment of ocular pain following ophthalmic surgery. DEXTENZA is the first FDA-approved intracanalicular insert delivering dexamethasone to treat post-surgical ocular pain for up to 30 days with a single administration. In June 2019, the FDA approved our supplemental new drug application, or sNDA, for DEXTENZA to treat post-surgical ocular inflammation. On July 1, 2019, we commercially launched DEXTENZA in the United States for the treatment of post-surgical ocular inflammation and pain. We have initiated an 80-subject, pivotal Phase 3 clinical trial evaluating DEXTENZA for the treatment of ocular itching in connection with allergic conjunctivitis.

We are developing our product candidate OTX-TP (intracanalicular travoprost insert) for the reduction of intraocular pressure, or IOP, in patients with glaucoma and ocular hypertension. Both DEXTENZA and OTX-TP are local programmed-release, drug-eluting, preservative-free intracanalicular inserts that are placed into the canaliculus through a natural opening called the punctum located in the portion of the lower eyelid near the nose.

Our earlier stage assets include two development programs that have initiated clinical trials: OTX-TIC, an intracameral travoprost implant for the reduction of IOP in patients with glaucoma and ocular hypertension when greater IOP reduction is needed, and OTX-TKI, an intravitreal injection by fine gauge needle of a hydrogel, anti-angiogenic formulation of a tyrosine kinase inhibitor, or TKI, for the treatment of wet AMD. We also have a 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 ReSure® Sealant, a hydrogel ophthalmic wound sealant approved by the FDA to seal corneal incisions following cataract surgery.

Inflammation and Pain after Ocular Surgery

DEXTENZA® (dexamethasone ophthalmic insert)

DEXTENZA incorporates the FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient into a hydrogel, drug-eluting intracanalicular insert. In November 2018 the FDA approved our NDA for DEXTENZA

for the treatment of post-surgical ocular pain. In June 2019, the FDA approved our sNDA, for DEXTENZA to treat post-surgical ocular inflammation. In connection with our July 1, 2019 commercial launch of DEXTENZA, we have built our own highly targeted, key account manager, or KAM, sales force that will focus on the ambulatory surgical centers, or ASCs, responsible for the largest volumes of cataract surgery. Since the commercial launch of DEXTENZA, we have expanded our field sales team by 50% to a total of 30 KAMs. DEXTENZA is now available through distributors and our key account managers are fully trained. Commencing in May 2019, our KAMs worked actively with select ASCs in a sampling program that we refer to as DEXTENZA Days. Our initial commercial efforts are focused on the two million cataract procedures performed annually under Medicare Part B. Following our receipt of FDA approval on November 30, 2018, we submitted an application for a C-code for transitional pass-through payment status. On May 29, 2019, we received formal notification from the Centers for Medicare and Medicaid Services, or CMS, that it had approved transitional pass-through payment status and established a new reimbursement code for DEXTENZA. The code, C9048, became effective on July 1, 2019. On December 28, 2018, we submitted an application for a J-code for permanent payment status. In July 2019, we subsequently received a specific and permanent J-code, J1096, that became effective October 1, 2019. With the effectiveness of our permanent J-code as of October 1, 2019, our C-code is no longer in effect.

A C-code is a unique temporary pricing code established by the CMS, for the Prospective Payment System and is only valid for claims for hospital outpatient department services and procedures and ambulatory surgery settings. A J-Code is a permanent code used to report drugs that ordinarily cannot be self-administered. J-codes are familiar to both medical practices and their billing staffs, as well as Medicare (Part B and Part C) and commercial insurers. As a result, J-codes allow for a simpler and more convenient reimbursement process.

We have completed three Phase 3 clinical trials of DEXTENZA for the treatment of post-surgical ocular inflammation and pain. The data from two of these three completed Phase 3 clinical trials and a prior Phase 2 clinical trial were used to support our NDA for post-surgical ocular pain. We submitted a sNDA for DEXTENZA for the treatment of post-surgical ocular inflammation in January 2019. In June 2019, the FDA approved the sNDA. We have also completed two Phase 3 clinical trials of DEXTENZA for the treatment of allergic conjunctivitis and a Phase 2 clinical trial of DEXTENZA for the treatment of dry eye disease.

In the third quarter of 2019, we began dosing patients in an 80-subject, pivotal Phase 3 clinical trial evaluating DEXTENZA for the treatment of ocular itching in connection with allergic conjunctivitis. This Phase 3 clinical trial is a U.S.-based, multi-center, 1:1 randomized, double-masked, placebo-controlled trial that intends to enroll approximately 80 subjects, testing the safety and efficacy of DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg versus a placebo vehicle punctum plug using the Ophthalmic Research Associates' modified Conjunctival Allergen Challenge (Ora-Cac®) Model for the treatment of ocular itching associated with allergic conjunctivitis. The trial is designed to assess the effect of DEXTENZA compared with a placebo on allergic reactions using a series of successive allergen challenges over a 30-day period. The primary efficacy endpoint being evaluated in the study is ocular itching following insertion of DEXTENZA at multiple time points during the 30-day period. DEXTENZA is administered by a physician as a bioresorbable intracanalicular insert and designed for drug release to the ocular surface for up to 30 days. This trial represents the third Phase 3 clinical trial in allergic conjunctivitis conducted by us and, if successful, we plan to submit a supplemental NDA to the FDA for ocular itching associated with allergic conjunctivitis. Topline data from this trial are anticipated in the first half of 2020.

We are also planning to evaluate DEXTENZA in pediatric subjects that are 0 to 3 years of age undergoing cataract surgery beginning in the fourth quarter of 2020. The planned pediatric trial is a post-approval commitment to the FDA. Additionally, we have received proposals for, and plan to support, several investigator-initiated trials evaluating DEXTENZA in different clinical situations.

Glaucoma Programs

Glaucoma is a large market and a disease that is estimated to impact more than 2.7 million people age 40 or older in the U.S. The primary goal of glaucoma treatment is to slow the progression of this chronic disease by reducing intraocular pressure, and many medications can accomplish this. Importantly, however, adherence to current topical glaucoma therapies is known to be particularly poor with reported rates of non-adherence from 30% to 80%. These low compliance rates may be associated with disease progression and loss of vision, and may be part of the reason that glaucoma is a leading cause of blindness in people over 60 years of age.

Prostaglandins are the most commonly used class of medications to treat patients with glaucoma and are administered via daily eye drops as the current standard of care. The ability of patients to use and place daily eye drops is challenging. The products that we are developing are designed to address the issue of compliance by delivering a prostaglandin analog formulated with our programmed release hydrogel to lower intraocular pressure for several months with a single insert.

OTX-TP (intracanalicular travoprost insert)

Our product OTX-TP is an intracanalicular insert that delivers a preservative-free formulation of the drug travoprost for the reduction of intraocular pressure, or IOP, in patients with primary open-angle glaucoma or ocular hypertension. OTX-TP is designed to lower IOP for up to 90 days and to address the poor adherence associated with chronic, daily eye drop regimens, the current standard of care.

On May 20, 2019, we reported topline results of the Phase 3 randomized, double blind, placebo-controlled clinical trial that was conducted across more than 50 sites and enrolled 554 subjects with open-angle glaucoma or ocular hypertension in the full analysis set, or FAS, population. The trial's primary efficacy endpoint was an assessment of mean IOP at nine different time points, three diurnal time points (8 AM, 10 AM, and 4 PM) at each of 2, 6, and 12 weeks following insertion. The secondary endpoints included an evaluation of whether OTX-TP demonstrated a statistically superior mean reduction of IOP from baseline for OTX-TP treated subjects compared with placebo insert treated subjects (Table 1) compared with placebo insert treated subjects at the same nine time points. Topline results show that the trial did not achieve its endpoint of statistically significant superiority in mean reduction of IOP compared with placebo at all nine time points. OTX-TP treated subjects did have a greater reduction in IOP from baseline relative to placebo insert at all nine time points (Table 2), and these differences were statistically significant (p value < 0.05) for eight of the nine time points (Tables 2 and Table 3). The reductions from baseline for OTX-TP treated subjects in this trial ranged from 3.27-5.72 millimeters of mercury (mm Hg) across the nine time points with higher levels of intraocular pressure reduction seen at the earlier time points in this trial (Table 3).

Table 1: Baseline Values

Baseline	OTX-TP	Placebo
8:00 AM	26.63	26.92
10:00 AM	25.1	25.03
4:00 PM	24.76	24.58

Table 2: Mean Intraocular Pressure Values

Diurnal Time points	2 Weeks			6 Weeks			12 Weeks		
	mm Hg		LS Mean p-value	mm Hg		LS Mean p-value	mm Hg		LS Mean p-value
	OTX-TP	Placebo		OTX-TP	Placebo		OTX-TP	Placebo	
8:00 AM	21.02	22.86	<.0001	21.93	22.73	0.0181	*22.83*	*23.23*	*0.2521*
10:00 AM	20.16	21.92	<.0001	21.05	21.85	0.0077	21.74	22.45	0.0234
4:00 PM	19.46	21.51	<.0001	20.53	21.55	0.0004	21.41	22.08	0.0310

FAS Population (OTX-TP=343 subjects, Placebo=211 subjects) ***Least Squares (LS) Means***

Table 3: Reduction in Intraocular Pressure (Change from Baseline)

Diurnal Time points	2 Week			6 Week			12 Week		
	mm Hg			mm Hg			mm Hg		
	OTX-TP	Placebo	p-value	OTX-TP	Placebo	p-value	OTX-TP	Placebo	p-value
8:00 AM	-5.72	-3.88	<.0001	-4.81	-4.01	0.0181	-3.91	-3.52	0.2521
10:00 AM	-4.92	-3.16	<.0001	-4.03	-3.23	0.0077	-3.34	-2.63	0.0234
4:00 PM	-5.22	-3.18	<.0001	-4.16	-3.14	0.0004	-3.27	-2.60	0.0310

FAS Population (OTX-TP=343 subjects, Placebo=211 subjects) ***Least Squares (LS) Means***

OTX-TP was generally well tolerated and no ocular serious adverse events were observed. The most common ocular adverse events seen in the study eye were dacryocanaliculitis (approximately 7.0% in OTX-TP vs. 3.0% in placebo) and lacrimal structure disorder (approximately 6.0% in OTX-TP vs. 4.0% in placebo).

We have met with the FDA to discuss data we reported in May 2019 from our completed phase three trial. Our conversation with the FDA was productive and involved a discussion around the importance of compliance and how a product like OTX-TP could address the issue of non-compliance by delivering a prostaglandin analog formulated with our programmed release hydrogel to lower intraocular pressure for up to 12 weeks with a single insert. While the FDA did not feel that the data from this clinical trial met the standard of clinical meaningfulness in the population studied, there were constructive discussions about potential pathways forward in specific patient populations for whom drops are problematic. Therefore, we do not intend to initiate a second Phase 3 clinical trial at this time without the assistance of a collaborative partner. Given the anticipated use of OTX-TP as a chronic therapy, we continue to generate six-month (300 patients) and one-year (100 patients) safety data from in an open-label one-year safety extension study to support a potential product registration.

OTX-TIC (intracanalicular 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 reduction in humans. Our investigational new drug application, or IND, for our U.S. trial became effective in the first quarter of 2018, and we dosed the first patient in May 2018. This clinical trial is a multi-center, open-label, dose-escalation, proof-of-concept study designed to evaluate the safety, durability, tolerability, and efficacy of OTX-TIC in patients with primary open-angle glaucoma or ocular hypertension. We presented initial results from the first cohort, comprised of five patients, in this clinical trial at the Association of Research and Vision of Ophthalmology (ARVO) meeting in April 2019 and the American Society of Cataract and Refractive Surgery annual meeting in May 2019. This data demonstrated that, with a single implant, subjects were able to achieve IOP lowering for up to thirteen months at a level least as good as topical travoprost that was placed in each subject's non-study eye. In addition, the hydrogel carrier, as designed, biodegraded in five to seven months. There were no clinically meaningful changes in corneal health as measured by endothelial cell evaluation and corneal pachymetry. Several subjects reported low grade inflammation and peripheral anterior synechiae that we believe may be addressable with modifications to the implants. We are currently collecting additional data from the first two cohorts and have begun a third cohort to assess the impact of a faster degrading implant with the same therapeutic dose as administered in cohort one. We have developed an additional formulation to test a smaller implant of OTX-TIC and expect to evaluate this formulation in a fourth cohort of this clinical trial in the future.

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 nine month period thereby reducing the frequency of the current monthly or bi-monthly immediate release intravitreal injection regimen for wet AMD and other retinal diseases.

OTX-TKI (intravitreal tyrosine kinase inhibitor ophthalmic 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. In the first quarter of 2019, we began dosing patients in a Phase 1 clinical trial in Australia. This clinical trial is a multi-center, open-label study designed to evaluate 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. The independent Data Safety and Monitoring Committee met to review the safety from the first cohort of subjects in the Phase 1 clinical trial and recommended moving to a higher dose of OTX-

TKI for the next cohort of subjects to be treated, as the first cohort of subjects reported no safety concerns. We are currently dosing this second, higher dose cohort.

OTX-IVT (intravitreal aflibercept 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.

Under the terms of the Collaboration Agreement, Regeneron is responsible for funding an initial preclinical tolerability study. 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.

In December 2017, we delivered to Regeneron a proposed final formulation for the initial preclinical tolerability study. Regeneron initiated the preclinical study in early 2018. We and Regeneron have subsequently reached an understanding that the proposed formulation was not final and have ceased development of it. We are currently in discussions with Regeneron, in accordance with the terms of the Collaboration Agreement, regarding the development of an alternative formulation.

ReSure® Sealant

We commercially launched this product in the United States in 2014. ReSure Sealant is approved to seal corneal incisions following cataract surgery. 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.

The FDA required two post-approval studies as a condition for approval of our premarket approval, 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 in eyes treated with ReSure Sealant. We submitted the final study report 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 Study, 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. The Device Exposure Registry Study is required to include at least 4,857 patients.

Due to difficulties in establishing an acceptable way to link ReSure Sealant to the Medicare database and lack of investigator interest, we have been unable to enroll trial sites and patients, collect patient data and report study data to the FDA. We have provided regular periodic reports to the FDA on the progress of this post-approval study.

We received a warning letter from the FDA in October 2018 relating to our compliance with data collection and information reporting obligations in the Device Exposure Registry Study. The FDA warning letter refers to a lack of progress with the enrollment and related data collection and information reporting obligations for a required post-approval trial. In November 2018, we appealed this warning letter. In December 2018, the FDA rejected our appeal. Failure by us to conduct the required post-approval trial for ReSure Sealant to the FDA's satisfaction may result in withdrawal of the FDA's approval of ReSure Sealant or other regulatory action.

A teleconference was held with the FDA in January 2019 resulting in tentative agreement on a proposed retrospective registry study of endophthalmitis rates to satisfy the Device Exposure Registry Study requirements. In a letter dated June 7, 2019 from the FDA, the agency acknowledged receipt of a letter dated March 29, 2019 from us in which we proposed conducting the proposed retrospective analysis of the IRIS Registry, comparing endophthalmitis rates from sites that purchased ReSure versus those sites that did not purchase ReSure. If the rates are no different, the FDA has indicated that it will consider the post-approval requirement to have been fulfilled. If there is a statistically significant increase in endophthalmitis rates at sites purchasing ReSure compared with those not purchasing ReSure, a prospective study will be required. The FDA has indicated it will consider our response to the warning letter adequate once it approves the study protocol for the retrospective analysis of the IRIS Registry and the outline of the prospective study. We are currently working on completing the protocol for the retrospective study and expect to submit the protocol to the FDA during the fourth quarter of 2019. ReSure Sealant currently remains commercially available in the United States, though there is no sales support provided to the product at this time. We have received only limited revenues from ReSure Sealant to date and anticipate only limited sales for 2019.

Additional Potential Areas for Growth

We continue to leverage the potential of our hydrogel platform to explore areas for growth with 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 other areas of the body and are studying several localized delivery platforms including via wound inlays; sinus and ear inserts; and subcutaneous, peripheral, and intra-articular injections. In September 2018, we entered into a second amended and restated license agreement, or Second Amended Agreement, with Incept LLC, an intellectual property holding company, or Incept. The Second Amended Agreement expands the scope of our intellectual property license to include products delivered for the treatment of acute post-surgical pain or for the treatment of ear, nose and/or throat diseases or conditions, subject to specified exceptions.

Financial Position

We have generated limited revenue to date. All of our programmed-release drug delivery products are in various phases of early commercial, clinical and preclinical development. Our ability to generate product revenues sufficient to achieve profitability will depend heavily on our commercialization of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery and our obtaining marketing approval for and commercializing other products with significant market potential, including DEXTENZA for additional indications. Since inception, we have incurred significant operating losses. Our net loss was $18.8 million and $15.0 million and $60.4 million and $42.6 million for the three and nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $357.6 million.

Our total costs and operating expenses were $24.0 million and $66.4 million for the three and nine months ended September 30, 2019, including $3.9 million and $8.7 million in non-cash stock-based compensation expense and depreciation expense. Our operating expenses have grown as we prepared for the commercial launch of DEXTENZA in July 2019; continue to pursue the clinical development OTX-TIC, OTX-TKI and DEXTENZA for additional indications; continue the internal development of our intravitreal hydrogel formulation for the local programmed-release of protein-based or small molecule anti-angiogenic drugs, such as OTX-IVT for the treatment of wet AMD and other back-of-the-eye diseases; continue the research and development of our other product candidates; and seek marketing approval for any such product candidate for which we obtain favorable pivotal clinical trial results. We expect to incur

substantial sales and marketing expenses in connection with the ongoing DEXTENZA commercial launch and that of any of our other product candidates. In addition, we will continue to incur additional costs associated with operating as a public company, including legal costs associated with any pending legal proceedings.

Although we expect to generate revenue from sales of DEXTENZA and potentially ReSure Sealant, we will need to obtain substantial additional funding to fully support our continuing operations and the commercialization of DEXTENZA. If we are unable to raise capital or access our borrowing capacity 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 a controlled equity offering sales agreement, or the 2016 Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, under which we could offer and sell our common stock having aggregate proceeds of up to $40.0 million from time to time. Through March 31, 2019, we sold an aggregate of 6,330,222 shares of common stock under the 2016 Sales Agreement, resulting in net proceeds of approximately $38.4 million after underwriting discounts and commissions and other offering expenses. As of February 25, 2019, we had no amounts remaining available for future sale under the 2016 Sales Agreement. On February 28, 2019, pursuant to the 2016 Sales Agreement, we delivered a termination notice to Cantor, terminating the 2016 Sales Agreement.

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 commissions and offering expenses.

On March 1, 2019, we issued $37.5 million of unsecured senior subordinated convertible notes, or the 2026 Convertible Notes. The 2026 Convertible Notes accrue interest at an annual rate of 6% of its outstanding principal amount, payable at maturity, on March 1, 2026, unless earlier converted, repurchased or redeemed. The holders of the 2026 Convertible Notes may convert all or part of the outstanding principal amount of their 2026 Convertible Notes into shares of our common stock, par value $0.0001 per share, prior to maturity and provided that no conversion results in a holder beneficially owning more than 19.99% of our issued and outstanding common stock. The conversion rate is initially 153.8462 shares of our common stock per $1,000 principal amount of the 2026 Convertible Notes, which is equivalent to an initial conversion price is $6.50 per share. The conversion rate is subject to adjustment in customary circumstances such as stock splits or similar changes to our capitalization.

On April 5, 2019, we entered into an Open Market Sale Agreement℠, or the 2019 Sales Agreement, with Jefferies LLC, or Jefferies, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million from time to time through Jefferies, acting as agent. In the second quarter of 2019, we sold 1,180,367 shares of common stock at-the-market under the 2019 Sales Agreement, resulting in net proceeds of approximately $5.1 million after underwriting discounts and commissions and expenses. In the third quarter of 2019, we sold 3,961,643 shares of common stock at-the-market under the 2019 Sales Agreement, resulting in net proceeds of approximately $18.6 million after underwriting discounts and commissions and expenses. From inception to November 2, 2019, we have sold 5,142,010 shares of common stock at-the-market under the 2019 Sales Agreement, resulting in net proceeds of approximately $23.7 million after underwriting discounts and commissions and expenses.

On August 2, 2019, we entered into the Second Amendment of our Third Amended and Restated Credit and Security Agreement, between us and our senior note lenders MidCap Financial and Silicon Valley Bank, whereby the lenders agreed to remove the restrictions on the $5.0 million of restricted cash required under the Third Amended and Restated Credit and Security Agreement as of June 30, 2019.

Based on our current plans and forecast expenses, we believe that our existing cash and cash equivalents of $65.4 million, as of September 30, 2019 and anticipated cash inflows from DEXTENZA product sales, along with the expected cost savings from the operational restructuring announced in early November 2019, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements through the end of the fourth quarter of 2020. This estimate is subject to a number of assumptions related to the revenues and expenses associated with the commercialization of DEXTENZA as well as the pace of our research and clinical development programs, and other aspects of our business. DEXTENZA has only recently launched and anticipated cash flows are subject to uncertainty,

and we do not expect that DEXTENZA revenue will be substantial in 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 will need to raise additional capital to support our ongoing operations. See "—Liquidity and Capital Resources."

Financial Operations Overview

Revenue

From our inception through September 30, 2019, we have generated limited amounts of revenue from the sales of our products. We began to recognize limited product revenue from DEXTENZA during the second quarter of 2019 with the first commercial shipments to customers in June 2019. Our ReSure Sealant product received premarket approval 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 2019. Until June 2019, ReSure Sealant was our only source of revenue from product sales. We may generate revenue in the future if we successfully commercialize DEXTENZA and develop and commercialize 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

Cost of Product Revenue

Cost of product revenue consists primarily of costs of DEXTENZA product revenue, which include:

- Direct materials costs;
- Direct labor, which includes employee-related expenses, including salaries, related benefits and payroll taxes, travel and stock-based compensation expense for employees engaged in the production process;
- Manufacturing overhead costs, which includes rent, depreciation, and indirect labor costs associated with the production process;
- Transportation costs; and
- Cost of scrap material.

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 trial 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
ReSure Sealant	$ 57	$ 58	$ 130	$ 96
DEXTENZA for post-surgical ocular inflammation and pain	274	458	789	825
DEXTENZA for allergic conjunctivitis	576	—	691	20
OTX-TP for glaucoma and ocular hypertension	252	1,445	1,410	4,181
OTX-TIC for glaucoma and ocular hypertension	181	—	480	—
OTX-TKI for Wet AMD	246	—	424	—
Preclinical programs	421	—	1,552	—
Unallocated expenses	8,227	7,724	25,489	21,535
Total research and development expenses	$ 10,234	$ 9,685	$ 30,965	$ 26,657

We expect our expenses will decrease in calendar year 2020, as a result of the operational restructuring in November 2019 that will delay certain clinical programs in the near term as we continue to concentrate our research and development activities on DEXTENZA, OTX-TIC, OTX-TKI and other product candidates and other research and development activities.

The successful development and commercialization of our products or 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 products or product candidates compared to alternative treatments, including any standard of care;
- the market acceptance of our products or 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 early commercial, 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.

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 and nine months ended September 30, 2019 and 2018, we incurred limited marketing expenses in connection with ReSure Sealant, which we began commercializing in 2014, and selling and marketing expenses in connection with the commercial launch and ongoing sales of DEXTENZA in July 2019. As we have now commercially launched DEXTENZA, our selling and marketing expenses will continue to increase.

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, human resources 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.

Other Income (Expense)

Interest Income. In 2018, interest income consists primarily of interest income earned on cash and cash equivalents. In the three and nine months ended September 30, 2019 and 2018, 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. We borrowed $15.0 million in aggregate principal amount in April 2014. In December 2015, we amended our credit and security agreement, or, as amended, our Credit Agreement, in connection with our credit facility, or our Credit Facility, to increase the aggregate principal amount to $15.6 million, extend the interest-only payment period through December 2016, and extend the maturity date to December 1, 2019. In March 2017, we amended the Credit Agreement to increase the aggregate principal amount under the Credit Facility to $18.0 million, extend the interest-only payment period through February 2018, and extend the maturity date to December 1, 2020. In December 2018, we amended the Credit Agreement to increase the aggregate principal amount under the Credit Facility to $25.0 million, extend the interest-only payment period through December 2020, and extend the maturity date to December 2023. In March 2019, we issued $37.5 million of unsecured senior subordinated convertible notes, or the 2026 Convertible Notes. The 2026 Convertible Notes accrue interest at an annual rate of 6% of its outstanding principal amount, payable at maturity, on March 1, 2026, unless earlier converted, repurchased or redeemed.

Change in Fair Value of Derivative Liability. In 2019, in connection with the issuance of our 2026 Convertible Notes, we identified an embedded derivative liability, which we are required to measure at fair value at inception and then at the end of each reporting until the embedded derivative is settled. The changes in fair value are recorded through the statement of operations and comprehensive loss and are presented under the caption change in fair value of derivative liability.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of our consolidated 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 consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments. 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 and nine months ended September 30, 2019, 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 7, 2019 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;
- and, derivative liability.

During the three months ended March 31, 2019, in connection with issuance of our 2026 Convertible Notes, we identified an embedded derivative liability, which we are required to measure at fair value at inception and then at the end of each reporting until the embedded derivative is settled.

Given the judgment and complexity involved in determining the fair value of this liability, we concluded that this derivative liability is a critical accounting policy. The fair value of the 2026 Convertible Notes with and without the conversion option is estimated using a binomial lattice approach. The key inputs to valuing the 2026 Convertible Notes with the conversion option include our stock price on the valuation date, the expected annual volatility of our common stock and the bond yield, which was derived by making the fair value of the 2026 Convertible Notes equal to the face value on the issuance date. Fair value measurements are highly sensitive to changes in these inputs and significant changes in these inputs would result in a significantly higher or lower fair value.

Accordingly, we believe the policies set forth in our Annual Report on Form 10-K filed with the SEC on March 7, 2019 are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

Results of Operations

Comparison of the Three Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Increase (Decrease)
	2019	2018	
	(in thousands)		
Revenue:			
Product revenue, net	$ 829	$ 498	$ 331
Total revenue	829	498	331
Costs and operating expenses:			
Cost of product revenue	806	115	691
Research and development	10,235	9,685	550
Selling and marketing	6,777	1,067	5,710
General and administrative	6,155	4,447	1,708
Total costs and operating expenses	23,973	15,314	8,659
Loss from operations	(23,144)	(14,816)	(8,328)
Other income (expense):			
Interest income	308	230	78
Interest expense	(1,651)	(424)	(1,227)
Change in fair value of derivative liability	5,717	—	5,717
Other income (expense), net	(8)	—	(8)
Total other income (expense), net	4,366	(194)	4,560
Net loss	$ (18,778)	$ (15,010)	$ (3,768)

Revenue

We generated $0.8 million of revenue during the three months ended September 30, 2019 from sales of our DEXTENZA and ReSure Sealant product. We generated $0.5 million of revenue during the three months ended September 30, 2018, from sales of our ReSure Sealant product. We began to recognize product revenue from DEXTENZA during the second quarter of 2019 with the first commercial shipments to customers in June 2019. In 2018, we only had product revenue from ReSure Sealant.

Research and Development Expenses

	Three Months Ended September 30,		Increase (Decrease)
	2019	2018	
	(in thousands)		
Direct research and development expenses by program:			
ReSure Sealant	$ 57	$ 58	$ (1)
DEXTENZA for post-surgical ocular inflammation and pain	274	458	(184)
DEXTENZA for allergic conjunctivitis	576	—	576
OTX-TP for glaucoma and ocular hypertension	252	1,445	(1,193)
OTX-TIC for glaucoma and ocular hypertension	181	—	181
OTX-TKI for Wet AMD	246	—	246
Preclinical programs	421	—	421
Unallocated expenses:			
Personnel costs	5,305	4,428	877
All other costs	2,922	3,296	(374)
Total research and development expenses.	$ 10,234	$ 9,685	$ 549

Research and development expenses were $10.2 million for the three months ended September 30, 2019, compared to $9.7 million for the three months ended September 30, 2018. Research and development costs increased by $0.5 million primarily due to an increase of $0.9 million in unallocated personnel costs offset by a decrease of $0.4 million in unallocated all other costs, and a net decrease of $0.1 million in costs incurred in connection with our DEXTENZA program, our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension, our OTX-TIC program for glaucoma and ocular hypertension, OTX-TKI for Wet AMD and our other preclinical programs.

For the three months ended September 30, 2019, we incurred $2.0 million in direct research and development expenses for our programmed-release drug delivery product candidates, including $0.6 million for DEXTENZA for the treatment of allergic conjunctivitis, $0.3 million for DEXTENZA for the treatment of post-surgical inflammation and $0.3 million for OTX-TP. For the three months ended September 30, 2018, we incurred $1.9 million in direct research and development expenses for our sustained release drug delivery product candidates, including $0.5 million for our DEXTENZA product candidate for the treatment of post-surgical ocular inflammation and pain which was in Phase 3 clinical trials, and $1.4 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 $0.5 million for the three months ended September 30, 2019, compared to the three months ended September 30, 2018, due primarily to an increase in personnel costs of $0.9 million due to additional hiring primarily in our clinical, regulatory and quality departments offset by a decrease of $0.4 million in all other costs.

Selling and Marketing Expenses

	Three Months Ended September 30,		Increase (Decrease)
	2019	2018	
	(in thousands)		
Personnel related (including stock-based compensation)	$ 3,607	$ 394	$ 3,213
Professional fees	2,345	562	1,783
Facility related and other	825	111	714
Total selling and marketing expenses	$ 6,777	$ 1,067	$ 5,710

Selling and marketing expenses were $6.8 million for the three months ended September 30, 2019, compared to $1.1 million for the three months ended September 30, 2018. The increase of $5.7 million was primarily due to increases of $3.2 million in personnel costs, including stock-based compensation, $1.8 million in professional fees including consulting, trade shows, marketing material and conferences and $0.7 million in facility related and other costs as we continued the support of the launch of DEXTENZA.

We expect our selling and marketing expenses to continue to increase in 2019 and beyond, due to the approval of DEXTENZA as we support the commercial launch.

General and Administrative Expenses

	Three Months Ended September 30,		Increase (Decrease)
	2019	2018	
	(in thousands)		
Personnel related (including stock-based compensation)	$ 3,790	$ 2,068	$ 1,722
Professional fees	1,587	2,044	(457)
Facility related and other	778	335	443
Total general and administrative expenses	$ 6,155	$ 4,447	$ 1,708

General and administrative expenses were $6.2 million for the three months ended September 30, 2019, compared to $4.4 million for the three months ended September 30, 2018. The increase of $1.7 million was primarily due to an increase of $1.7 million in personnel costs, including stock-based compensation, and $0.4 million in facility related costs offset by a decrease in professional fees.

Other Income (Expense), Net

Other income, net was $4.4 million for the three months ended September 30, 2019, compared to other expense, net of $0.2 million for the three months ended September 30, 2018. The change of $4.6 million, was due to the change in fair value of the derivative liability associated with the 2026 Convertible Notes of $5.7 million offset by higher interest expense of $1.2 million associated with the Credit Facility and the 2026 Convertible Notes. The change in fair value of the derivative liability was a gain in the amount of $5.7 million during the three months ended September 30, 2019 due changes in the underlying assumptions of the derivative liability, primarily related to a decline in our common stock price. We expect the change in fair value of the derivative liability will continue to fluctuate until it is settled based on the extent changes occur in the underlying assumptions. There was no change in fair value of derivative liability during the three months ended September 30, 2018 as there was no were no embedded derivatives during that period.

Comparison of the Nine months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,		Increase (Decrease)
	2019	2018	
	(in thousands)		
Revenue:			
Product revenue, net	$ 1,971	$ 1,486	$ 485
Total revenue, net	1,971	1,486	485
Costs and operating expenses:			
Cost of product revenue	1,486	348	1,138
Research and development	30,966	26,657	4,309
Selling and marketing	17,349	2,651	14,698
General and administrative	16,571	13,665	2,906
Total costs and operating expenses	66,372	43,321	23,051
Loss from operations	(64,401)	(41,835)	(22,566)
Other income (expense):			
Interest income	1,016	621	395
Interest expense	(4,296)	(1,365)	(2,931)
Change in fair value of derivative liability	7,334	—	7,334
Other income (expense), net	(8)	—	(8)
Total other income (expense), net	4,046	(744)	4,790
Net loss	$(60,355)	$(42,579)	$(17,776)

Revenue

We generated $2.0 million of revenue during the nine months ended September 30, 2019 from sales of our DEXTENZA and ReSure Sealant products compared to $1.5 million for the nine months ended September 30, 2018. We began to recognize product revenue from DEXTENZA during the second quarter of 2019 with the first commercial shipments to customers in June 2019. In 2018, we only had product revenue from ReSure Sealant.

Research and Development Expenses

	Nine Months Ended September 30,		Increase (Decrease)
	2019	2018	
	(in thousands)		
Direct research and development expenses by program:			
ReSure Sealant	$ 130	$ 96	$ 34
DEXTENZA for post-surgical ocular inflammation and pain	789	825	(36)
DEXTENZA for allergic conjunctivitis	691	20	671
OTX-TP for glaucoma and ocular hypertension	1,410	4,181	(2,771)
OTX-TIC for glaucoma and ocular hypertension	480	—	480
OTX-TKI for Wet AMD	424	—	424
Preclinical activities	1,552	—	1,552
Unallocated expenses:			
Personnel costs	15,391	12,704	2,687
All other costs	10,098	8,831	1,267
Total research and development expenses	$30,965	$26,657	$ 4,308

Research and development expenses were $31.0 million for the nine months ended September 30, 2019, compared to $26.7 million for the nine months ended September 30, 2018. Research and development costs increased by $4.3 million primarily as a result of increases of $2.7 million in unallocated personnel costs, $1.3 million in all other costs, and $0.3 million in costs incurred in connection with the clinical trials of our DEXTENZA product candidate for the treatment of post-surgical ocular inflammation and pain, our DEXTENZA product candidate for the treatment of allergic

conjunctivitis, our DEXTENZA product candidate for the treatment of dry eye disease and our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension, and other preclinical activities.

For the nine months ended September 30, 2019, we incurred $5.3 million in direct research and development expenses for our sustained release drug delivery product candidates for the front of the eye, including $0.8 million for our DEXTENZA product candidate for the treatment of post-surgical ocular inflammation and pain and $1.4 million for our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension which was in Phase 3 clinical trials. For the nine months ended September 30, 2018, we incurred $5.0 million in direct research and development expenses for our sustained release drug delivery product candidates for the front of the eye, including $0.8 million for our DEXTENZA product candidate for the treatment of post-surgical ocular inflammation and pain which was in Phase 3 clinical trials and $4.2 million for our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension which was in Phase 3 clinical trials. Unallocated research and development expense increased $4.0 million for the nine months ended September 30, 2019, compared to the nine months ended September 30, 2018, due primarily to an increase in personnel costs of $2.7 million due to additional hiring primarily in our clinical, regulatory and quality departments and $1.3 million in all other costs.

Selling and Marketing Expenses

	Nine Months Ended September 30,		Increase
	2019	2018	(Decrease)
	(in thousands)		
Personnel related (including stock-based compensation)	$ 8,542	$ 1,185	$ 7,357
Professional fees	6,729	1,104	5,625
Facility related and other	2,078	362	1,716
Total selling and marketing expenses	$17,349	$ 2,651	$14,698

Selling and marketing expenses were $17.3 million for the nine months ended September 30, 2019, compared to $2.7 million for the nine months ended September 30, 2018. The increase of $14.7 million was primarily due to an increase of $7.4 million in personnel costs, including stock-based compensation, an increase of $5.6 million in professional fees including consulting, trade shows and conferences and an increase of $1.7 million in facility-related and other costs. The increase is primarily related to the addition of the KAMs in the second quarter of 2019 to support the launch of DEXTENZA.

General and Administrative Expenses

	Nine Months Ended September 30,		Increase
	2019	2018	(Decrease)
	(in thousands)		
Personnel related (including stock-based compensation)	$ 8,474	$ 6,140	$ 2,334
Professional fees	6,174	6,389	(215)
Facility related and other	1,923	1,136	787
Total general and administrative expenses	$16,571	$13,665	$ 2,906

General and administrative expenses were $16.6 million for the nine months ended September 30, 2019, compared to $13.7 million for the nine months ended September 30, 2018. The increase of $2.9 million was primarily due to an increase of $2.3 million in personnel costs, including stock-based compensation expense, an increase of $0.8 million in facility-related and other costs offset by decrease of $0.2 million in professional fees.

Other Income (Expense), Net

Other income, net was $4.0 million for the nine months ended September 30, 2019, compared to other expense, net of $0.7 million for the nine months ended September 30, 2018. The change of $4.8 million, was due to the change in fair value of the derivative liability associated with the 2026 Convertible Notes of $7.3 million partially offset by higher interest expense of $2.9 million associated with the Credit Facility and the 2026 Convertible Notes. The change in fair value of the derivative liability was a gain in the amount of $7.3 million during the nine months ended September 30, 2019 due changes in the underlying assumptions of the derivative liability, primarily related to a decline in our common

stock price. We expect the change in fair value of the derivative liability will continue to fluctuate until it is settled based on the extent changes occur in the underlying assumptions. There was no change in fair value of derivative liability during the nine months ended September 30, 2018 as there was no were no embedded derivatives during that period.

Operational Restructuring – November 2019

On November 6, 2019, we announced an operational restructuring plan to eliminate a portion of our workforce and defer certain development programs as part of an initiative to reduce expenses and prioritize our resources to focus on commercializing DEXTENZA for post-surgical ocular pain and inflammation as well as completing the ongoing Phase 3 clinical trial of DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis, a Phase 1 clinical trial of OTX-TIC for the treatment of glaucoma and ocular hypertension, and a Phase 1 clinical trial of OTX-TKI for the treatment of wet age-related macular degeneration. This operational restructuring included a reduction in force. We currently expect to substantially complete the restructuring and to record the restructuring charges in the fourth quarter of 2019. We anticipate incurring total restructuring costs of approximately $0.7 million, which includes severance, benefits and related costs, all of which are expected to result in cash expenditures. Of the approximately $0.7 million in severance, benefits and related costs, we expect that approximately $0.6 million would be paid during the three months ending December 31, 2019, and the remaining approximately $0.1 million would be paid during 2020. We estimate the restructuring and other cost-saving efforts to result in approximately $11 million in future annualized savings and $14 million in one-time program deferrals once fully implemented.

Liquidity and Capital Resources

Since inception, we have incurred significant operating losses. Our net losses were $60.4 million and $42.6 million for the nine months ended September 30, 2019 and 2018, respectively, and $60.0 million and $63.4 million for the years ended December 31, 2018 and 2017, respectively. As of September 30, 2019, we had an accumulated deficit of $357.6 million.

We have generated limited revenue to date. In 2014, we began recognizing revenue from sales of ReSure Sealant. We commercially launched DEXTENZA for post-surgical ocular inflammation and pain in July 2019. All of our other sustained drug delivery products are in various phases of pre-commercial, clinical and preclinical development. Our ability to generate product revenues sufficient to achieve profitability will depend heavily on our commercialization of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery and our obtaining marketing approval for and commercializing other products with significant market potential, including DEXTENZA for additional indications.

Through September 30, 2019, we have financed our operations primarily through private placements of our preferred stock, public offerings of our common stock, private placements of our convertible notes and borrowings under credit facilities. 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 commissions and offering expenses.

In November 2016, we entered into the 2016 Sales Agreement with Cantor, under which we could offer and sell our common stock having aggregate proceeds of up to $40.0 million from time to time. Through February 25, 2019, we have sold an aggregate of 6,330,222 shares of common stock under the 2016 Sales Agreement resulting in net proceeds of approximately $38.4 million after underwriting discounts and commissions and other offering expenses. On February 28, 2019, pursuant to the 2016 Sales Agreement, we delivered a termination notice to Cantor, terminating the 2016 Sales Agreement.

In December 2018, we amended our Credit Agreement to increase the total indebtedness to $25.0 million. The interest-only payment period was extended through December 2020.

On March 2019, we issued $37.5 million of unsecured senior subordinated convertible notes, or the 2026 Convertible Notes. The 2026 Convertible Notes accrue interest at an annual rate of 6% of its outstanding principal amount, payable at maturity, on March 1, 2026, unless earlier converted, repurchased or redeemed. The holders of the

2026 Convertible Notes may convert all or part of the outstanding principal amount of their 2026 Convertible Notes into shares of our common stock, par value $0.0001 per share, prior to maturity and provided that no conversion results in a holder beneficially owning more than 19.99% of our issued and outstanding common stock. The conversion rate is initially 153.8462 shares of our common stock per $1,000 principal amount of the 2026 Convertible Notes, which is equivalent to an initial conversion price is $6.50 per share. The conversion rate is subject to adjustment in customary circumstances such as stock splits or similar changes to our capitalization.

On April 5, 2019, we entered into the 2019 Sales Agreement with Jefferies, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million from time to time through Jefferies, acting as agent. In the third quarter of 2019, we sold 3,961,643 shares of common stock at-the-market under the 2019 Sales Agreement, resulting in net proceeds of approximately $18.6 million after underwriting discounts and commissions and expenses. From inception through November 2, 2019, we have sold 5,142,010 shares of common stock at-the-market under the 2019 Sales Agreement, resulting in net proceeds of approximately $23.7 million after underwriting discounts and commissions and expenses.

We may receive $10.0 million under our 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. However, if the option is exercised, Regeneron will conduct further preclinical development and an initial clinical trial under a collaboration plan and 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.

As of September 30, 2019, we had cash and cash equivalents of $65.4 million; outstanding debt of $25.0 million, net of unamortized discount; and convertible notes, of $37.5 million of aggregate principal amount of senior subordinated convertible notes, plus accrued interest of $1.3 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 of $65.4 million, as of September 30, 2019 and anticipated cash inflows from DEXTENZA product sales, along with the expected cost savings from the operational restructuring announced in early November 2019, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements through the end of the fourth quarter of 2020. This estimate is subject to a number of assumptions related to the revenues and expenses associated with the commercialization of DEXTENZA as well as the pace of our research and clinical development programs, and other aspects of our business. DEXTENZA has only recently launched and anticipated cash flows are subject to uncertainty, and we do not expect that DEXTENZA revenue will be substantial in 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. 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:

	Nine Months Ended September 30,	
	2019	2018
Cash used in operating activities	$ (58,111)	$ (35,579)
Cash used in investing activities	(1,637)	(1,410)
Cash provided by financing activities	66,250	52,312
Net increase in cash and cash equivalents	$ 6,502	$ 15,323

Operating activities. Net cash used in operating activities was $58.1 million for the nine months ended September 30, 2019, primarily resulting from our net loss of $60.4 million and changes in our operating assets and liabilities of $1.6 million, partially offset by $3.8 million of non-cash items. Our net loss was primarily attributed to research and development activities, selling and marketing expenses, and our general and administrative expenses, which are significantly offset any contributions from our revenues to date. Our net non-cash charges during the nine months ended September 30, 2019 consisted primarily of $11.1 million of stock-based compensation expense, depreciation expense and other non-cash expenses partially offset by the change in fair value of the derivative liability of $7.3 million. Net

cash used by changes in our operating assets and liabilities during the nine months ended September 30, 2019 consisted primarily of increases in accounts receivable and inventories as we continue with the commercialization of DEXTENZA.

Net cash used in operating activities was $35.6 million for the nine months ended September 30, 2018, primarily resulting from our net loss of $42.6 million and changes in our operating assets and liabilities of $0.5 million, partially offset by non-cash charges of $7.5 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 nine months ended September 30, 2018 consisted primarily of $7.2 million of stock-based compensation expense and depreciation expense. Net cash used by changes in our operating assets and liabilities during the nine months ended September 30, 2018 consisted primarily of an increase in accounts payable and accrued expenses of $0.9 million, partially offset by increases in prepaid expenses and other current assets of $0.4 million. The changes in accounts payable and accrued expenses were due to the timing of vendor invoicing and payments.

Investing activities. Net cash used in investing activities for the nine months ended September 30, 2019 and 2018 totaled $1.6 million and $1.4 million, respectively. For the nine months ended September 30, 2019, net cash used in investing activities is due to $1.6 million of purchases of property and equipment, which consisted primarily of laboratory equipment. For the nine months ended September 30, 2018, net cash used in investing activities is due to the $1.4 million of purchases of property and equipment, which consisted primarily of laboratory equipment.

Financing activities. Net cash provided by financing activities for the nine months ended September 30, 2019 was $66.3 million and for the nine months ended September 30, 2018 was $52.3 million. Net cash provided by financing activities for the nine months ended September 30, 2019 consisted primarily of proceeds from the 2026 Convertible Notes of $37.3 million and the 2016 Sales Agreement of $5.0 million, net of underwriting discounts and commissions and other offering expenses and 2019 Sales Agreement of $23.6 million, net of underwriting discounts and commissions and other offering expenses. Net cash provided by financing activities for the nine months ended September 30, 2018 was $52.3 million and for the nine months ended September 30, 2017 was $30.8 million. Net cash provided by financing activities for the nine months ended September 30, 2018 consisted primarily of proceeds from our follow-on offering in January 2018 and the 2016 Sales Agreement of $56.0 million, net of underwriting discounts and other offering expenses, and $0.3 million from the exercise of common stock options, partially offset by $4.1 million for principal payments under our Credit Facility.

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 commercialize DEXTENZA in the United States;
- continue to develop and expand our sales, marketing and distribution capabilities for DEXTENZA and any of our product candidates;
- continue to pursue the clinical development of DEXTENZA for additional indications;
- continue 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 and potential opportunities outside the field of ophthalmology;
- seek marketing approvals for any of our product candidates that successfully complete clinical development;
- 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 any corresponding 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;
- defend ourselves against legal proceedings;
- 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.

On November 6, 2019, our board of directors approved an operational restructuring plan to eliminate a portion of our workforce and defer certain development programs as part of an initiative to reduce expenses and prioritize our resources to focus on commercializing DEXTENZA® for post-surgical ocular pain and inflammation as well as completing the ongoing Phase 3 clinical trial of DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis, a Phase 1 clinical trial of OTX-TIC for the treatment of glaucoma and ocular hypertension, and a Phase 1 clinical trial of OTX-TKI for the treatment of wet age-related macular degeneration. This operational restructuring included a reduction in force of 55 full-time employees of the Company, representing approximately twenty-two percent (22%) of our workforce, and the elimination of an additional 31 positions that were vacant.

We currently expect to substantially complete the restructuring and to record the restructuring charges in the fourth quarter of 2019. We anticipate incurring total restructuring costs of approximately $0.7 million, which includes severance, benefits and related costs, all of which are expected to result in cash expenditures. Of the approximately $0.7 million in severance, benefits and related costs, we expect that approximately $0.6 million would be paid during the three months ending December 31, 2019, and the remaining approximately $0.1 million would be paid during 2020. We estimate the restructuring and other cost-saving efforts to result in approximately $11 million in future annualized savings and $14 million in one-time program deferrals once fully implemented.

Based on our current plans and forecasted expenses, we believe that our existing cash and cash equivalents of $65.4 million, as of September 30, 2019 and anticipated cash inflows from DEXTENZA product sales, along with the expected cost savings from the operational restructuring announced in early November 2019, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements through the end of the fourth quarter of 2020. This estimate is subject to a number of assumptions related to the revenues and expenses associated with the commercialization of DEXTENZA as well as the pace of our research and clinical development programs, and other aspects of our business. DEXTENZA has only recently launched and anticipated cash flows are subject to uncertainty, and we do not expect that DEXTENZA revenue will be substantial in 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.

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

- our ability to successfully commercialize and sell DEXTENZA in the United States;

- the costs, timing and outcome of regulatory review of our product candidates by the FDA, the EMA or other regulatory authorities;
- the level of product sales from DEXTENZA and any additional products for which we obtain marketing approval in the future;
- the costs of manufacturing, sales, marketing, distribution and other commercialization efforts with respect to DEXTENZA and any additional products for which we obtain marketing approval in the future;
- the costs of expanding our facilities to accommodate our manufacturing needs and headcount;
- the progress, costs and outcome of the clinical trials of our extended-delivery drug delivery product candidates, in particular DEXTENZA for additional indications;
- 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 scope, progress, costs and outcome of preclinical development and clinical trials of our other product candidates;
- the extent of our debt service obligations;
- the amounts we are entitled to receive, if any, from Regeneron for potential option exercise, development, regulatory and sales milestones and royalty payments;
- the extent to which we choose to establish additional collaboration, distribution or other marketing arrangements for our products and product candidates;
- the costs and outcomes of legal actions and proceedings, including the current lawsuits described under "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, royalty agreements, and marketing and distribution arrangements. We do not have any committed external source of funds, although our collaboration agreement with Regeneron provides for the potential receipt of option exercise, development, regulatory and sales milestones and royalties payments. 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 Agreement, 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, royalty agreements, 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 financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, 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 and anticipated cash inflows from DEXTENZA product sales, along with the expected cost savings from the operational restructuring announced in early November 2019, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements through the end of the fourth quarter of 2020, based on our current plans and forecasted expenses, 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 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, 2018, we had federal net operating loss carryforwards of $190.6 million, which begin to expire in 2026, and state net operating loss carryforwards of $161.8 million, which begin to expire in 2026. As of December 31, 2018, we also had federal research and development tax credit carryforwards of $7.0 million and state research and development tax credit carryforwards $3.6 million, which begin to expire in 2026 and 2025, respectively. We have not completed a study to assess whether an ownership change, generally defined as a greater than 50% change (by value) in the equity ownership of our corporate entity over a three-year period, has occurred or whether there have been multiple ownership changes since our inception, due to the significant costs and complexities associated with such studies. Accordingly, our ability to utilize our tax carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at September 30, 2019 and the effects such obligations are expected to have on our liquidity and cash flow in future periods:

	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
			(in thousands)		
Operating lease commitments	$ 15,799	$ 2,421	$ 4,999	$ 4,213	$ 4,166
Purchase commitments	3,395	2,125	1,189	81	—
Debt obligations including interest	32,788	2,484	18,250	12,054	—
2026 Convertible Notes	53,469	—	—	—	53,469
Total	$105,451	$ 7,030	$24,438	$16,348	$57,635

In the table above, we set forth our enforceable and legally binding obligations and future commitments at September 30, 2019, as well as obligations related to contracts that we are likely to continue, regardless of the fact that they may be cancelable at September 30, 2019. Some of the figures that we include in this table are based on management's estimates and assumptions about these obligations, including their duration, and other factors. Because these estimates and assumptions are necessarily subjective, the obligations we will actually pay in future periods may vary from those reflected in the table.

Operating lease commitments represent payments due under our leases of office, laboratory and manufacturing space in Bedford, Massachusetts and certain office equipment under operating leases that expire in July 2023, March 2024 and July 2027.

In June 2016, we entered into a lease agreement for approximately 70,712 square feet of general office, research and development and manufacturing space. The lease term commenced on February 1, 2017 and expires on July 31,

2027. No base rent was due under the lease until August 1, 2017. The initial annual base rent is approximately $1.2 million and will increase annually beginning on February 1 of each year. We are obligated to pay all real estate taxes and costs related to the premises, including costs of operations, maintenance, repair, and replacement and management of the new leased premises. We posted a customary letter of credit in the amount of $1.5 million as a security deposit. The lease agreement allowed for a construction allowance not to exceed approximately $2.8 million to be applied to the total construction costs of the new leased premises.

On October 10, 2017, we entered into an amendment to the lease agreement for our laboratory and manufacturing space located at 34 Crosby Drive and 36 Crosby Drive, each in Bedford, Massachusetts, which we refer to as the Second Amendment. The Second Amendment extends the term of our lease for 36 Crosby Drive from June 30, 2018 to July 31, 2023. Further, the Second Amendment acknowledges that we have previously vacated and surrendered, and the lease has expired with regards to 34 Crosby Drive, reducing the total laboratory and manufacturing space subject to the lease to 20,445 square feet. Accordingly, the Second Amendment reduces the required security deposit under the lease from $0.2 million to $0.1 million. Under the Second Amendment, the annual base rent for 36 Crosby Drive shall be approximately $0.5 million until June 30, 2018, shall be $0 from July 1, 2018 to July 31, 2018, and shall be approximately $0.5 million from August 1, 2018 to July 31, 2019. The annual base rent shall increase annually thereafter. The Second Amendment also provides us a one-time option to terminate the Lease on July 31, 2021, upon the delivery to the landlord on or before July 31, 2020, of a termination notice and the payment to the landlord of a termination fee of approximately $0.3 million.

On April 4, 2019, we entered into a sublease agreement for approximately 30,036 square feet of general office space located at 24 Crosby Drive in Bedford, Massachusetts. The lease term commenced on April 4, 2019 and expires on March 31, 2024. No base rent was due under the lease until July 2019. The initial annual base rent is approximately $0.6 million and will increase annually beginning on April 1 of each year. We are obligated to pay all real estate taxes and costs related to the premises. We posted a customary letter of credit in the amount of approximately $0.2 million as a security deposit. These rent payments have not been included in the table of contractual obligations and commitments above. We relocated our corporate headquarters to the new leased premises in August 2019.

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

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

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

In April 2014, we entered into the Credit Agreement to establish the Credit Facility with Silicon Valley Bank and MidCap Financial SBIC, LP, pursuant to which we were able to borrow an aggregate principal amount of up to $20.0 million, of which we borrowed $15.0 million. We did not borrow the remaining $5.0 million, and this amount is no longer available to us. The Credit Facility carried a fixed annual interest rate of 8.25% on outstanding borrowings. In April 2014, we issued the lenders warrants to purchase 100,000 shares of our Series D-1 redeemable convertible preferred stock with an exercise price of $3.00 per share. Upon the closing of our IPO in July 2014, the preferred stock warrants became warrants to purchase an aggregate of 37,878 shares of our common stock with an exercise price of $7.92 per share.

In December 2015, we amended the Credit Agreement to increase the aggregate principal amount under the Credit Facility to $15.6 million to capitalize certain accrued interest. The Credit Facility provided for monthly, interest-only payments on outstanding borrowings through December 2016. Thereafter, we were required to pay thirty-six consecutive, equal monthly installments of principal and interest through December 1, 2019. In March 2017, we further amended the Credit Agreement increase the aggregate principle borrowed under the Credit Facility to $18.0 million. The interest-only payment period was extended through February 1, 2018. There were no financial covenants associated with the Credit Agreement.

In December 2018, we further amended the Credit Agreement to increase the aggregate principal amount borrowed under the Credit Facility to $25.0 million. The interest-only payment period was extended through December 2020. Commencing in January 2021, we are required to make 36 equal monthly installments of principal in the amount of $0.7 million, plus interest, through December 2023. Under the December 2018 amendment, we were required to maintain a minimum of $5.0 million of cash and/or cash equivalents on hand as a financial covenant to the borrowing arrangement. There are no other financial covenants associated with the Credit Agreement; however, there are negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions; incurring indebtedness, liens or encumbrances; paying dividends; making certain investments; and engaging in certain other business transactions. The obligations under the Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition. The debt is collateralized by a first-priority lien on all of our assets, including our intellectual property.

In connection with our entry into the Purchase Agreement, as described below, in February 2019, we further amended the Credit Agreement to permit our issuance and sale of the 2026 Convertible Notes in March 2019. The February amendment added, among other provisions, a negative covenant restricting us from paying the holders of the 2026 Convertible Notes ahead in priority to the senior lenders, for so long as indebtedness remains outstanding under the Credit Facility, and a cross-default provision to establish that an event of default under the Purchase Agreement also constituted an event of default under the Credit Agreement. In August 2019, we entered into the Second Amendment to the Credit Agreement to further amended the Credit Agreement to remove restrictions on us to maintain a minimum of $5.0 million of cash on hand as a financial covenant.

We have in-licensed a significant portion of our intellectual property from Incept, an intellectual property holding company, under an amended and restated license agreement, or the License Agreement, that we entered into with Incept in January 2012, which was most recently amended in September 2018. We are obligated to pay Incept a royalty equal to a low-single-digit percentage of net sales made by us or our affiliates of any products, devices, materials, or components thereof, or the Licensed Products, including or covered by Original IP (as defined in the License Agreement), excluding the Shape-Changing IP (as defined in the License Agreement), in the Ophthalmic Field of Use (as defined in the License Agreement). We are obligated to pay Incept a royalty equal to a mid-single-digit percentage of net sales made by us or our affiliates of any Licensed Products including or covered by Original IP, excluding the Shape-Changing IP, in the Additional Field of Use (as defined in the License Agreement). We are obligated to pay Incept a royalty equal to a low-single-digit percentage of net sales made by us or our affiliates of any Licensed Products including or covered by Incept IP (as defined in the License Agreement) or Joint IP (as defined in the License Agreement) in the field of drug delivery. Any sublicensee of ours also will be obligated to pay Incept a royalty on net sales of Licensed Products made by it and will be bound by the terms of the agreement to the same extent as we are. We are obligated to reimburse Incept for our share of the reasonable fees and costs incurred by Incept in connection with the prosecution of the patent applications licensed to us under the agreement. Our share of these fees and costs is equal to the total amount of such fees and costs divided by the total number of Incept's exclusive licensees of the patent application. We have not included in the table above any payments to Incept under this license agreement as the amount, timing and likelihood of such payments are not known.

In October 2016, we entered into the Collaboration Agreement with Regeneron. 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 $25.0 million, which cap may be increased by up to $5.0 million under certain circumstances. We have not included in the table above any payments to Regeneron under this Collaboration Agreement as the timing of such payments are not known. Regeneron will be responsible for funding an initial preclinical tolerability study, which Regeneron initiated in early 2018. We do not expect our funding requirements under our collaboration with Regeneron 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.

On March 2019, we issued the 2026 Convertible Notes pursuant to a note purchase agreement, or the Purchase Agreement. The 2026 Convertible Notes accrue interest at an annual rate of 6% of its outstanding principal amount, payable at maturity, on March 1, 2026, unless earlier converted, repurchased or redeemed. The holders of the 2026 Convertible Notes may convert all or part of the outstanding principal amount of their 2026 Convertible Notes into shares of our common stock, par value $0.0001 per share, prior to maturity and provided that no conversion results in a holder beneficially owning more than 19.99% of our issued and outstanding common stock. The conversion rate is

initially 153.8462 shares of our common stock per $1,000 principal amount of the 2026 Convertible Notes, which is equivalent to an initial conversion price is $6.50 per share. The conversion rate is subject to adjustment in customary circumstances such as stock splits or similar changes to our capitalization. At our election, we may choose to make such conversion payment in cash, in shares of common stock, or in a combination thereof. Upon any conversion of any 2026 Convertible Note, we are obligated to make a cash payment to the holder of such 2026 Convertible Note for any interest accrued but unpaid on the principal amount converted. Upon the occurrence of a Corporate Transaction (as defined in the 2026 Convertible Notes), the holder of a 2026 Convertible Note is entitled, at such holder's option, to convert all of the outstanding principal amount of the 2026 Convertible Note in accordance with the foregoing and receive an additional, "make-whole" cash payment in accordance with a table set forth in each 2026 Convertible Note.

Upon the occurrence of a Corporate Transaction, each holder of a 2026 Convertible Note has the option to require us to repurchase all or part of the outstanding principal amount of such 2026 Convertible Note at a repurchase price equal to 100% of the outstanding principal amount of the 2026 Convertible Note to be repurchased, plus accrued and unpaid interest to, but excluding, the repurchase date.

On or after March 1, 2022, if the last reported sale price of the common stock has been at least 130% of the conversion rate then in effect for twenty of the preceding thirty trading days (including the last trading day of such period), we are entitled, at our option, to redeem all or part of the outstanding principal amount of the 2026 Convertible Notes, on a pro rata basis, at an optional redemption price equal to 100% of the outstanding principal amount of the 2026 Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the optional redemption date.

The Purchase Agreement contains customary representations and warranties by us and the noteholder. The Purchase Agreement does not include any financial covenants. Our obligations under the Purchase Agreement and the 2026 Convertible Notes are subject to acceleration upon the occurrence of specified events of default, including a default or breach of certain contracts material to us and the delisting and deregistration of our common stock.

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 consolidated 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 September 30, 2019, we had cash and cash equivalents of $65.4 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 September 30, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed,

summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2019 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 consolidated 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. On July 6, 2018, defendants filed a motion to dismiss the consolidated amended complaint. Plaintiffs filed an opposition to the motion to dismiss on September 4, 2018, and defendants filed a reply on October 4, 2018. The court held oral argument on the motion to dismiss on February 6, 2019. By order dated April 30, 2019, the court granted defendants' motion to dismiss. On May 31, 2019, the plaintiffs filed a notice of appeal to the United States Court of Appeals for the First Circuit regarding the District Court's opinion and order of dismissal of the Complaint. The plaintiffs/appellants filed their opening brief on the appeal on October 23, 2019. Defendants'/appellees' response brief is due on November 22, 2019, and plaintiffs'/appellants' reply brief is due on December 13, 2019.

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/or 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. On June 22, 2018, plaintiffs served their opposition to the motion to dismiss and a cross-motion to stay the proceedings pending a decision on the motion to dismiss in the above-referenced securities class action in the District of Massachusetts. On July 30, 2018, the parties filed a joint motion to stay the proceedings pending a decision on the motion to dismiss in the above-referenced securities class action in the District of Massachusetts. On August 3, 2018, the court granted the motion to stay.

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, all defendants filed a motion to dismiss or stay the complaint. Plaintiff filed his opposition on June 22, 2018. On July 26, 2018, the parties filed a joint motion to extend the deadline for defendants to file their reply brief pending

the potential substitution of the named shareholder plaintiff. On August 20, 2018, the parties filed a joint stipulation and proposed order regarding plaintiff's unopposed request to substitute a new shareholder plaintiff and the parties' joint request that the court stay the proceedings pending a decision on the motion to dismiss in the above-referenced securities class action in the District of Massachusetts. On September 4, 2018, the court entered the requested order substituting the named plaintiff and staying the matter.

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. On June 11, 2018, the parties filed a stipulation staying the lawsuit pending final judgment in the consolidated derivative action pending in Massachusetts state court under the *Corwin* docket, described above. The court entered an order staying the case on June 12, 2018.

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

In addition, we 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 received a second subpoena from the SEC on August 21, 2018, requesting documents and information concerning its participation in two investor conferences in June 2017. By letter dated May 2, 2019, the SEC notified us that the SEC had concluded its investigation and did not intend to recommend an enforcement action against us or any individuals.

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 $63.4 million for the year ended December 31, 2017, $60.0 million for the year ended December 31, 2018, and $60.4 million for the nine months ended September 30, 2019. As of September 30, 2019, we had an accumulated deficit of $357.6 million. Through September 30, 2019, we have financed our operations primarily through private placements of our preferred stock, public offerings of our common stock, private placements of our convertible notes 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 the commercial launch of DEXTENZA® for the treatment of ocular inflammation and pain following ophthalmic surgery in July 2019. Although we expect to generate revenue from sales of DEXTENZA following its commercial launch, 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 commercialize DEXTENZA in the United States;
- continue to develop and expand our sales, marketing and distribution capabilities for DEXTENZA and any of our product candidates;
- continue to pursue the clinical development of DEXTENZA for additional indications;
- continue 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 and potential opportunities outside the field of ophthalmology;
- seek marketing approvals for any of our product candidates that successfully complete clinical development;
- 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 any corresponding 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;
- defend ourselves against legal proceedings;
- 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.

Through May 2019, ReSure Sealant was our only source of revenue from product sales. However, sales of ReSure Sealant have not generated significant revenue. For us to become and remain profitable, we will need to succeed in developing and commercializing DEXTENZA and potentially other products with significant market potential. This will require us or our current or future collaborators to be successful in a range of challenging activities, including:

- successfully commercializing DEXTENZA in the United States, including by further developing our sales force, marketing and distribution capabilities;
- successfully completing clinical development of our product candidates;
- obtaining marketing approval for these product candidates, including DEXTENZA for additional indications;
- manufacturing at commercial scale, marketing, selling and distributing DEXTENZA or 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.

Our ability to generate revenue from operations will depend, in part, on the timing and success of commercial sales of DEXTENZA, which we launched in the United States in July 2019. However, the successful commercialization of DEXTENZA in the United States is subject to many risks. We are currently undertaking our first commercial launch with DEXTENZA, and we may not be able to do so successfully or on the currently expected timeline or at all. There are numerous examples of unsuccessful product launches and failures to meet expectations of market potential, including by pharmaceutical companies with more experience and resources than us. While we commercially launched DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery in July 2019, we do not anticipate revenue from such sales of DEXTENZA will be sufficient for us to become profitable for several years, if ever. Furthermore, if we are unable to achieve our revenue estimates for DEXTENZA our ability to raise additional capital may be impacted.

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

We 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 continue to commercialize DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery, including expanding our product manufacturing, sales, marketing and distribution capabilities. We also expect to devote substantial financial resources as we conduct late stage clinical trials for our local programmed-release drug delivery product candidates, in particular DEXTENZA for additional indications, and seek marketing approval for any such product candidate for which we obtain favorable pivotal clinical results. In addition, we plan to devote significant financial resources to conducting research and development and potentially seeking regulatory approval for our other product candidates. Accordingly, we will need to obtain substantial additional funding to fully support our continuing operations and the planned commercial launch of DEXTENZA. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

As of September 30, 2019, we had cash and cash equivalents of $65.4 million, outstanding debt of $24.9 million, net of unamortized discount and $37.5 million aggregate principal amount of senior subordinated convertible notes plus accrued interest of $1.3 million. Based on our current plans and forecasted expenses, we believe that our existing cash and cash equivalents of $65.4 million, as of September 30, 2019 and anticipated cash inflows from DEXTENZA product sales, along with the expected cost savings from the operational restructuring announced in early November 2019, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements through the end of the fourth quarter of 2020. This estimate is subject to a number of assumptions related to the revenues and expenses associated with the commercialization of DEXTENZA as well as the pace of our research and clinical development programs, and other aspects of our business. DEXTENZA has only recently launched and anticipated cash flows are subject to uncertainty, and we do not expect that DEXTENZA revenue will be substantial in 2019. Such projection is subject to a number of assumptions related to the revenues and expenses associated with the commercialization of DEXTENZA as well as the pace of our research and clinical development programs and other aspects of our business. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including :

- our ability to successfully commercialize and sell DEXTENZA in the United States;
- the costs, timing and outcome of regulatory review of our product candidates by the FDA, the EMA or other regulatory authorities;
- the level of product sales from DEXTENZA and any additional products for which we obtain marketing approval in the future;
- the costs of manufacturing, sales, marketing, distribution and other commercialization efforts with respect to DEXTENZA and any additional products for which we obtain marketing approval in the future;
- the costs of expanding our facilities to accommodate our manufacturing needs and headcount;
- the progress, costs and outcome of the clinical trials of our extended-delivery drug delivery product candidates, in particular DEXTENZA for additional indications;
- 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 scope, progress, costs and outcome of preclinical development and clinical trials of our other product candidates;
- the extent of our debt service obligations;
- the amounts we are entitled to receive, if any, from Regeneron for potential option exercise, development, regulatory and sales milestones and royalty payments;
- the extent to which we choose to establish additional collaboration, distribution or other marketing arrangements for our products and product candidates;
- the costs and outcomes of legal actions and proceedings, including the current lawsuits described under "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, seeking market approvals and commercializing products are 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 consolidated financial statements included in this Annual Report on Form 10-K.

Our audited consolidated financial statements for the period ended December 31, 2018 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 consolidated 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 products 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, royalty agreements, and marketing and distribution arrangements. We do not have any committed external source of funds, although our collaboration agreement with Regeneron provides for the potential receipt of option exercise, development, regulatory and sales milestones and royalty payments. To the extent that we raise additional capital through the sale of equity, preferred 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 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.

If we raise additional funds through collaborations, strategic alliances, licensing arrangements, royalty agreements, or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, products or product candidates or grant licenses on terms that may not be favorable to us.

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 Credit Facility, as amended to date, we had $25.0 million, net of unamortized discount, of outstanding principal indebtedness. Under the accompanying Credit Agreement, we are permitted to make interest-only payments until January 1, 2021, subject to potential extension to January 1, 2022 if net sales of DEXTENZA exceed $40.0 million in the aggregate during any trailing twelve-month period. Our obligations under the Credit Agreement are secured by all of our assets, including our intellectual property. The Credit Agreement also includes customary affirmative and negative covenants, including limitations on dispositions, mergers or acquisitions; incurring indebtedness, liens or encumbrances; paying dividends; making certain investments; and engaging in certain other business transactions. In March 2019, we issued $37.5 million aggregate principal amount of Convertible Notes. The Convertible Notes mature on March 1, 2026 and interest on the Convertible

Notes is payable at maturity or if earlier converted, repurchased or redeemed pursuant to their terms. We could in the future incur additional indebtedness beyond such amounts, including by potentially amending our Credit Agreement.

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, commercialization expenditures associated with DEXTENZA, 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, anticipated product revenue from DEXTENZA 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 Agreement or the Convertible Notes could result in an event of default under those instruments. In the event of an acceleration of amounts due under our Credit Agreement or the Convertible Notes 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 Agreement and the pledge of our assets, including our intellectual property, as collateral 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, commercializing ReSure Sealant, and, since July 2019, commercializing DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery. We have a limited history of commercializing products, commercially launched DEXTENZA on July 1, 2019 and, to date, have not generated material revenue from the sale of DEXTENZA. 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 are in early stages of the process of transitioning 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 DEXTENZA and our product candidates, in particular DEXTENZA for additional indications. 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 maintain marketing approval or 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 products and 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 allergic conjunctivitis, OTX-TIC for glaucoma and ocular hypertension and OTX-TKI for wet age-related macular degeneration, or wet AMD. We cannot accurately predict when or if any of our product candidates will prove effective or safe in humans or whether our products and product candidates will receive marketing approval or reach successful commercialization. In addition, in November 2019 we announced that we would defer certain development programs as part of an initiative to reduce expenses and prioritize our resources to focus on commercializing DEXTENZA for post-surgical ocular pain and inflammation as well as completing the ongoing Phase 3 clinical trial of DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis, a Phase 1 clinical trial of OTX-TIC and a Phase 1 clinical trial of OTX-TKI for the treatment of wet age-related macular degeneration. Our ability to generate product revenues sufficient to achieve profitability will depend heavily on our commercialization of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery and our obtaining marketing approval for and commercializing other products with significant market potential, including DEXTENZA for additional indications.

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

- successful completion of preclinical studies and clinical trials;
- applying for and receiving and maintaining 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 DEXTENZA or 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 products and 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 products and product candidates, which would materially harm our business.

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

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

In general, the FDA requires two adequate and well controlled clinical trials to support the effectiveness of a new drug for marketing approval. In a Phase 2 clinical trial of DEXTENZA that we completed in 2013 in which we were evaluating DEXTENZA for post-surgical ocular inflammation and pain 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 inflammation and pain 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.

We announced topline results from a third Phase 3 clinical trial of DEXTENZA for post-surgical ocular inflammation and pain in November 2016, which we used to support the potential labeling expansion of DEXTENZA's indications for use. 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 inflammation and pain, achieving statistically significant differences between the treatment group and the placebo group for the absence of inflammatory cells on day 14 and the absence of pain on day 8, respectively. Secondary analyses on the primary efficacy measures have also been completed. DEXTENZA achieved each of the secondary endpoints related to absence of inflammatory cells, absence of pain, and absence of anterior chamber flare with statistical significance compared to placebo at each of the pre-specified time points, 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 subsequent approval in November 2018 for the pain indication pursuant to the initial NDA, we submitted an NDA supplement, or sNDA, for DEXTENZA for the treatment of post-surgical ocular inflammation in January 2019, and the FDA approved the sNDA in June 2019.

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 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 6.1 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 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 enrolled more subjects at a greater number of sites, had a different randomization, measured the primary efficacy endpoints on different days and at different time points, and had a longer washout period. As a result, the first Phase 3 clinical trial of OTX-TP was a randomized, double blind, placebo-controlled clinical trial conducted across more than 50 sites, and it enrolled 554 subjects with open-angle glaucoma or ocular hypertension in the full analysis set population. The trial's primary efficacy endpoint was to evaluate the mean IOP at three diurnal time points (8 a.m., 10 a.m., and 4 p.m.) at each of 2, 6, and 12 weeks following insertion for OTX-TP treated subjects compared with placebo insert treated subjects. The trial's secondary efficacy endpoints included the evaluation of the mean reduction and mean percent reduction of IOP from baseline for OTX-TP treated subjects compared with placebo insert treated subjects at the same time points. Topline results from this trial show that OTX-TP did not achieve its primary and secondary endpoints of statistically significant

superiority in mean, mean reduction, or mean percentage reduction of IOP compared with placebo at all nine time points. OTX-TP treated subjects did have a lower mean IPO and a greater reduction in IOP from baseline relative to placebo insert at all nine time points, but these differences were statistically significant (p value < 0.05) for only eight of the nine time points. We do not intend to initiate a second Phase 3 clinical trial at this time without a collaborative partner. If we do not achieve our primary endpoint in an additional Phase 3 clinical trial with statistical significance, assuming we conduct such clinical trials, 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 local programmed-release drug delivery products. As part of our restructuring plan announced in November 2019, we have paused further activities in connection with our OTX-TP program for the treatment of primary open-angle glaucoma or ocular hypertension, other than the ongoing open-label safety extension study.

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 inflammation and pain following cataract surgery until after approval of such product in adult populations for that indication. While the FDA ultimately approved our request, if the FDA had required us to conduct pediatric studies in advance of FDA approval in adult populations, we would have experienced significant delays in our ability to obtain marketing approval for DEXTENZA for these indications, particularly in light of our decision announced in November 2019 to postpone our clinical trial to evaluate DEXTENZA in pediatric subjects following cataract surgery until the fourth quarter of 2020. 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 local programmed-release drug delivery product candidates or our other product candidates that we may develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or similar regulatory authorities outside the United States. Although there is a significant prevalence of disease in the areas of ophthalmology in which we are focused, we may nonetheless experience unanticipated difficulty with patient enrollment. For example, in the third quarter of 2017, we initiated a Phase 1 clinical trial of OTX-TIC outside the United States. After several months, after not enrolling any patients, we closed this trial in the second quarter of 2018. Additionally, we intended to initiate a Phase 1 clinical trial of OTX-TKI outside the United States in 2018, and we started dosing patients in the first quarter of 2019.

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 reached the target enrollment of 550 patients at approximately 50 sites in the United States and is the largest clinical trial we have conducted to date. While now complete, enrollment in this trial was slower than projected. Our inability to enroll a sufficient number of patients in 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 or commercialization of our extended-delivery drug delivery products or product candidates or any other product candidates that we may develop, we may need to abandon or limit our development of such products or product candidates.

If DEXTENZA or any of our local programmed-release drug delivery product candidates or other product candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In each of our first two Phase 3 clinical trials of DEXTENZA for the treatment of post-surgical ocular inflammation and pain 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 inflammation and pain, there were three subjects that experienced serious adverse events in the DEXTENZA group, one of which was ocular in nature and none of which were considered by the investigator to be related to the study treatment. There was one ocular serious adverse event in the vehicle control group in the three completed Phase 3 clinical trials, which was hypopyon, or inflammatory cells in the anterior chamber. In our earlier Phase 2 clinical trial of DEXTENZA for the same indication, there were three serious adverse events, none of which was considered by the investigator to be related to the study treatment. In the DEXTENZA group of this Phase 2 clinical trial of DEXTENZA, the only adverse event that occurred more than once for the same subject was reduced visual acuity, which occurred twice but 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. In the Phase 3 clinical trial, OTX-TP was generally well tolerated and no ocular serious adverse events were observed. The most common ocular adverse events seen in the clinical trial were dacryocanaliculitis (approximately 7% in OTX-TP vs. 3% in placebo) and lacrimal structure disorder (approximately 6% in OTX-TP vs. 4% in placebo). 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 products and product candidates based on our bioresorbable hydrogel technology platform other than DEXTENZA and ReSure Sealant or expand the use of our bioresorbable hydrogel technology for treating additional diseases and conditions.

We are currently directing most of our development efforts towards applying our proprietary, bioresorbable hydrogel technology platform to products and 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 products and 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 biological 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 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 products and 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, 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. As part of our restructuring plan announced in November 2019, we have decided to defer certain development programs as part of an initiative to reduce expenses and prioritize our resources to focus on commercializing DEXTENZA for post-surgical ocular pain and inflammation as well as completing the ongoing Phase 3 clinical trial of DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis, a Phase 1 clinical trial of OTX-TIC for the treatment of glaucoma and ocular hypertension, and a Phase 1 clinical trial of OTX-TKI for the treatment of wet age-related macular degeneration. 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 or product candidate, we may relinquish valuable rights to that product or 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 products or 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 DEXTENZA, 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 products and 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 our products, 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 Complete Response Letter, or 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, stating that the FDA had determined that it could not approve the NDA in its then-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. 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 undertook in response to the FDA's inspectional observations and as a result of further internal review included upgrades to our manufacturing equipment and updates to our manufacturing processes and quality oversight. These changes were 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. We resubmitted our NDA for DEXTENZA for the treatment of post-surgical ocular pain in June 2018, which was approved in November 2018. We may be subject to similar inspections and requirements in connection with subsequent applications for other product candidates or DEXTENZA for additional indications.

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 DEXTENZA, 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 $26.2 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 DEXTENZA, 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 DEXTENZA, 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 DEXTENZA, 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 DEXTENZA, 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 products and 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 DEXTENZA and ReSure Sealant have 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.

DEXTENZA, 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 have commercially launched DEXTENZA for the treatment of post-surgical ocular inflammation and pain in July 2019 and cannot yet accurately predict whether either product 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 DEXTENZA, 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 products and 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 DEXTENZA and ReSure Sealant, the lack of separate reimbursement when used as part of a cataract surgery procedure;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

For example, because we have not conducted any clinical trials to date comparing the effectiveness of DEXTENZA directly to currently approved alternative treatments for either post-surgical ocular inflammation and pain following cataract surgery or allergic conjunctivitis, it is possible that the market acceptance of DEXTENZA 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 DEXTENZA, 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 DEXTENZA, 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 DEXTENZA, 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 DEXTENZA, 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 have built our own highly targeted, key account sales force for DEXTENZA that will focus on ambulatory surgical centers responsible for the largest volumes of cataract surgery. 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 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. 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 products or 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 products or 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. Such third parties may have interests that differ from ours. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to market, sell and distribute our products effectively. Our product revenues and our profitability, if any, under third-party collaboration including our collaboration with Regeneron, distribution or other marketing arrangements may also be lower than if we were to sell, market and distribute a product ourselves. On the other hand, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of any product or 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 DEXTENZA, 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 products and product candidates, 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 products and 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 products and 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, encourage the use of generic products. Given that we are developing products based on FDA-approved therapeutic agents, our products and 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 products and 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 products and 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, programmed-release drug delivery product candidates that could compete with our intracanalicular insert products and 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.

DEXTENZA, 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 DEXTENZA, 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 DEXTENZA, 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, DEXTENZA, 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 DEXTENZA, 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 or product candidate to other available therapies. Adverse pricing limitations may hinder our ability to recoup our investment in one or more products or product candidates, even if our product candidates obtain marketing approval.

DEXTENZA, 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 products and 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, 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.

We applied for a transitional pass-through reimbursement status, or C-code, on November 30, 2018 for DEXTENZA from the Centers for Medicare and Medicaid Services, or CMS. In May 2019, we received formal notification from CMS that it had approved transitional pass-through payment status and established a new C-Code for DEXTENZA that subsequently became effective on July 1, 2019. We expected pricing for DEXTENZA while in pass-through status to be approximately $538 per surgery, and we expected pass-through status would remain in effect for up to three years from the effective date of the C-code, or July 1, 2019. We also submitted an application to the CMS for a J-code for DEXTENZA on December 28, 2018, and received a specific and permanent J-code in July 2019 which became effective on October 1, 2019. With the effectiveness of our permanent J-code as of October 1, 2019, our C-code is no longer in effect. We expect to submit to the CMS for a standard J-code for OTX-TP for the treatment of glaucoma and ocular hypertension, 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 products and product candidates.

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 DEXTENZA and 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 DEXTENZA, ReSure Sealant and any 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 what we believed to be the final formulation for Regeneron's initial preclinical tolerability study. Regeneron initiated the preclinical study in early 2018. We and Regeneron have subsequently reached an understanding that the proposed formulation was not final and have ceased development of it and the corresponding option period under the Collaboration Agreement for the initial proposed formulation has stopped. We are currently in discussions with Regeneron, in accordance with the terms of the Collaboration Agreement, regarding the development of an alternative formulation and the related impact on the designated option period. Although we are engaged in ongoing discussions with Regeneron, Regeneron has not informed us of its decision to exercise the option. While we await a decision from Regeneron, we are not actively pursuing further formulation development or other preclinical testing under the Collaboration Agreement. 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 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 DEXTENZA, 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 products or 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 DEXTENZA, 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 products and 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, such as OTX-TP. 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 products or 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 products or product candidates, might lead to additional responsibilities for us with respect to products or 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 products or product candidates.

Collaboration agreements may not lead to development or commercialization of products or 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 products or product candidates could be delayed and we may need additional resources to develop our products or product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus supplement 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 or 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 inflammation and pain following cataract surgery. However, we have relied and may continue to rely on third parties, such as contract research organizations, or CROs, to conduct future clinical trials of 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, products 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 patent portfolio expire have already expired. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our candidates might expire before or shortly after such candidates are commercialized. As a result, our 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 certain 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 such licensed patents in our fields, other Incept licensees may also have the

right to enforce these 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 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 such 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, certain of 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 patent rights, including our licensed patent rights, are highly uncertain. Our and 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 products and 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 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 products and 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 our patents or any patents that we license. These 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 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 and 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 products 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 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 products or 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 products or 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 DEXTENZA, 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 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 have been made aware by a third party of three patents relating to intracanalicular inserts that may relate to, and potentially could be asserted against our intracanalicular insert product and product candidates, including DEXTENZA. We believe that DEXTENZA does not

infringe the claims of one of more of these patents. 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. We initiated legal proceedings against one of these patents and administrative proceedings against the other two patents in order to show that DEXTENZA does not infringe the claims of these patents or that these patents are invalid. We have settled the legal proceedings related to one of these patents. The USPTO has decided to proceed with the administrative proceeding related to one of the patents while declining to do so for the other. We continue to believe that DEXTENZA does not infringe the claims of these patents and that, if and to the extent they were asserted against DEXTENZA, they would be subject to a claim of invalidity.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent and could be forced to indemnify our customers or collaborators. A finding of infringement could also result in an injunction that prevents us from commercializing our products or product candidates or forces us to cease some of our business operations. In addition, we may be forced to redesign our products or 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 DEXTENZA, 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 certain patent applications 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 a significant portion of 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 certain patent applications may restrict our ability to use certain of our licensed rights to expand our business outside of the specified fields. If we determine to pursue a strategy of expanding the use of the hydrogel technology outside of the specified fields, 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 or utilize technologies that do not infringe on such licensed rights. We may not be able to obtain any such required amendment or new license or to invent or otherwise access other technology 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 products and 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 DEXTENZA and ReSure Sealant in the United States, and have not received approval to market any of our product candidates or to market DEXTENZA or ReSure Sealant in any jurisdiction outside the United States. Further, we have only received approval to market DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery and have not received approval to market DEXTENZA for any other indications. 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 DEXTENZA, ReSure Sealant, or any of our 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 of the NDA for DEXTENZA for post-surgical ocular pain, the FDA 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.

The FDA 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. In November 2017, we submitted our complete responses to the FDA in an effort to close out the Form 483 deficiencies. We resubmitted our NDA for DEXTENZA for the treatment of post-surgical ocular pain in June

2018, and in November 2018 the FDA approved our NDA. We may be subject to similar inspections in the future for DEXTENZA or for other product candidates for which we seek FDA approval. If we are unable to address any identified issues successfully or if the FDA determines that the actions we take to remediate any identified 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 products or product candidates from being marketed abroad.

In order to market and sell DEXTENZA, 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 approval 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. The United Kingdom had a period of a maximum of two years from the date of its formal notification to negotiate the terms of its withdrawal from, and future relationship with, the European Union. If no formal withdrawal agreement can be reached between the United Kingdom and the European Union, then it is expected that the United Kingdom's membership of the European Union would automatically terminate on the deadline, which was initially March 29, 2019. On October 28, 2019, that deadline was extended from October 31, 2019, to January 31, 2020, to allow the parties to continue to negotiate a withdrawal agreement. The United Kingdom could leave the European Union earlier if the Parliament approves the withdrawal but that has proven to be extremely difficult to date. Discussions between the United Kingdom and the European Union will continue to focus on withdrawal issues and transition agreements. However, limited progress to date in these negotiations and ongoing uncertainty within the government of the United Kingdom sustains the possibility of the United Kingdom leaving the European Union without a withdrawal agreement and associated transition period in place, which is likely to cause significant market and economic disruption. On July 24, 2019, Boris Johnson was appointed Prime Minister of the United Kingdom, who has previously suggested that the country should leave the European Union without an agreement.

Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of our products or 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 products or 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 for ReSure Sealant. The first post-approval study, identified as the Clinical PAS, was to enroll at least 598 patients 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 Study, 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. The Device Exposure Registry Study is required to include at least 4,857 patients. In December 2015, the CMS denied our application for a tracking or research code for ReSure Sealant commercial use. In July 2016, the FDA approved the Device Exposure Registry Study protocol. 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. Due to difficulties in establishing an acceptable way to link ReSure Sealant to the Medicare database and lack of investigator interest, we have been unable to enroll trial sites and patients, collect patient data and report study data to the FDA. On October 18, 2018, we received a warning letter from the FDA, dated October 17, 2018, relating to our compliance with data collection and information reporting obligations in this study. We appealed the warning letter from the FDA. In December 2018, the FDA rejected our appeal. A teleconference was held with the FDA in January 2019 resulting in tentative agreement on a proposed retrospective registry study of endophthalmitis rates to satisfy the Device Exposure Registry Study requirements. We are working with the registry vendor to finalize a formal study protocol which we intend to submit to the FDA for comment before the study is conducted. Following review of the results from these post-approval studies, any concerns with respect to endophthalmitis that we are unable to address due to the lack of completion of the study would negatively affect our ability to commercialize ReSure Sealant. Failure by us to conduct the Device Exposure Registry Study to the FDA's satisfaction may result in withdrawal of the FDA's approval of ReSure Sealant or other regulatory action.

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 United States Federal Food, Drug, and Cosmetic Act, or 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 DEXTENZA, ReSure Sealant and any 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 or the operations of our present and future collaborators are found to be in violation of any of the laws described above or any governmental regulations that apply to us or them, we or they 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 or their 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 with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. We do not have a fully developed compliance program and will need to establish a more robust compliance infrastructure to address our needs in this area. We may fail to establish appropriate compliance measures, and even with a stronger program in place, 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.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the European Union General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will continue to be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

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 products or 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 or product 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.

With enactment of the Tax Cuts and Jobs Act of 2017, or the 2017 Tax Act, which was signed by President Trump 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, has become effective. 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. Moreover, on December 14, 2018, a United States District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the 2017 Tax Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Furthermore, since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs 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. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, the United States Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the 2017 Tax Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018, the same judge issued an order staying the judgment pending appeal. The Trump administration has represented to the U.S. Court of Appeals for the Fifth Circuit considering this judgment that it does not oppose the lower court's ruling. To that end, on May 1, 2019, the Justice Department filed a brief asking the Court to strike down the entirety of the ACA. Thereafter, on July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case. In those arguments, the Trump administration argued in support of upholding the lower court decision. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

In addition, the CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the proposed rule changes would allow Medicare Advantage plans to use pre authorization, or PA, and step therapy, or ST, for six protected classes of drugs, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs; and change the definition of "negotiated prices" while adding a definition of "price concession" in the regulations. It is unclear whether these proposed changes we be accepted, and if so, what effect such changes will have on our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

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 such 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 amend the ACA 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 or 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.

In addition, on May 11, 2018, the Administration issued a plan to lower drug prices. Under this blueprint for action, the Administration indicated that the Department of Health and Human Services, or the HHS, will: take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies; advance biosimilars and generics to boost price competition; evaluate the inclusion of prices in drug makers' ads to enhance price competition; speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers; avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid; work to give Part D plan sponsors more negotiation power with drug makers; examine which Medicare Part B drugs could be negotiated for a lower price by Part D plans, and improving the design of the Part B Competitive Acquisition Program; update Medicare's drug-pricing dashboard to increase transparency; prohibit Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance; and require that Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases.

At the same time, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. It is unclear what, if any, of these measures will be enacted during the Congressional session. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. Increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

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

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

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

including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

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

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

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

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

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

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

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

Although we maintain general liability insurance as well as workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental

liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

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

The comprehensive tax reform bill enacted in 2017 could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed the 2017 Tax Act into law, which significantly revised the Internal Revenue Code of 1986, as amended. The 2017 Tax Act, among other things, contains significant changes to corporate federal income 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 2017 Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the 2017 Tax Act. The impact of the 2017 Tax Act 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 the 2017 Tax Act 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, 2018, we had federal and state net operating loss carryforwards of $190.6 million, which begin to expire in 2026, and state net operating loss carryforwards of $161.8 million, which begin to expire in 2026. As of December 31, 2018, we also had federal research and development tax credit carryforwards of $7.0 million and state research and development tax credit carryforwards $3.6 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 2017 Tax Act, 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 2017 Tax Act. 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 our 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 have recently reduced the size of our organization, and we may encounter difficulties in managing our business as a result of this reduction, or the attrition that may occur following this reduction, which could disrupt our operations. In addition, we may not achieve anticipated benefits and savings from the reduction.

In November 2019, our board of directors approved an operational restructuring to eliminate a portion of the Company's workforce as part of an initiative to reduce expenses and prioritize our resources to focus on commercializing DEXTENZA for post-surgical ocular pain and inflammation as well as completing the ongoing clinical trials for our product candidates. Under this plan, we reduced our workforce by 55 employees, representing approximately 22% of our workforce, effective November 8, 2019. We also eliminated an additional 31 positions that were vacant. We expect to substantially complete the restructuring and to record the restructuring charges in the fourth quarter of 2019. This reduction in force, and the attrition that may occur following this reduction, will result in the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations.

The restructuring and additional measures we might take to reduce costs could divert management attention, yield attrition beyond our intended reduction if force, reduce employee morale, or cause us to delay, limit, reduce or eliminate certain product development plans.

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 2019, we expect our drug development, clinical, regulatory affairs, manufacturing and our sales and marketing capabilities in the longer term to grow as we commercialize DEXTENZA and any other product candidates that may receive marketing approval. 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. We relocated our corporate headquarters to 24 Crosby Drive, Bedford, MA to accommodate our growth. We are evaluating expanding our manufacturing operations into 15 Crosby Drive, Bedford, MA while maintaining our existing operations located at 36 Crosby Drive, Bedford, MA. 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 products and 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 large portion of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of voting power may:

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

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

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

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

- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

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

We are currently subject to legal 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 then 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 and August 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 were transferred to the United States District Court for the District of Massachusetts at our request and were subsequently consolidated. The court dismissed the consolidated cases in April 2019; that dismissal has been appealed. 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. We also received subpoenas from the SEC in December 2017 and August 2018 seeking documents and information concerning DEXTENZA, including related communications with the FDA and investors. In May 2019, the SEC notified us that the SEC had concluded its investigation. Due to the volatility in our stock price, we may be the target of similar proceedings in the future.

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.

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 DEXTENZA, ReSure Sealant and any product candidates for which we obtain marketing approval;
- 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 products or 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 or our other product candidates. As described in “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.

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 a "smaller reporting company" and the reduced disclosure requirements applicable to such companies may make our common stock less attractive to investors. Commencing January 1, 2020, we will no longer be an emerging growth company.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will lose our status as an emerging growth company on January 1, 2020. As an emerging growth company, we have been permitted 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 until we cease to be an emerging growth company on January 1, 2020.

We are also a "smaller reporting company," as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended. We would cease to be a smaller reporting company if we have a non-affiliate public float in excess of $250 million and annual revenues in excess of $100 million, or a non-affiliate public float in excess of $700 million, determined on an annual basis. After we cease to qualify as an emerging growth company, we may still qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements. In addition to the above reduced disclosure requirements applicable to emerging growth companies, as a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies. These exemptions include:

- being permitted to provide only two years of audited consolidated financial statements in this Annual Report on Form 10-K, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to furnish a contractual obligations table in "Management's Discussion and Analysis of Financial Condition and Results of Operations"; and
- not being required to furnish a stock performance graph in our annual report.

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 commencing January 1, 2020, when we are no longer an emerging growth company, we incur and will continue to 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. Commencing January 1, 2020, we will no longer be an emerging growth company and as such we will not be able to take advantage of these exemptions.

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. Commencing January 1, 2020, we will also be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm because we will no longer be an emerging growth company. 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 consolidated 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 Agreement 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

On July 9, 2019, we issued to Christopher White, the Senior Vice President, Head of Business Development, a non-statutory stock option to purchase an aggregate of 60,000 shares of our common stock at an exercise price of $5.13 per share. Subject to Mr. White'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

our 2014 Stock Incentive Plan as an inducement material to Mr. White's acceptance of entering into employment with us in accordance with Nasdaq Listing Rule 5635(c)(4). We anticipate registering the shares underlying this grant on a Form S-8 registration statement prior to the first vesting event.

On October 30, 2019, our compensation committee granted non-statutory stock options to purchase up to an aggregate of 54,000 shares of common stock to nine newly-hired employees under our 2019 Inducement Stock Incentive Plan as an inducement material to each employee's acceptance of employment with us in accordance with Nasdaq Listing Rule 5635(c)(4). Each stock option was granted effective as of October 31, 2019 and has an exercise price of $3.24 per share, the closing price of the Company's common stock on October 31, 2019. Each stock option has a ten-year term and is scheduled to vest over four years, with 25% of the original number of shares vesting on the one-year anniversary of the applicable employee's employment commencement date and the remainder vesting in equal monthly installments over the three years thereafter, subject to the employee's continued service to the Company through the applicable vesting dates. We anticipate registering the shares underlying these grants on a Form S-8 registration statement prior to the first vesting event applicable to each such grant.

Item 5. Other Information.

None.

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+	2019 Inducement Stock Incentive Plan.					X
10.2+	Form of Inducement Nonstatutory Stock Option Agreement.					X
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: November 12, 2019

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

Exhibit 10.1

OCULAR THERAPEUTIX, INC.

2019 INDUCEMENT STOCK INCENTIVE PLAN

1. Purpose

The purpose of this 2019 Inducement Stock Incentive Plan (the "Plan") of Ocular Therapeutix, Inc., a Delaware corporation (the "Company"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company with an inducement material for such persons to enter into employment with the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company's stockholders. Except where the context otherwise requires, the term "Company" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations thereunder (the "Code") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "Board").

2. Eligibility

Awards under the Plan may only be granted to persons who (a) were not previously an employee or director of the Company or (b) are commencing employment with the Company following a bona fide period of non-employment, in either case as an inducement material to the individual's entering into employment with the Company and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). For the avoidance of doubt, neither consultants nor advisors shall be eligible to participate in the Plan. Each person who is granted an Award under the Plan is deemed a "Participant." The Plan provides for the following types of awards, each of which is referred to as an "Award": Options (as defined in Section 5), SARs (as defined in Section 6), Restricted Stock (as defined in Section 7), Restricted Stock Units (as defined in Section 7) and Other Stock-Based Awards (as defined in Section 8).

3. Administration and Delegation

(a) Administration by Board of Directors. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient and it shall be the sole and final judge of such expediency. All decisions by the Board with respect to the Plan and any Awards shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award. The Board may delegate administration of the Plan to a Committee or Committees, as provided in Section 3(b). Notwithstanding the foregoing or anything in the Plan to the contrary, the grant of any Award under the Plan must be approved by the Company's independent compensation

committee or a majority of the Company's independent directors (as defined in Nasdaq Stock Market Rule 5605(a)(2)) in order to comply with the exemption from the stockholder approval requirement for "inducement grants" provided under Nasdaq Stock Market Rule 5635(c)(4).

(b) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "Committee"). All references in the Plan to the "Board" shall mean the Board or a Committee of the Board to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.

4. Stock Available for Awards

(a) Number of Shares; Share Counting.

(1) Authorized Number of Shares. Subject to adjustment under Section 9, Awards may be made under the Plan for up to 500,000 shares of common stock, $0.0001 par value per share, of the Company (the "Common Stock"). Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

(2) Share Counting. For purposes of counting the number of shares available for the grant of Awards under the Plan:

(A) all shares of Common Stock covered by SARs shall be counted against the number of shares available for the grant of Awards under the Plan; provided, however, that (i) SARs that may be settled only in cash shall not be so counted and (ii) if the Company grants an SAR in tandem with an Option for the same number of shares of Common Stock and provides that only one such Award may be exercised (a "Tandem SAR"), only the shares covered by the Option, and not the shares covered by the Tandem SAR, shall be so counted, and the expiration of one in connection with the other's exercise will not restore shares to the Plan;

(B) if any Award (i) expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or (ii) results in any Common Stock not being issued (including as a result of an SAR that was settleable either in cash or in stock actually being settled in cash), the unused Common Stock covered by such Award shall again be available for the grant of Awards; provided, however, that (1) in the case of the exercise of an SAR, the number of shares counted against the shares available under the Plan shall be the full number of shares subject to the SAR multiplied by the percentage of the SAR actually exercised, regardless of the number of shares actually used to settle such SAR upon exercise and (2) the shares covered by a Tandem SAR shall not again become available for grant upon the expiration or termination of such Tandem SAR; and

(C) shares of Common Stock delivered (either by actual delivery, attestation, or net exercise) to the Company by a Participant to (i) purchase shares of Common Stock upon the exercise of an Award or (ii) satisfy tax withholding obligations with respect to

Awards (including shares retained from the Award creating the tax obligation) shall be added back to the number of shares available for the future grant of Awards.

5. Stock Options

(a) General. The Board may grant options to purchase Common Stock (each, an "Option") and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable. All Options under the Plan shall be Nonstatutory Stock Options. A "Nonstatutory Stock Option" is an Option which is not intended to be an "incentive stock option" within the meaning of Section 422 of the Code.

(b) Exercise Price. The Board shall establish the exercise price of each Option and specify the exercise price in the applicable Option agreement. The exercise price shall be not less than 100% of the Grant Date Fair Market Value (as defined below) of the Common Stock on the date the Option is granted; provided that if the Board approves the grant of an Option with an exercise price to be determined on a future date, the exercise price shall be not less than 100% of the Grant Date Fair Market Value on such future date. "Grant Date Fair Market Value" of a share of Common Stock for purposes of the Plan will be determined as follows:

(1) if the Common Stock trades on a national securities exchange, the closing sale price (for the primary trading session) on the date of grant; or

(2) if the Common Stock does not trade on any such exchange, the average of the closing bid and asked prices on the date of grant as reported by an over-the-counter marketplace designated by the Board; or

(3) if the Common Stock is not publicly traded, the Board will determine the Grant Date Fair Market Value for purposes of the Plan using any measure of value it determines to be appropriate (including, as it considers appropriate, relying on appraisals) in a manner consistent with the valuation principles under Section 409A (as defined below), except as the Board may expressly determine otherwise.

For any date that is not a trading day, the Grant Date Fair Market Value of a share of Common Stock for such date will be determined by using the closing sale price or average of the bid and asked prices, as appropriate, for the immediately preceding trading day and with the timing in the formulas above adjusted accordingly. The Board can substitute a particular time of day or other measure of "closing sale price" or "bid and asked prices" if appropriate because of exchange or market procedures or can, in its sole discretion, use weighted averages either on a daily basis or such longer period as complies with Section 409A.

The Board has sole discretion to determine the Grant Date Fair Market Value for purposes of the Plan, and all Awards are conditioned on the Participants' agreement that the Board's determination is conclusive and binding even though others might make a different determination.

(c) Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable Option agreement; provided, however, that no Option will be granted with a term in excess of 10 years.

(d) Exercise of Options. Options may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with payment in full (in the manner specified in Section 5(e)) of the exercise price for the number of shares for which the Option is exercised. Shares of Common Stock subject to the Option will be delivered by the Company as soon as practicable following exercise.

(e) Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(1) in cash or by check, payable to the order of the Company;

(2) except as may otherwise be provided in the applicable Option agreement or approved by the Board, in its sole discretion, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) to the extent provided for in the applicable Option agreement or approved by the Board, in its sole discretion and subject to compliance with applicable law, by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Board), provided (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board in its discretion and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent provided for in the applicable Nonstatutory Stock Option agreement or approved by the Board in its sole discretion and subject to compliance with applicable law, by delivery of a notice of "net exercise" to the Company, as a result of which the Participant would receive (i) the number of shares underlying the portion of the Option being exercised, less (ii) such number of shares as is equal to (A) the aggregate exercise price for the portion of the Option being exercised divided by (B) the fair market value of a share of Common Stock (valued in the manner determined by (or in a manner approved by) the Board) on the date of exercise;

(5) to the extent permitted by applicable law and provided for in the applicable Option agreement or approved by the Board, in its sole discretion, by payment of such other lawful consideration as the Board may determine; or

(6) by any combination of the above permitted forms of payment.

(f) Limitation on Repricing. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 9): (1) amend any outstanding Option granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Option, (2) cancel any outstanding option (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan covering the same or a different number of shares of Common Stock and having an exercise price per share lower than the then-current exercise price per share of the cancelled option, (3) cancel in exchange for a cash payment any outstanding Option with an exercise price per share above the then-current fair market value of a share of Common Stock (valued in the manner determined by (or in a manner approved by) the Board), or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the Nasdaq Stock Market ("Nasdaq").

6. Stock Appreciation Rights

(a) General. The Board may grant Awards consisting of stock appreciation rights ("SARs") entitling the holder, upon exercise, to receive an amount of Common Stock or cash or a combination thereof (such form to be determined by the Board) determined by reference to appreciation, from and after the date of grant, in the fair market value of a share of Common Stock (valued in the manner determined by (or in a manner approved by) the Board) over the measurement price established pursuant to Section 6(b). The date as of which such appreciation is determined shall be the exercise date.

(b) Measurement Price. The Board shall establish the measurement price of each SAR and specify it in the applicable SAR agreement. The measurement price shall not be less than 100% of the Grant Date Fair Market Value of a share of Common Stock on the date the SAR is granted; provided that if the Board approves the grant of an SAR effective as of a future date, the measurement price shall be not less than 100% of the Grant Date Fair Market Value on such future date.

(c) Duration of SARs. Each SAR shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable SAR agreement; provided, however, that no SAR will be granted with a term in excess of 10 years.

(d) Exercise of SARs. SARs may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with any other documents required by the Board.

(e) Limitation on Repricing. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 9): (1) amend any outstanding SAR granted under the Plan to provide a measurement price per share that is lower than the then-current measurement price per share of such outstanding SAR, (2) cancel any outstanding SAR (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan covering the same or a different number of shares of Common Stock and having a measurement price per share lower than the then-current measurement price per share of the cancelled SAR, (3) cancel in exchange for a cash payment any outstanding SAR with a measurement price per share above the then-current fair market value of a share of Common

Stock (valued in the manner determined by (or in a manner approved by) the Board), or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of Nasdaq.

7. Restricted Stock; Restricted Stock Units

(a) General. The Board may grant Awards entitling recipients to acquire shares of Common Stock ("Restricted Stock"), subject to the right of the Company to repurchase (in accordance with applicable law and the Award agreement) all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. The Board may also grant Awards entitling the recipient to receive shares of Common Stock or cash to be delivered at the time such Award vests ("Restricted Stock Units") (Restricted Stock and Restricted Stock Units are each referred to herein as a "Restricted Stock Award").

(b) Terms and Conditions for All Restricted Stock Awards. The Board shall determine the terms and conditions of a Restricted Stock Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

(c) Additional Provisions Relating to Restricted Stock.

(1) Dividends. Any dividends (whether paid in cash, stock or property) declared and paid by the Company with respect to shares of Restricted Stock ("Accrued Dividends") shall be paid to the Participant only if and when such shares become free from the restrictions on transferability and forfeitability that apply to such shares. Each payment of Accrued Dividends will be made no later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following the lapsing of the restrictions on transferability and the forfeitability provisions applicable to the underlying shares of Restricted Stock.

(2) Stock Certificates. The Company may require that any stock certificates issued in respect of shares of Restricted Stock, as well as dividends or distributions paid on such Restricted Stock, shall be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to his or her Designated Beneficiary. "Designated Beneficiary" means (i) the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or (ii) in the absence of an effective designation by a Participant, the Participant's estate.

(d) Additional Provisions Relating to Restricted Stock Units.

(1) Settlement. Upon the vesting of and/or lapsing of any other restrictions (i.e., settlement) with respect to each Restricted Stock Unit, the Participant shall be entitled to receive from the Company such number of shares of Common Stock or (if so provided in the

applicable Award agreement or otherwise determined by the Board) an amount of cash equal to the fair market value (valued in the manner determined by (or in a manner approved by) the Board) of such number of shares of Common Stock as are set forth in the applicable Restricted Stock Unit agreement, or a combination thereof. The Board may, in its discretion, provide that settlement of Restricted Stock Units shall be deferred, on a mandatory basis or at the election of the Participant in a manner that complies with Section 409A of the Code or any successor provision thereto, and the regulations thereunder ("Section 409A").

(2) Voting Rights. A Participant shall have no voting rights with respect to any Restricted Stock Units.

(3) Dividend Equivalents. The Award agreement for Restricted Stock Units may provide Participants with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding shares of Common Stock ("Dividend Equivalents"). Dividend Equivalents shall be credited to an account for the Participant, may be settled in cash and/or shares of Common Stock as set forth in the applicable Award agreement, and shall be subject to the same restrictions on transfer and forfeitability as the Restricted Stock Units with respect to which paid.

8. Other Stock-Based Awards

(a) General. Other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property, may be granted hereunder to Participants ("Other Stock-Based Awards"). Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock or cash, as the Board shall determine.

(b) Terms and Conditions. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other Stock-Based Award, including any purchase price applicable thereto.

(c) Dividend Equivalents. The Award agreement for Other Stock-Based Awards may provide Participants with the right to receive Dividend Equivalents. Dividend Equivalents shall be credited to an account for the Participant, may be settled in cash and/or shares of Common Stock as set forth in the applicable Award agreement, and shall be subject to the same restrictions on transfer and forfeitability as the Other Stock-Based Awards with respect to which paid.

9. Adjustments for Changes in Common Stock and Certain Other Events

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under the Plan, (ii) the share counting rules set forth in Section 4(a), (iii) the number and class of securities and exercise price per share of each outstanding Option, (iv) the share and

per-share provisions and the measurement price of each outstanding SAR, (v) the number of shares subject to and the repurchase price per share subject to each outstanding Restricted Stock Award and (vi) the share and per-share-related provisions and the purchase price, if any, of each outstanding Other Stock-Based Award, shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(b) Reorganization Events.

(1) Definition. A "Reorganization Event" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property or is cancelled, (b) any transfer or disposition of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company.

(2) Consequences of a Reorganization Event on Awards Other than Restricted Stock.

(A) In connection with a Reorganization Event, the Board may take any one or more of the following actions as to all or any (or any portion of) outstanding Awards other than Restricted Stock on such terms as the Board determines (except to the extent specifically provided otherwise in an applicable Award agreement or another agreement between the Company and the Participant): (i) provide that such Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that all of the Participant's unvested and/or unexercised Awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become exercisable, realizable, or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "Acquisition Price"), make or provide for a cash payment to Participants with respect to each Award held by a Participant equal to (A) the number of shares of Common Stock subject to the vested portion of the Award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such Award and any applicable tax withholdings, in exchange for the termination of such Award, (v) provide that, in connection with a liquidation or

dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of the actions permitted under this Section 9(b)(2), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically.

(B) Notwithstanding the terms of Section 9(b)(2)(A), in the case of outstanding Restricted Stock Units that are subject to Section 409A: (i) if the applicable Restricted Stock Unit agreement provides that the Restricted Stock Units shall be settled upon a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i), and the Reorganization Event constitutes such a "change in control event", then no assumption or substitution shall be permitted pursuant to Section 9(b)(2)(A)(i) and the Restricted Stock Units shall instead be settled in accordance with the terms of the applicable Restricted Stock Unit agreement; and (ii) the Board may only undertake the actions set forth in clauses (iii), (iv) or (v) of Section 9(b)(2)(A) if the Reorganization Event constitutes a "change in control event" as defined under Treasury Regulation Section 1.409A-3(i)(5)(i) and such action is permitted or required by Section 409A; if the Reorganization Event is not a "change in control event" as so defined or such action is not permitted or required by Section 409A, and the acquiring or succeeding corporation does not assume or substitute the Restricted Stock Units pursuant to clause (i) of Section 9(b)(2)(A), then the unvested Restricted Stock Units shall terminate immediately prior to the consummation of the Reorganization Event without any payment in exchange therefor.

(C) For purposes of Section 9(b)(2)(A)(i), an Award (other than Restricted Stock) shall be considered assumed if, following consummation of the Reorganization Event, such Award confers the right to purchase or receive pursuant to the terms of such Award, for each share of Common Stock subject to the Award immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); provided, however, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise or settlement of the Award to consist solely of such number of shares of common stock of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determined to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

(3) Consequences of a Reorganization Event on Restricted Stock. Upon the occurrence of a Reorganization Event other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company with respect to outstanding Restricted Stock shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and

to the same extent as they applied to such Restricted Stock; provided, however, that the Board may provide for termination or deemed satisfaction of such repurchase or other rights under the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, either initially or by amendment. Upon the occurrence of a Reorganization Event involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted Stock then outstanding shall automatically be deemed terminated or satisfied.

10. General Provisions Applicable to Awards

(a) Transferability of Awards. Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution or pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant; provided, however, that, except with respect to Awards subject to Section 409A, the Board may permit or provide in an Award for the gratuitous transfer of the Award by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act of 1933, as amended, for the registration of the sale of the Common Stock subject to such Award to such proposed transferee; provided further, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Award. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 10(a) shall be deemed to restrict a transfer to the Company.

(b) Documentation; Press Release. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan. Following the grant of an Award hereunder, if the Company is required by law or Nasdaq listing rules to disclose in a press release the material terms of the grant, the number of shares involved, and/or the identity of the Participant, each Participant, by accepting the Award, consents to the foregoing.

(c) Board Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) Termination of Status. The Board shall determine the effect on an Award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights, or receive any benefits, under an Award.

(e) Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver stock certificates or otherwise recognize ownership of Common Stock under an Award. The Company may elect to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise, vesting or release from forfeiture of an Award or at the same time as payment of the exercise or purchase price, unless the Company determines otherwise. If provided for in an Award or approved by the Board in its sole discretion, a Participant may satisfy such tax obligations in whole or in part by delivery (either by actual delivery or attestation) of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Company); provided, however, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income) except that, to the extent that the Company is able to retain shares of Common Stock having a fair market value (determined by, or in a manner approved by, the Company) that exceeds the statutory minimum applicable withholding tax without financial accounting implications or the Company is withholding in a jurisdiction that does not have a statutory minimum withholding tax, the Company may retain such number of shares of Common Stock (up to the number of shares having a fair market value equal to the maximum individual statutory rate of tax (determined by, or in a manner approved by, the Company)) as the Company shall determine in its sole discretion to satisfy the tax liability associated with any Award. Shares used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

(f) Amendment of Award. Except as otherwise provided in Sections 5(f) and 6(e) with respect to repricings, the Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type and changing the date of exercise or realization; provided that no amendment that would require stockholder approval under the rules of Nasdaq may be made effective unless and until the Company's stockholders approve such amendment. The Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Plan or (ii) the change is permitted under Section 9.

(g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously issued or delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and

delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(h) Acceleration. The Board may at any time provide that any Award shall become immediately exercisable in whole or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

11. Miscellaneous

(a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award by virtue of the adoption of the Plan, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights As Stockholder; Clawback. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares. In accepting an Award under the Plan, the Participant agrees to be bound by any clawback policy that the Company has in effect or may adopt in the future.

(c) Effective Date. The Plan shall become effective on the date on which it is adopted by the Board. It is expressly intended that approval of the Company's stockholders not be required as a condition to the effectiveness of the Plan, and the Plan's provisions shall be interpreted in a manner consistent with such intent for all purposes.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time, provided that no amendment that would require stockholder approval under the rules of Nasdaq may be made effective unless and until the Company's stockholders approve such amendment. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 11(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment, taking into account any related action, does not materially and adversely affect the rights of Participants under the Plan.

(e) Authorization of Sub-Plans (including for Grants to non-U.S. Employees). The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable securities, tax or other laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to the Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Compliance with Section 409A. Except as provided in individual Award agreements initially or by amendment, if and to the extent (i) any portion of any payment, compensation or other benefit provided to a Participant pursuant to the Plan in connection with his or her employment termination constitutes "nonqualified deferred compensation" within the meaning of Section 409A and (ii) the Participant is a specified employee as defined in Section 409A(a)(2)(B)(i), in each case as determined by the Company in accordance with its procedures, by which determinations the Participant (through accepting the Award) agrees that he or she is bound, such portion of the payment, compensation or other benefit shall not be paid before the day that is six months plus one day after the date of "separation from service" (as determined under Section 409A) (the "New Payment Date"), except as Section 409A may then permit. The aggregate of any payments that otherwise would have been paid to the Participant during the period between the date of separation from service and the New Payment Date shall be paid to the Participant in a lump sum on such New Payment Date, and any remaining payments will be paid on their original schedule.

The Company makes no representations or warranty and shall have no liability to the Participant or any other person if any provisions of or payments, compensation or other benefits under the Plan are determined to constitute nonqualified deferred compensation subject to Section 409A but do not satisfy the conditions of that section.

(g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, employee or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as a director, officer, employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, employee or agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the Plan unless arising out of such person's own fraud or bad faith.

(h) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than the State of Delaware.

* * * * *

Exhibit 10.2

OCULAR THERAPEUTIX, INC.
NONSTATUTORY STOCK OPTION AGREEMENT

Ocular Therapeutix, Inc. (the "Company") hereby grants the following stock option pursuant to its 2019 Inducement Stock Incentive Plan. The terms and conditions attached hereto are also a part hereof.

Notice of Grant

Name of optionee (the "Participant"):	
Date of this option grant:	
Number of shares of the Company's Common Stock subject to this option ("Shares"):	
Option exercise price per Share:	
Number, if any, of Shares that vest immediately on the grant date:	
Shares that are subject to vesting schedule:	
Vesting Start Date:	
Final Exercise Date:	

Vesting Schedule:

All vesting is dependent on the Participant remaining an Eligible Participant, as provided herein.	

[Signature Page follows]

This option satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

OCULAR THERAPEUTIX, INC.

Signature of Participant

By: _____

Street Address

Name of Officer

Title:

City/State/Zip Code

Signature of Participant's Spouse (if applicable)*

Street Address

City/State/Zip Code

* Required for Participants residing in Arizona, California, Idaho, Louisiana, Nevada, New Mexico, Texas, Wisconsin, or the Commonwealth of Puerto Rico.

OCULAR THERAPEUTIX, INC.

Nonstatutory Stock Option Agreement
Incorporated Terms and Conditions

1. Grant of Option.

This agreement evidences the grant by the Company, on the grant date (the "Grant Date") set forth in the Notice of Grant that forms part of this agreement (the "Notice of Grant"), to the Participant, an employee of the Company, of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2019 Inducement Stock Incentive Plan (the "Plan"), the number of Shares set forth in the Notice of Grant of common stock, $0.0001 par value per share, of the Company ("Common Stock"), at the exercise price per Share set forth in the Notice of Grant. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the Final Exercise Date set forth in the Notice of Grant (the "Final Exercise Date").

The option evidenced by this agreement was granted to the Participant pursuant to the inducement grant exception under Nasdaq Stock Market Rule 5635(c)(4), as an inducement that is material to the Participant's employment with the Company.

It is intended that the option evidenced by this agreement shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

This option will become exercisable ("vest") in accordance with the vesting schedule set forth in the Notice of Grant.

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing, in the form of the Stock Option Exercise Notice attached as Annex A, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, or in such other form (which may be electronic) as is approved by the Company, together with payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an employee,

director or officer of, or consultant or advisor to, the Company or any other entity the service providers of which are eligible to receive option grants under the Plan (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of 180 days following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's employment or other relationship with the Company is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination of employment or other relationship. "Cause" shall have the meaning set forth in any employment or other agreement between the Participant and the Company or, in the absence of such an agreement, shall mean, in the good faith determination of the Company, the Participant has: (i) committed gross negligence or willful malfeasance in the performance of the Participant's work or duties; (ii) committed a breach of fiduciary duty or a breach of any non-competition, non-solicitation or confidentiality obligations to the Company; (iii) failed to follow the proper directions of the Participant's direct or indirect supervisor after written notice of such failure; (iv) been convicted of, or pleaded "guilty" or "no contest" to, any misdemeanor relating to the affairs of the Company or any felony; (v) disregarded the material rules or material policies of the Company which has not been cured within 15 days after notice thereof from the Company; or (vi) engaged in intentional acts that have generated material adverse publicity toward or about the Company.

4. Withholding.

No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

5. Transfer Restrictions; Clawback.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant. In accepting this option, the Participant agrees to be bound by any clawback policy that the Company has adopted or may adopt in the future.

6. Provisions of the Plan.

This option is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is furnished to the Participant with this option.

* * * * *

ANNEX A

OCULAR THERAPEUTIX, INC.

Stock Option Exercise Notice

Ocular Therapeutix, Inc.
24 Crosby Drive
Bedford, MA 01730

Dear Sir or Madam:

I, _____ (the "Participant"), hereby irrevocably exercise the right to purchase _____ shares of the Common Stock, $0.0001 par value per share (the "Shares"), of Ocular Therapeutix, Inc. (the "Company") at $_____ per share pursuant to the Company's 2019 Inducement Stock Incentive Plan and a stock option agreement with the Company dated _____ (the "Option Agreement"). Enclosed herewith is a payment of $_____, the aggregate purchase price for the Shares. The certificate for the Shares should be registered in my name as it appears below or, if so indicated below, jointly in my name and the name of the person designated below, with right of survivorship.

Dated: _____

_____
Signature
Print Name:

Address:

_____
_____

Name and address of persons in whose name the Shares are to be jointly registered (if applicable):

_____

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: November 12, 2019

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: November 12, 2019

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 September 30, 2019 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: November 12, 2019

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 September 30, 2019 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: November 12, 2019

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